Notable Changes to the IRB Manual of Policies and Procedures

November 2020

Section 3
Definition of Human Subject (when following FDA requirements)
Definition of Research (when following FDA requirements)

Section 4
IRB Minutes, Convened Board

Section 5
GSU’s Policy for Required Training

Section 6
Advertisements

Section 8
Waiver of Documentation of Informed Consent

Section 12
Research Involving Decisionally Impaired Individuals

Section 16
Amazon Mechanical Turk (MTurk), Crowdsourcing Platforms

Section 24
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IRB of Record, Georgia State University
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1.1 PURPOSE AND SCOPE OF MANUAL
This manual details policies to promote the mission of the Human Research Protection Program ("HRPP") and Institutional Review Board ("IRB") panels at Georgia State University ("GSU"). Review and approval or exempt determination is required before engaging in any human subjects research. See Section 7.2 for information on what activities fall under the jurisdiction of the GSU IRB.

1.2 APPLICABILITY
The procedures set forth in this manual are applicable to all faculty, staff, employees, students, and agents who propose to conduct research involving human subjects under the jurisdiction of GSU.

1.3 MISSION
The IRBs are charged with the responsibility of protecting the rights and welfare of human subjects participating in research under the auspices of the institution with which they are affiliated. GSU’s program on human research protection is based on the three basic ethical tenets of respect for persons, beneficence, and justice, and the application of these tenets set forth in the Belmont Report, issued in 1979 by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. GSU’s IRBs will apply these tenants to all human subjects research, regardless of funding.
1.4 FEDERAL ADMINISTRATION OF HUMAN RESEARCH ETHICS

The Office for Human Research Protections (OHRP) provides leadership in the protection of the rights, safety, and welfare of subjects involved in research conducted or supported by the U.S. Department of Health and Human Services (DHHS). OHRP helps ensure this by providing clarification and guidance, developing educational programs and materials, maintaining regulatory oversight, and providing advice on ethical and regulatory issues in biomedical and social-behavioral research. OHRP is part of the U.S. Department of Health and Human Services. OHRP also supports the Secretary’s Advisory Committee on Human Research Protections (SACHRP) which advises the HHS Secretary on issues on human subject protections.

The Federalwide Assurance (FWA) is the only type of assurance currently accepted and approved by OHRP. Through the FWA, an institution commits to HHS that it will comply with the requirements in the HHS Protection of Human Subjects regulations at 45 CFR 46. Before obtaining an FWA, an institution must either register its own IRB (an “internal” IRB) or designate an already registered IRB operated by another organization (an “external” IRB) after establishing a written agreement with that other organization. At GSU, determination of whether the institution is engaged in human subjects research that is conducted or supported by the Department of Health and Human Services and non-exempt is based upon OHRP’s guidance “Engagement of Institutions in Human Subjects Research” and additional correspondence; see additional discussion in this policy of Engaged in Human Subjects Research. For more information regarding research activity within GSU’s Jurisdiction see Section 7.2.

OHRP has a Division of Compliance Oversight (DCO) that evaluates, at OHRP’s discretion, written substantive indications of non-compliance with HHS regulations—Title 45, Part 46, Code of Federal Regulations (45 CFR 46). OHRP asks the institution involved to investigate the allegations and to provide OHRP with a written report of its investigation. The Office then determines what, if any, regulatory action needs to be taken to protect human research subjects. DCO also conducts a program of not-for-cause surveillance evaluations of institutions, and receives, reviews, and responds to incident reports from Assured Institutions.

To enhance the protection of human subjects in HHS conducted or supported research, OHRP has a Division of Education and Development (DED) that provides education to individuals involved in the human subjects research enterprise. Specifically, the DED produces and coordinates conferences on human subjects protection issues, develops and conducts quality improvement activities to improve human research protection programs; promotes cooperative education and development efforts among external groups and consortia to improve human subjects protections and related processes; responds to requests for clarification and guidance regarding ethical issues in biomedical and behavioral research involving human subjects; provides assistance to institutions engaged in HHS-conducted or-sponsored
research involving human subjects; and maintains, promulgates, and updates educational and institutional review guidance materials.

OHRP also works to ensure that human subjects outside of the United States who participate in research projects conducted or funded by DHHS receive the same level of protections as research participants inside the United States. Therefore, the OHRP International Activities program offers consultation services, disseminates pertinent reports, and provides research ethics training.

The Food and Drug Administration (FDA) is an HHS agency that regulates clinical investigations of products under its jurisdiction such as drugs, biological products, and medical devices. FDA regulations are published as a part of Chapter 21 Code of Federal Regulations, and FDA’s human subject protection regulations are in parts 50, 56, 312, and 812. See Section 4.6 for a discussion of the types of FDA-regulated research conducted at GSU.

For more information, please visit FDA’s website page on Running Clinical Trials and the sub-page on Regulations.

Office for Human Research Protections
1101 Wootton Parkway, Suite 200
Rockville, MD 20852

Toll-Free Telephone within the United States: (866) 447-4777
Telephone: (240) 453-6900
Fax: (240) 453-6909
E-mail: OHRP@hhs.gov
Please see About OHRP for staff listing or visitor information https://www.hhs.gov/ohrp/

Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857
1-888-INFO-FDA (1-888-463-6332)
www.fda.gov

1.5 APPLICABLE LAWS RELATED TO HUMAN PARTICIPANT RESEARCH

GSU’s IRBs are subject to the laws of the State of Georgia. The IRBs and GSU researchers should contact the Office of Legal Affairs for guidance on the interpretation and application of Georgia law. Where human subjects research takes place outside Georgia, the IRBs and GSU researchers should consult with the Office of Legal Affairs for determination of applicable law and any interpretation thereof.

1.5.1 GEORGIA LAW

Occasionally state law provides for additional protections or requirements with regard to human
subjects research. The following addresses certain requirements for research conducted in Georgia. GSU researchers and the IRB should contact the Office of Legal Affairs for assistance with how Georgia law may affect GSU research.

a. Age of Consent: In Georgia, the basic age of consent for participation in research is 18 years, which is also the age at which Georgians may enter contracts or consent to medical services. Those under the age of 18 are considered “children.” Parental permission must be provided for children to participate in research; exceptions to this requirement may only be granted by the IRB.

b. Emancipated Minors: Georgia law recognizes the concept of the emancipated minor. "Emancipation" means termination of the rights of the parents to the custody, control, services, and earnings of a minor. "Minor" means a person who is at least 16 but less than 18 years of age. Emancipation may occur by operation of law (when a minor is validly married or reaches 18 or during the period when the minor is on active duty within the US armed forces) or pursuant to a petition filed by a minor with the juvenile court. Emancipated minors may consent to research participation for themselves. Special precautions need to be taken to ensure that the participant is, in fact, an emancipated minor.

c. Reporting Requirements: Georgia law requires certain individuals to report the abuse, neglect, or exploitation of children, disabled adults, and elderly persons (See OCGA § 19-7-5; OCGA § 30-5-4; OCGA § 31-8-82). For more information, please see Section 12.10.

Legal incompetence: These policies and procedures include guidance to be used to determine if a Legally Authorized Representative can give informed consent on behalf of a research subject in Georgia. If the research is to take place outside the State of Georgia, then a determination as to who may provide informed consent on behalf of a decisionally impaired research subject must be made under the laws of the jurisdiction in which the research takes place. For more information, please see Section 8.7. State law and federal rules allow consent to be granted, under specific circumstances, by a legally authorized representative instead of by the subject (e.g., spouse for a spouse who is decisionally impaired).

d. Lotteries, raffles and games of chance: The State of Georgia has specific laws regulating lotteries, raffles and other games of chance. For more information, please see Section 6.10.

If a study is being conducted in another state, the Principal Investigator (“PI”) is responsible for complying with any additional requirements of the local jurisdiction that might impact human subjects research. The PI should contact the Office of Legal Affairs for assistance.
1.5.2 INTERNATIONAL LAW

If a study is being conducted outside of the United States, the PI is responsible for applicable laws in the local jurisdiction that might impact human subjects research. Researchers should ensure that participants outside the United States have the equivalent protections that participants would be afforded in the United States. OHRP provides a compilation of regulations and guidelines that govern human subjects research in other countries, as well as standards from a number of international and regional organizations. See International Compilation of Human Research Standards 2018 Edition and Section 13 for more information.

If a study is being conducted in another country, the PI is responsible for complying with any additional requirements of the local jurisdiction that might impact human subjects research. The PI should contact the Office of Legal Affairs for assistance.

1.6 FERPA and Research Conducted at GSU

The Family Educational Rights and Privacy Act ("FERPA") (20 U.S.C. § 1232g; 34 CFR Part 99) is a federal law that gives parents certain rights with respect to their children’s education records. These rights transfer to the student when he or she reaches the age of 18 or attends a school beyond the high school level (“Eligible Students”). The law applies to all schools that receive funds under an applicable program of the U.S. Department of Education (ED), such as Title I.

FERPA requires that written permission from parents or Eligible Students be obtained before releasing any information from student Education Records, except in the case of specific exceptions set forth in 34 CFR § 99.31. While FERPA does not have a research exception to the written consent requirement per se, FERPA does allow educational agencies or institutions to share Personally Identifiable Information ("PII") from Education Records under certain circumstances. This document provides guidance to GSU researchers who wish to access FERPA-protected information from either GSU or other educational institutions or agencies.

GSU researchers are responsible for complying with FERPA and human subject protection regulations (i.e., IRB requirements); and if GSU Education Records are involved, the GSU FERPA policy. Under FERPA, the educational institution is responsible for determining whether and what information may be accessed from an Education Record. The IRB does not have authority to require access to information from an Education Record. If an institution denies a researcher access to information in an Education Record, the IRB cannot overrule the decision.

For all studies that involve access to Education Records held by a school other than GSU, a letter from such school indicating its willingness to participate in the study AND the manner under FERPA the Education Records will be accessed (e.g., researcher is obtaining student consent, researcher is accessing
Directory Information, etc.) must be included in the study application to the GSU IRB. The options for Education Record access include the following and are discussed more fully herein:

- **Obtaining Student Consent to Access Records for Research Purposes**
- **Access to Directory Information**
- **School Officials with Legitimate Educational Interest**
- **Studies to develop, validate, or administer predictive tests; administer student aid programs; or improve instruction**
- **Removal of all Personally Identifiable Information**

I. **FERPA Definitions (34 CFR § 99.3)**

**Record** means any information recorded in any way, including, but not limited to, handwriting, print, computer media, video or audio tape, film, microfilm, and microfiche.

**Education Records** means Records that contain information directly related to a student and that are maintained by an educational agency or institution or by a party acting for the agency or institution.

**Eligible Student** means a student who has reached 18 years of age or is attending an institution of postsecondary education.

**Disclosure** means to permit access to or the release, transfer, or other communication of Personally Identifiable Information contained in Education Records to any party, by any means, including oral, written, or electronic means.

**Parent** means a parent of a student and includes a natural parent, a guardian, or an individual acting as a parent in the absence of a parent or a guardian.

**Personally Identifiable Information** includes, but is not limited to, the student’s name; the name of the student’s parent or other family members; the address of the student or student’s family; a personal identifier, such as the student’s Social Security Number, student number, or biometric record; other indirect identifiers, such as the student’s date of birth, place of birth, and mother’s maiden name; other information that, alone or in combination, is linked or linkable to a specific student that would allow a reasonable person in the school community, who does not have personal knowledge of the relevant circumstances, to identify the student with reasonable certainty; and information requested by a person
who the educational agency or institution reasonably believes knows the identity of the student to whom the education record relates.

**Directory Information** means information contained in an Education Record of a student that would not generally be considered harmful or an invasion of privacy if disclosed. It includes, but is not limited to, the student's name, address, telephone listing, electronic mail address, photograph, date and place of birth, major field of study, dates of attendance, grade level, enrollment status (e.g., undergraduate or graduate; full-time or part-time), participation in officially recognized activities and sports, weight and height of members of athletic teams, degrees, honors and awards received, and the most recent educational agency or institution attended. Each educational institution designates what information is considered directory information.

**School Official** is defined by each individual educational institution. At GSU, a school official is:

- A person employed by GSU (which, for purposes of this guidance includes persons employed by the Board of Regents of the University System of Georgia) in an administrative, supervisory, academic or research, or support staff position, including health or medical staff.
- A person or entity employed by or under contract to GSU to perform a special task, such as a University affiliated organization, attorney, auditor, or outside vendor.
- A person who is employed by the GSU law enforcement unit.
- A student serving on an official committee, such as a disciplinary or grievance committee, or who is assisting another school official in performing his or her tasks.

II. **Obtaining Student Consent to Access Records for Research Purposes**

FERPA regulations specify that a parent or Eligible Student must provide a signed and dated written consent in accordance with the requirements of 34 CFR § 99.30 before Personally Identifiable Information from Education Records is disclosed, unless the disclosure falls within one of the exceptions set forth in 34 CFR § 99.31.

FERPA’s consent provisions require a specification of 1) the records that may be disclosed; 2) the purpose of the disclosure; and 3) the identity of the party or class of parties to whom the records may be disclosed. The consent language may be included within an informed consent document.
III. Access to Records for Research Purposes without Obtaining Student Consent

A. Directory Information

FERPA allows schools to designate and disclose, without consent, certain items of information as Directory Information, such as a student's name, address, telephone number, date and place of birth, honors and awards, and dates of attendance. Each educational institution designates what information is considered directory information. FERPA requires that students be given the opportunity to file a request to prevent disclosure of directory information, commonly known as “opting out.” An institution will not release any information on a student, even directory information, if a student has “opted out.”

The researcher should contact each institution from which he/she proposes to access student records and follow that institution’s FERPA policy and procedures when accessing directory information. GSU’s definition of Directory Information is found in the GSU FERPA Policy located at http://registrar.gsu.edu/academic-records/records-management/ferpa/. GSU has designated the following types of information to be directory information: student name, mailing addresses, telephone number, date and place of birth, major field of study, full or part-time status, participation in officially recognized activities and sports, degrees and awards applied for and/or received, dates of attendance, previous educational institutions attended by the student, photographs and other recorded images, and, with respect to members of athletic teams, height, weight, age, hometown, hobbies, and general items of interest. Email addresses are NOT considered Directory Information.

B. Disclosure to School Officials with Legitimate Educational Interest

FERPA allows for the disclosure of Personally Identifiable Information without consent to “school officials, including teachers, within the agency or institution whom the agency or institution has determined to have legitimate educational interests.” The agency or institution holding the information decides who is considered a “school official” and what is considered a “legitimate educational interest.” The agency or institution must also ensure that that school officials obtain access to only those education records in which they have legitimate educational interests.

Access to Personally Identifiable Information in Education Records Held by GSU

According to GSU’s FERPA Policy, a “school official” includes a person employed by GSU in an administrative, supervisory, academic or research, or support staff position, including health or medical staff. The FERPA Policy also states that a school official has a legitimate educational interest if, among
other things, the official is performing a task that is specified in his or her position description or contract agreement. Therefore, those GSU employees whose job descriptions include conducting research would be considered school officials with a legitimate educational interest.

After IRB approval is obtained, the researcher will only be granted access to the records that are specifically needed for the research. When a GSU researcher is seeking access to Personally Identifiable Information in records held by GSU at the institutional level (as opposed to records maintained by individual faculty or departments), the researcher should contact the GSU Registrar for approval. If obtaining the records will require assistance from the Office of Institutional Research, then the researcher should contact the Director of Institutional Research at (404) 413-2590. The researcher may not redisclose personally identifiable information to others and is responsible for ensuring the confidentiality of the information. If the researcher is collaborating with another researcher not employed by GSU, he or she must de-identify the information before disclosing it to the other researcher. If the outside researcher needs access to identifiable information, the GSU researcher should contact the Office of Legal Affairs for assistance prior to submitting the IRB application.

Access to Personally Identifiable Information in Education Records Held by an Outside Educational Institution or Agency

If the proposed research is to be conducted by a GSU researcher who is employed by the educational institution or agency from whom the records are sought, the researcher should include in the IRB application a letter of permission to conduct the study from the participating educational institution. The letter should state that the researcher is a school official with a legitimate educational interest. In most cases involving Education Records held by elementary and secondary schools, this letter should come from the school district’s superintendent.

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1 Note regarding subject recruitment and email addresses: Email addresses are not considered Directory Information. Also, even though a GSU researcher may be considered a school official with a legitimate educational interest, it is GSU policy not to provide email addresses. If a researcher wishes to contact via email GSU students who are potential study subjects, the researcher may provide the content of the recruitment email to the Office of Institutional Research for distribution to the pool of students requested by the researcher. Both the Registrar and the Office of Institutional Research reserve the right to delay the email to the students. Please keep this in mind when planning your research.
C. Studies to develop, validate, or administer predictive tests; administer student aid programs; or improve instruction

FERPA allows an educational agency or institution to disclose Personally Identifiable Information from the Education Record of a student without consent if the disclosure is to organizations conducting studies for, or on behalf of, the educational agency or institution to:

- Develop, validate, or administer predictive tests.
- Administer student aid programs.
- Improve instruction.

GSU faculty and staff are often asked to perform these types of studies. Note, however, that the fact that a researcher’s work could potentially benefit the educational agency or institution does not automatically invoke this exception. A school district or postsecondary institution that invokes this exception to allow a GSU researcher access to an Education Record without consent must enter into a written agreement with GSU that specifies:

- The determination of the exception.
- The purpose, scope, and duration of the study.
- The information to be disclosed.
- That information from education records may only be used to meet the purposes of the study stated in the written agreement and must contain the current requirements in 34 CFR 99.31(a)(6) on re-disclosure and destruction of information.
- That the study will be conducted in a manner that does not permit personal identification of parents and students by anyone other than representatives of the organization with legitimate interests.
- That the organization is required to destroy or return all personally identifiable information when no longer needed for the purposes of the study.
- The time period during which the organization must either destroy or return the information.

Such agreement should be reviewed by the Office of Legal Affairs or the Office of Sponsored Proposals and Awards. The agreement must be included in the researcher’s application to the GSU IRB.
D. Removal of all Personally Identifiable Information

Education Records may be released without consent under FERPA with the agreement of the school if all Personally Identifiable Information has been removed, including:

− Student’s name and other direct personal identifiers, such as the student’s social security number or student number.
− Indirect identifiers, such as the name of the student’s parent or other family members; the student’s or family’s address, and personal characteristics or other information that would make the student’s identity easily traceable; date and place of birth and mother’s maiden name.
− Biometric records, including one or more measurable biological or behavioral characteristics that can be used for automated recognition of an individual, including fingerprints, retina and iris patterns, voiceprints, DNA sequence, facial characteristics, and handwriting.
− Other information that, alone or in combination, is linked or linkable to a specific student that would allow a reasonable person in the school community, who does not have personal knowledge of the relevant circumstances, to identify the student with reasonable certainty.

Note: The US Department of Education indicates that “data that cannot be linked to a student by those reviewing and analyzing the data are not ‘personally identifiable.’” As such, the data are not “directly related” to any students. Accordingly, a document containing only non-personally identifiable data, even when originally taken from a student’s Education Record, is not a part of the student’s Education Records for purposes of FERPA.

An educational institution may release information from student Education Records without the consent required under FERPA after all personally identifiable information has been removed from the records, provided that the educational institution has made a reasonable determination that a student’s identity would not be personally identifiable.

Also note that an educational institution can release de-identified student level data from Education Records for the purpose of research by attaching a code to each record that may allow the GSU researcher to match information, provided that the educational institution does not disclose any information about how it generated and assigned the code, or that would allow the GSU researcher to identify a student based on a code; the code is not used for any purpose other than identifying a de-identified record for purposes of education research; and the code is not based on a student’s social security number or other personal information.
1.7 HIPAA

Background Information

In response to requirements in the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), the Health Information Technology for Economic and Clinical Health Act ("HITECH") and the Genetic Information Nondiscrimination Act ("GINA"), the Department of Health and Human Services has issued regulations that are commonly referred to as the HIPAA Privacy Rule and the HIPAA Security Rule. The Privacy Rule is a response to public concern over potential abuses of the privacy of health information. The Privacy Rule establishes a category of health information, referred to as Protected Health Information or PHI, which may only be used or disclosed to others in certain circumstances or under certain conditions. PHI is a subset of what is termed Individually Identifiable Health Information. With certain exceptions, Individually Identifiable Health Information becomes PHI when it is created or received by a Covered Entity. Covered Entities are health plans, health care clearinghouses, and health care providers that transmit health information electronically in connection with certain defined HIPAA transactions, such as claims or eligibility inquiries.

GSU is not primarily engaged in the activities that define a Covered Entity, but it does have units that perform functions that fit the “Covered Entity” definition. HIPAA allows a single legal entity whose business activities include both functions that are covered by the regulations and those that are not covered to designate itself as a “Hybrid Entity” regardless of whether those functions that are not covered are a primary part of the educational and research purposes or just a small percentage. Accordingly, GSU has formally designated itself a “Hybrid Entity” for HIPAA compliance purposes. As a Hybrid Entity, GSU is required to document identification of those of its units that perform covered functions (“Covered Units”).

GSU has designated the GSU Student Health Clinic and the GSU Physical Therapy and Wellness Clinic as its health care components and Covered Units of GSU. While the Student Health Clinic is a Covered Unit, it does not hold PHI, as the patient population consists only of GSU students; therefore, the records are considered “treatment records” under the Family Education Rights and Privacy Act (“FERPA”). For more information on the intersection of HIPAA and FERPA, go to the Guidance Document located here: https://studentprivacy.ed.gov/resources/joint-guidance-application-ferpa-and-hipaa-student-health-records or contact the Office of Legal Affairs. The Physical Therapy and Wellness Clinic is required to comply with HIPAA’s privacy rules and standards. More information about the policies and procedures of the clinic may be obtained by the practice manager of the clinic.

The HIPAA Privacy Rule will impact GSU research projects if the PHI is obtained from the GSU Physical Therapy and Wellness Clinic or from another Covered Entity outside GSU, such as a hospital or pharmacy.
If your research involves the GSU Physical Therapy and Wellness Clinic, contact the Office of Legal Affairs prior to submitting your application for research to the GSU IRB.

**HIPAA and Research at GSU**

**Key Points:**

- Personal health information that is not obtained from a Covered Entity, that is self-disclosed by research participants, and that is kept only in the researcher’s records is not subject to HIPAA but is regulated by human subjects protection regulations.
- De-identified health information, as described in the Privacy Rule, is not PHI, and thus is not protected by the Privacy Rule.
- PHI may be used and disclosed for research with an individual's written permission in the form of an Authorization.
- PHI may be used and disclosed for research without an Authorization in limited circumstances:
  1. under a waiver of the Authorization requirement,
  2. as a limited data set with a data use agreement,
  3. in a review preparatory to research, and
  4. for research on decedents' information.

**A. IRB Role under the Privacy Rule**

The GSU IRB has the authority to consider, and act upon, requests for a partial or complete waiver or alteration of the Privacy Rule's Authorization requirement for uses and disclosures of PHI for research. Also, under the Privacy Rule, an Authorization may be combined with the informed consent document for research. If the informed consent document is combined with an Authorization meeting the Privacy Rule's requirements, Protection of Human Subjects Regulations (45 CFR part 46) would require IRB review of the combined document.

**B. De-identifying PHI**

Covered Entities may use or disclose health information that is de-identified without restriction under the Privacy Rule. When a GSU researcher requests de-identified health information from a Covered Entity, the Covered Entity must determine that the information has been de-identified using either statistical verification of de-identification or by removing certain pieces of information from each record as specified in the Privacy Rule.
The Privacy Rule allows a Covered Entity to de-identify data by removing all 18 elements that could be used to identify the individual or the individual’s relatives, employers, or household members; these elements are enumerated in the Privacy Rule. The Covered Entity also must have no actual knowledge that the remaining information could be used alone or in combination with other information to identify the individual who is the subject of the information. Under this method, the identifiers that must be removed are the following:

1. Names.
2. All geographic subdivisions smaller than a state, including street address, city, county, precinct, ZIP Code, and their equivalent geographical codes, except for the initial three digits of a ZIP Code if, according to the current publicly available data from the Bureau of the Census:
   a. The geographic unit formed by combining all ZIP Codes with the same three initial digits contains more than 20,000 people.
   b. The initial three digits of a ZIP Code for all such geographic units containing 20,000 or fewer people are changed to 000.
3. All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older.
4. Telephone numbers.
5. Facsimile numbers.
6. Electronic mail addresses.
7. Social security numbers.
8. Medical record numbers.
9. Health plan beneficiary numbers.
10. Account numbers.
12. Vehicle identifiers and serial numbers, including license plate numbers.
15. Internet protocol (IP) address numbers.
16. Biometric identifiers, including fingerprints and voiceprints.
17. Full-face photographic images and any comparable images.
18. Any other unique identifying number, characteristic, or code, unless otherwise permitted by the Privacy Rule for re-identification.

De-identified health information is not PHI and is not protected by the Privacy Rule.

De-identifying PHI according to Privacy Rule standards may enable many research activities; however, the Privacy Rule recognizes that researchers may need to access identifiable health information during the
course of research. Where PHI is needed for research activities, the Privacy Rule permits its use and
disclosure if certain standards are met. These standards are discussed in the following sections.

C. The Use of PHI with An Individual’s Authorization

“Research” is not part of “treatment,” “payment” or “health care operations” and therefore a researcher
must obtain a written authorization from the subject that complies with the requirements of the HIPAA
Privacy Regulations. Such a written authorization authorizes a Covered Entity to use and/or disclose his
or her PHI to the GSU researcher for research purposes. This requirement is in addition to the informed
consent to participate in research required under the HHS Protection of Human Subjects Regulations and
other applicable Federal and State law.

Elements of an Authorization

A valid authorization must be written in “plain language” and must contain certain “core elements,”
including:

1. The name of the individual whose information will be used or disclosed.
2. A meaningful and specific description of the information to be disclosed. A general statement
   of “all health information necessary for the study” is considered insufficient. The statement
   must describe with specificity the information to be used or disclosed, such as “laboratory
   results, x-rays,” etc.
3. The name or specific identification of the person or class of persons who are to receive the
   information. This is to permit the individual to reasonably identify who can receive the
   information. The identification should be specific and include specific names or a specific class
   of persons, such as “Dr. Smith” or the name of the research group, etc.
4. A description of the purpose of the disclosure. This requirement can be met by providing a
   brief description of the research study and the goal of the research.
5. An expiration date or expiration event. The Privacy Rule permits a research authorization to
   state “end of the study” or “none”.
6. The date and signature of the individual or the individual’s “personal representative.”

In addition to the “core elements,” the authorization must contain statements concerning:

1. The individual’s right to revoke the authorization in writing, the exceptions to the right to
revoke the authorization and a description of how the individual may revoke the authorization. In the research context, there are limitations on the effect of a revocation by a participant. Covered entities may continue to use and disclose health information obtained before (but not after) the authorization was revoked, to the extent it is necessary to maintain the integrity of the research, or if the disclosure is necessary to account to the FDA for a participant's withdrawal from the project, or to investigate scientific misconduct and report adverse events. Health information obtained after the authorization was revoked may not be used or disclosed by the Covered Entity for the research study.

2. The ability (or inability) of the Covered Entity to make the treatment, payment, enrollment or eligibility for benefits conditional on the authorization. Generally, a Covered Entity cannot make treatment conditional on the signing of an authorization. However, there is an exception for research involving clinical treatment of the patient. The Covered Entity may condition treatment that is part of a research study on the receipt of a signed authorization. In this context, the authorization may be combined with the informed consent.

3. The potential for the information to be re-disclosed by the recipient to others and to lose federal privacy protections concerning use and disclosure of the information.

4. The participant must be given a copy of his/her authorization.

D. Exceptions to the Authorization Requirement

There are several exceptions to the authorization requirement in the research context. These include IRB waivers, IRB modifications of authorization requirements, reviews preparatory to research, research involving a decedent's information, and "limited data set" disclosures.

1. Institutional Review Board Waivers and Modifications of Authorizations

**Application for Waiver or Modification.** The Privacy Rule permits a researcher to seek a waiver of the authorization requirements or a modification of the authorization requirements from an existing IRB. The GSU IRB will oversee waivers concerning research conducted by GSU researchers. The waiver need not be given from the IRB associated with the Covered Entity but note that the Covered Entity may require that its IRB oversee the review. In order to obtain a waiver, a researcher must satisfy the following three (3) criteria:

1. The use or disclosure of PHI involves no more than a minimal risk to the privacy of individuals based upon the presence of the following elements:
i. an adequate plan exists to protect the “identifiers” from disclosure or improper use;

ii. an adequate plan exists to destroy the identifiers at the earliest opportunity practical under the research, unless there is a health or research justification for retaining the identifiers or the retention is otherwise required by law; and

iii. adequate written assurances that the PHI will not be reused or disclosed to any other person or entity, except where required by law, for authorized oversight of the research project, or for other research conducted consistent with the requirements of the Privacy Rule.

II. The research could not practicably be conducted without the waiver or alteration to the authorization; and

III. The research could not practicably be conducted without access to and use of the PHI.

Approval of Waiver or Modification of Authorization by the IRB. If satisfied that the forgoing criteria are met, the GSU IRB must provide and maintain documentation of the waiver, and a Covered Entity may not disclose the PHI without receiving documentation of all the following:

− Identification of the IRB (or Privacy Board) and the date on which the alteration or waiver of authorization was approved;

− A statement that the IRB has determined that the alteration or waiver of authorization, in whole or in part, satisfies the 3 criteria stated above;

− A brief description of the PHI for which use or access has been determined to be necessary by the IRB;

− A statement that the alteration or waiver of authorization has been reviewed and approved under either normal or expedited review procedures; and

− The signature of the chair or other member, as designated by the chair of the IRB, as applicable.

Minimum Necessary Rule. If the authorization requirement is waived by the IRB, requests for PHI and the use and disclosure of PHI must be limited to the "minimum necessary to accomplish the intended purpose." Therefore, the researcher must consider and request access to only the minimum necessary to achieve the goals of the research project. Also, access to and use of the information should be limited to only those researchers or others who need access to PHI to carry out their duties, and all PHI must be maintained in a secure environment to ensure limited access to PHI and to avoid incidental disclosures of PHI.
2. **Reviews preparatory to research**

A Covered Entity may rely on a researcher’s oral or written representation that the use or disclosure of the PHI is solely to prepare a research protocol or for similar purposes preparatory to research, that the researcher will not remove the PHI from the premises (including by electronic transmission), and that the use or disclosure is necessary for research purposes. This exception permits an employee of a Covered Entity or Covered Component to use the information to recruit prospective participants for a study by using the PHI held by the Covered Entity. However, an outside researcher could not use the information to contact recruits without the patient’s authorization. This type of hardship on an outside researcher may support a partial IRB waiver to permit the researcher to use the information only to contact and recruit potential participants. Once contacted, a patient could choose to participate and could then sign an authorization to participate in the study. A copy of the certification form shall be provided to the GSU IRB.

3. **Research on Decedents**

A Covered Entity may rely on a researcher’s oral or written representation that the use or disclosure of the PHI is solely for research on the PHI of a decedent, that the PHI sought is necessary for the research, and, at the request of the Covered Entity, that documentation of the death of the affected individuals be provided.

4. **Limited Data Sets with a Data Use Agreement**

The requirements of de-identifying information are so extensive, that often the data is of limited value to researchers. The Privacy Rule permits the use and disclosure of a “limited data set” in conjunction with a “data use agreement.” With a limited data set, the “facial identifiers” must be deleted. These include:

- Names
- Postal address information (other than town or city, state and zip code)
- Telephone numbers
- Fax numbers
- E-mail addresses
- Social security numbers
- Medical record numbers
Health plan beneficiary numbers
Account numbers
Certificate/license numbers
Vehicle identifiers & serial numbers, including license plate numbers
Device identifiers & serial numbers
Web Universal Resource Locators (URL’s)
Internet Protocol (IP) address numbers
Biometric identifiers, including finger and voice prints
Full face photographic images and any comparable images

The limited data set can be disclosed for purposes of research, public health and health care operations, but the recipient GSU researcher must execute a “Data Use Agreement” with the Covered Entity which limits how the recipient GSU researcher may use the limited data set, ensures the security of the data and states that the recipient will not identify the information or use it to contact any individual. The GSU researcher should contact the Office of Legal Affairs for assistance with the Data Use Agreement. A copy of the Data Use Agreement shall be provided to the GSU IRB. If additional information is needed, please contact the Office of Legal Affairs.

1.8 GEORGIA STATE UNIVERSITY ADMINISTRATION OF HUMAN RESEARCH ETHICS

The Vice-President (VP) for Research and Economic Development is responsible for the administration and oversight of research ethics at GSU. The VP for Research and Economic Development oversees the functioning of the IRBs, the HRPP, compliance, and administrative staff. The VP for Research and Economic Development is also the individual responsible for assuring that the HRPP is functional, adequately staffed, funded, and respected in the research community. The VP for Research and Economic Development at GSU is the Institutional Official.

University Research Services and Administration (URSA) 100 Auburn Avenue Centennial Hall Atlanta, Georgia 30303

Phone: 404-413-3517
Fax: 404-413-3504
http://www.gsu.edu/irb

1.9 INSTITUTIONAL REVIEW BOARD DESIGNATION

GSU has two IRBs responsible for conducting initial, continuing, amendment, study closure, protocol
deviation and unanticipated problem reviews as well as reviews for serious and/or continuing non-compliance. The IRBs provide oversight for all research activities involving the use of human subjects and/or human derived materials or data performed on the campus under the scope of GSU. The IRBs conduct all reviews of research activities according to Section 7 and Section 9 of this manual. All review procedures meet or exceed requirements set forth in 45 CFR 46, 21 CFR 50, and 21 CFR 56.

1.10 INSTITUTIONAL REVIEW BOARD

An IRB is defined as being any board, committee or other group formally designated by an institution to review, to approve the initiation of, and to conduct periodic review of research involving human subjects (45 CFR 46). The primary function of the IRB is to protect the rights, welfare and safety of human subjects participating in research under the auspices of the institution in which it is affiliated. GSU and the IRBs are committed to protecting the rights, safety and welfare of human subjects participating in research, following the GSU policies and procedures as well as the federal mandates set forth in 45 CFR 46, “Protection of Human Subjects”. Thus, the charge of the IRBs is to:

- oversee compliance with federal regulations and ensure rights, safety, and welfare of human subjects who volunteer to participate in scientific research;
- provide accountability for the trust which the public places in institutions conducting research;
- protect human subjects involved in research from inappropriate risk;
- and ensure that human subjects are informed and consent to their involvement with full awareness of what the involvement entails.

The IRBs are composed of regular members and alternate voting members. At times, the IRBs may invite individuals with expertise in special areas for consultation in the review. These individuals serve in an advisory capacity to the Boards but will not vote on the IRB submission.

GSU, consistent with 45 CFR 46.107 and 21 CFR 56.107 makes every attempt to ensure the IRBs are sufficiently qualified through the experience and expertise of its members to review the most common types of studies submitted; review the inclusion of any vulnerable population regularly submitted; promote respect for its advice and counsel; assess the acceptability of the study in terms of institutional commitments and regulations; and assess applicable regulations as well as standards of professional conduct and practice. The membership of the IRBs is diverse including considerations of race, gender, cultural backgrounds, and sensitivity to community attitudes and values. The IRBs also include both men and women; several scientists; at least one non-scientist; and at least one individual who is not affiliated with the institution. Information on the evaluation of IRB members can be found in Section 4.4 of this manual.
1.10.1 HUMAN RESEARCH PROTECTION PROGRAM EVALUATION
As each fiscal year comes to an end, the Vice President for Research and Economic Development, who is also the Institutional Official, the Associate Vice President for Research Integrity, the IRB Chairs, and the HRPP Director conduct a formal evaluation of the HRPP. The programmatic evaluation includes an assessment of the support staff, financial resources, space allocation, computer support, education program, legal counsel, conflicts of interest, quality improvement plan, and community outreach. An annual report is included with the evaluation, which summarizes the nature and volume of the IRBs’ activities, compliance issues and conflict of interest reports from IRB members and investigators. Careful consideration is given to the volume of each IRB’s submissions in relationship to the number of appointed IRB members from each of the colleges and units within GSU, as well as to the number of staff and resources required for effective and efficient operation of the HRPP.

The IRBs’ leadership and each individual member are assessed during the annual evaluation process. This includes assessment of the level of expertise, affiliation, diversity and attendance for each member against the committee requirements for optimal operation. The education and training programs provided to IRB members, staff and investigators are reviewed. An analysis of the effectiveness as well as the topics requiring further education and training are identified. A summary of the quality improvement activities are reviewed and the plan for the upcoming year discussed including any potential high risk areas. Corrective actions that have been taken are reviewed and the sufficiency of each effort is evaluated. Additional resources that may be required are identified.

In addition to the annual review, monthly reports are provided to the Associate Vice President for Research Integrity and Vice President for Research and Economic Development, which track the level of activity and allow trends to be timely identified.
Section 2: Definitions

2.0 Policy
2.1 Purpose
2.2 Definitions Applicable to All Sections of this Manual

2.0 POLICY
Federal regulations contain definitions associated with human subject research and GSU utilizes these definitions.

2.1 PURPOSE
The purpose of this policy is to define terms associated with human subject research.

DEFINITIONS APPLICABLE TO ALL SECTIONS OF THIS MANUAL:

Agent
An individual who: (1) acts on behalf of the institution; (2) exercises institutional authority or responsibility; or (3) performs institutionally designated activities. “Employees and agents” can include staff, students, contractors, and volunteers, among others, regardless of whether the individual is receiving compensation.

Anonymous
Generally means that the identity of a research subject cannot be readily ascertained by anyone, including the Principal Investigator, either directly or through the use of coded data.

Benign Behavioral Intervention
Low risk behavioral [not biomedical] interventions in conjunction with collecting information from an adult subject through oral or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and certain conditions are met. Regulations specify that benign behavioral interventions are brief in duration, painless, harmless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the intervention offensive or embarrassing.

Broad Consent
Addresses elements of consent for the storage, maintenance, and secondary research use of private information or identifiable biospecimens. Also, may seek prospective consent to unspecified future research.
Clinical Trial
A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.

Coercion
An overt or implicit threat of harm that is intentionally presented by one person to another in order to obtain agreement. For example, if an investigator is the researcher of record, and would like for the student in their class to participate in the study, the students may feel that if they don’t participate they will be punished or receive a lower grade.

Common Rule
Refers to regulations of the U.S. Department of Health and Human Services, at 45 CFR Part 46, Subpart A.

Concealment
The withholding of full information from subjects about the nature of the experiment.

Confidentiality
Pertains to the treatment of information (data) that an individual has disclosed in a relationship of trust and with the expectation that it will not be divulged to others without permission in ways that are inconsistent with the understanding of the original disclosure.

Continuing non-compliance
A pattern of non-compliance that if allowed to continue is likely to increase risk to subjects, adversely affect the rights, welfare and safety of research subjects, or adversely affect the scientific integrity of the study.

Covered Entity
A health plan, a health care clearinghouse, or a health care provider who transmits health information in electronic form in connection with a transaction for which HHS has adopted a standard.

Data and Safety Monitoring Plan (DSMP)
This is an individualized plan, normally written by the Principal Investigator, who is responsible for the conduct of the study. The DSMP provides mechanisms for reviewing and evaluating unanticipated problems or other study-related data. The rationale for requiring a DSMP is the need to enhance research subject
safety by clearly defining safety related issues prior to subjects being enrolled in a study.

**Deception**
The intentional misleading of subjects about the nature of the experiment.

**Decisionally Impaired Individual**
An individual who has a diminished capacity for judgment and reasoning due to a psychiatric, organic, developmental, or other disorder that affects cognitive or emotional functions. Individuals who are decisionally impaired may suffer from many different conditions that could potentially affect their ability to reason and make sound choices. The level of impairment may fluctuate or progressively change over time. An individual's capacity may also be specific to the particular task, point-in-time, or decision-making circumstance. Examples of decisionally impaired individuals include those impaired by a stroke, traumatic brain injury, Alzheimer's disease, individuals under the influence of or dependent on drugs or alcohol, terminally ill patients, and mental illness such as schizophrenia, depression, or Post-Traumatic Stress Disorder. Other individuals, who may be considered decisionally impaired with limited decision-making ability, include individuals who have lost cognitive ability due to trauma, anesthetics, analgesics, or extreme pain, such as in an emergency room setting or preparatory to surgery.

**Emancipated Minor**
"Emancipated" means that the rights of the parents to the custody, control, services, and earnings of a minor have been terminated. "Minor" means a person who is at least 16 but less than 18 years of age. Emancipation may occur by operation of law (when a minor is validly married or reaches 18 or during the period when the minor is on active duty within the US armed forces) or pursuant to a petition filed by a minor with the juvenile court. Emancipated minors may consent to research participation for themselves.

**Engaged in Human Subjects Research**
See [Human Subject Research Determinations](#)

**FDA**
Food and Drug Administration, an agency of the federal government that regulates food, drugs, medical devices, cosmetics, and other products to make sure they are safe and effective to use.

**FERPA**
Family Educational Rights and Privacy Act
Generalizable Knowledge
See Human Subjects Research Determination

Health Information
Any information, whether oral or recorded in any form or medium, that (1) is created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university, or health care clearinghouse; and (2) relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual.

Health-related biomedical or behavioral outcome
Pre-specified goal(s) or condition(s) that reflect the effect of one or more interventions on human subjects' biomedical or behavioral status or quality of life. Examples include: positive or negative changes to physiological or biological parameters (e.g., improvement of lung capacity, gene expression); positive or negative changes to psychological or neurodevelopmental parameters (e.g., mood management intervention for smokers; reading comprehension and/or information retention); positive or negative changes to disease processes; positive or negative changes to health-related behaviors; and, positive or negative changes to quality of life.

HIPAA
Health Information Portability and Accountability Act

Human Subject (As Defined by DHHS)
See Human Subjects Research Determinations

Human Embryonic Stem Cells
Pluripotent cells that are derived from early stage of embryos, up to and including the blastocyst stage, are capable of dividing without differentiating for a prolonged period in culture and are known to develop into cells and tissues of the three primary germ layers.

Human Research Protection Program (“HRPP”)
A comprehensive system designed to ensure the protection of the rights and welfare of human subjects participating in research.
**Individually Identifiable Health Information**

Information that is a subset of health information, including demographic information collected from an individual, and (1) is created or received by a health care provider, health plan, employer, or health care clearinghouse; and (2) relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual; and (a) that identifies the individual; or (b) with respect to which there is a reasonable basis to believe the information can be used to identify the individual.

**Informed Consent**

A person’s voluntary agreement based upon adequate knowledge and understanding of relevant information, to participate in research or to undergo a diagnostic, therapeutic, or preventive procedure.

**Incapacity**

A person’s mental status and an inability to understand information presented, to appreciate the consequences of acting (or not acting) on that information, and to make a choice. Often used as a synonym for incompetence.

**Incompetence**

Technically, a legal term meaning inability to manage one’s own affairs. Often used as a synonym for incapacity.

**Institutional Official (IO)**

The GSU official responsible for ensuring that the HRPP has the resources and support necessary to comply with all federal regulations and guidelines that govern human subjects research. The IO is legally authorized to represent the institution, is the signatory official for all Assurances and assumes the obligations of the institution’s Assurance. At GSU, the Vice President for Research and Economic Development is the IO.

**Institutional Review Board (“IRB”)**

Any board, committee or other group formally designated by an institution to review, to approve the initiation of, and to conduct periodic review of research involving human subjects.

**Investigator**

An individual (whether professional or student) who conducts an investigation. The investigator who directs the study and carries the ultimate responsibility for the research is referred to as the Principal Investigator (“PI”). The institution recognizes a single individual to serve as the PI of human subject research.
IRB Compliance Office
At GSU, the IRB Compliance Office (or “IRB staff”) is the administrative component of the HRPP that serves to support the IRB’s review functions, provide guidance to the GSU research community, and provide assessments/determinations (e.g. Exempt determinations, Not Human Subjects Research determinations) not required by regulation to be conducted via IRB review.

Key Personnel
The Principal Investigator (“PI”), Co-Investigators, Student PI, and other personnel who are responsible for the design and/or conduct of the study. Key personnel must be listed in the Key Personnel section of the iRIS application.

Legally Authorized Representative
An individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research. If there is no applicable law addressing this issue, legally authorized representative means an individual recognized by institutional policy as acceptable for providing consent in the non-research context on behalf of the prospective subject to the subject's participation in the procedure(s) involved in the research. For the purposes of these policies and procedures, a legally authorized representative may include, as applicable, a person appointed as a health care agent under a Durable Power of Attorney for Health Care (DPAHC), a court appointed guardian of the person, and in some cases, the next-of-kin in the order of priority set forth by state law.

Limited Review
Making and documenting the determination required by 46.111(a)(7), to ensure that there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data in the proposed research.

Magnetic Resonance Imaging ("MRI")
Produces multiple images of organs and structures within the body by using a large magnet to attract electrons with the body used; as a diagnostic tool.

Minimal Risk
The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.
**Minimal Risk for Prisoners**
The probability and magnitude of physical or psychological harm that is normally encountered in the daily lives or in the routine medical, dental, or psychological examination of a healthy person.

**Modifications that are Minor**
Minor modifications are changes that can be easily ascertained that they have been completed. They generally do not affect the criteria listed in 45 CFR 46.111.

**Non-Compliance**
Any action or activity associated with the conduct or oversight of research involving human subjects that fails to comply with either the research plan as approved by a designated IRB, or federal regulations or institutional policies governing such research. Non-compliance may range from minor to serious, be unintentional or willful, and may occur once or several times.

**PPRA**
Protection of Pupil Rights Amendment

**Privacy**
The control over the extent, timing, and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others.

**Prospective Studies**
Studies that gather information about events that occur after the identification of the group of subjects to be studies. Prospective studies may involve intervention or may be solely observations or may involve only the collection of data.

**Protected Health Information**
PHI is individually identifiable health information transmitted by electronic media, maintained in electronic media, or transmitted or maintained in any other form or medium. PHI excludes education records covered by the Family Educational Rights and Privacy Act, as amended, 20 U.S.C. 1232g, records described at 20 U.S.C. 1232g(a)(4)(B)(iv), and employment records held by a covered entity in its role as employer.

**Protocol**
The plan of a study. The protocol should include the study title; a summary; a description that includes a
rationale, objectives, methodology, and data management and analysis; ethical consideration, and references.

**Protocol Deviation**
A deviation from IRB-approved activities related to a research study. This means that the PI has performed activities that are different than those described in the protocol, that procedures not previously described in the protocol were performed, or that procedures described in the protocol were not performed.

**Quorum**
A majority of the voting members. In the instance of the IRB, a quorum will consist of greater than 50% of the voting IRB members for that IRB panel and must include at least one non-scientific member. All members present have equal voting power. At meeting of the IRB, a quorum must be established and maintained throughout the entire meeting. A member with a conflict of interest cannot contribute to a quorum.

**Research (DHHS)**
See Human Subjects Research Determinations

**Risk**
The probability and magnitude of harm or injury (physical, psychological, social, economic) occurring as a result of participation in a research study.

**Secondary Research Use**
Re-using identifiable and non-identifiable information and biospecimens that are collected for some other ‘primary’ or ‘initial’ activity.

**Serious Non-Compliance**
Failure to adhere to the terms of the IRB approval and/or abide by the applicable laws, regulations or institutional policies when that failure increases risks to subjects or others or adversely affect the rights and welfare of the subjects. Willful violation of policies and/or federal regulations may also constitute serious non-compliance. Serious non-compliance is a finding that is determined by the convened board.

**Sponsor**
Any person or entity that takes the responsibility for funding a study. The sponsor may be an individual, governmental agency, academic institution, private or other organization.
**Suspension**
An action by a convened IRB, the IRB Chair/Vice Chair or the IO, or his/her designee to stop, temporarily or permanently, some or all previously approved research activities short of permanently stopping all research activities. Suspended protocols are not closed with the IRB and require continuing review by the IRB.

**Systematic Investigation**
See Human Subjects Research Determination

**Termination**
A termination is an action by the convened IRB to stop permanently all activities of a previously approved research protocol. Terminated protocols are closed protocols, and they no longer require continuing review.

**Unanticipated Event/Unanticipated Problem Involving Risk to Subjects or Others**
Any problem, event, occurrence or new information related to the research project that is unanticipated and indicates subjects or others are at increased risk of Harm (including physical, psychological, economic or social harm) than was previously known or recognized. An unanticipated problem is one that is unforeseen in terms of nature, severity or frequency of occurrence as documented in the research or other materials approved by the IRB.

**Voluntary**
Free of coercion, duress, or undue inducement. Used in the research context to refer to a subject’s decision to participate (or to continue to participate) in a research activity.

**Written**
Written, or in writing, refers to writing on a tangible medium (e.g., paper) or in an electronic format.
Section 3: Human Subjects Research Determinations

3.0 Policy
3.1 Purpose
3.2 Definitions
3.3 General Information
3.4 Publicly Available Data Sets
   3.4.1 Pre-approved Publicly Available Data Sets
3.5 Student Projects
3.6 Oral Histories
3.7 Cell Lines and Cultures
3.8 Literature Review
3.9 Course Evaluations

3.0 POLICY

Prior to engaging in activities constituting human subjects research, GSU researchers must obtain either:

   a. Review and approval by the IRB, or
   b. A determination of “exemption” from IRB review issued by the IRB Compliance Office.

To promote compliance with this policy, the IRB Compliance Office offers formal assessments of whether a proposed activity constitutes human subjects research (via the Application for Designation of Not Human Subjects Research) or engagement therein (via the Not Engaged in Research application).

A researcher’s failure to secure IRB approval or an exempt determination before engaging in human subjects research constitutes non-compliance with GSU policy and may violate federal regulations for human subject protections.

The terms human subjects, research, and engaged are further discussed in this section.

3.1 PURPOSE

The purpose of this policy is to distinguish between activities engaged in by GSU faculty, staff, or students that do constitute human subjects research requiring IRB oversight or exemption therefrom, versus activities do not constitute engagement in human subjects research.
3.2 DEFINITIONS

Human Subject:
A living individual about whom an investigator (whether professional or student) conducting research:

a. Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or

b. Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

Intervention includes both physical procedures by which information or biospecimens are gathered (e.g., venipuncture) and manipulations of the subject or the subject’s environment that are performed for research purposes.

Interaction includes communication or interpersonal contact between investigator and subject.

Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (for example, a medical record).

Identifiable private information is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

An identifiable biospecimen is a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.

When following FDA requirements, “Human Subject” means:
An individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A participant might be either a healthy individual or a patient. For research involving medical devices a human participant is also an individual on whose specimen an investigational device is used. Refer to 21 CFR 50.3(g), 21 CFR 56.102(e), 21 CFR 812.3(p).

Research:
A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to Generalizable Knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities. For purposes of this part, the following activities are deemed not to be research:

1. Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that
focus directly on the specific individuals about whom the information is collected.

2. Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).

3. Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.

4. Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

**When following FDA requirements, “Research” means:**

Any experiment that involves a test article and one or more human participants, and that either must meet the requirements for prior submission to the FDA under section 505 (i) or 520 (g) of the Federal Food, Drug, and Cosmetic Act, or need not meet the requirements for prior submission to the FDA under these sections of the Federal Food, Drug and Cosmetic Act, but the results of which are intended to be later submitted to, or held for inspection by, the FDA as part of an application for a research or marketing permit. The terms research, clinical research, clinical study, study, and clinical investigation are synonymous for purposes of FDA regulations. Refer to 21 CFR 50.3(c), 21 CFR 56.102(c).

**Generalizable Knowledge:**

Data gathered with the intent to draw conclusions from the research which will develop or contribute to a general body of knowledge. Please note: Results that remain in the classroom or that are presented within the confines of the institution (i.e., at GSU’s Undergraduate Research Conference) are not considered generalizable. However, if the results will be published, presented at a conference off-campus, included in a dissertation, thesis or capstone project or generalized in some other way, the project will be considered generalizable per GSU IRB Policy and will thus be considered research.

**Systematic Investigation:**

For purposes of human subjects research at GSU, a "systematic investigation" is the gathering and analysis of information using a predetermined method to study a specific topic, answer a specific
Engaged in Human Subjects Research:

The DHHS provides guidance on Engagement of Institutions in Human Subjects Research advising that an institution is considered “engaged” in a particular non-exempt human subjects research project when its employees or agents, for the purposes of the research project obtain:

a. Data about the subjects of research through intervention or interaction with them,

b. Identifiable private information about the subjects of research, or

c. Informed consent of human subjects for the research.

Institutions are also considered engaged in federally-funded projects where the institution receives an award through a grant, contract or cooperative agreement directly from the funding agency for the non-exempt human subjects research (i.e. awardee institutions) even where all activities involving human subjects are carried out by employees or agents of another institution.

3.3 GENERAL INFORMATION

Only the IRB Compliance Office issues formal and independent determinations that a project does not constitute human subjects research or that a researcher is “not engaged” in activities that otherwise constitute human subjects research.

The IRB Compliance Office has determined that research using Pre-Approved Publicly Available Data Sets, some Student Projects meeting specific criteria, some Oral History projects, and some projects using readily available Cell Lines and Cultures do not, when observing the limitations/requirements detailed in this section, constitute human subjects research; researchers may conduct these activities without submitting any application or other materials to the IRB Compliance Office. Implementation of Bureau of Prisons programmatic or operational initiatives made through pilot projects is not considered to be research.

When to Submit an “Application for Designation of Not Human Subjects Research”

The NIH offers a decision tool at https://grants.nih.gov/policy/humansubjects hs-decision.htm as guidance for considering whether a research project: 1) involves human subjects; 2) may be considered exempt from IRB oversight (though the tool cannot be used in lieu of a formal exempt determination from the IRB Compliance Office); or 3) may not be considered human subjects research. In some cases, it may not be clear whether activities constitute “human subjects research.” In others, sponsors or publications may require verification independent of the research team that a study does not constitute human subjects research. The Application for Designation of Not Human Subjects Research form is available at the NIH website. Researchers are encouraged to consult with the IRB Compliance Office for clarification on any questions regarding the application process.
Subjects Research must be submitted to the IRB Compliance Office via iRIS for a formal and independent determination in these cases. **A formal assessment from the IRB Compliance Office is required for thesis, capstone and dissertation research involving humans even where the project appears not to constitute “human subjects research.”** A researcher’s failure to secure IRB approval or an exempt determination before engaging in human subjects research constitutes non-compliance with GSU policy and may violate federal regulations for human subject protections.

**When to Submit a “Not Engaged in Research” Application**

Researchers at GSU may contribute to the conduct of human subjects research in a manner that does not constitute “engagement” in research that would otherwise require IRB oversight. See this policy’s definition of [Engaged in Human Subjects Research](#) and OHRP’s guidance entitled [Engagement of Institutions in Human Subjects Research](#). Assessments of engagement are particularly important for federally funded studies, which may be subject to a single IRB requirement where multiple institutions are “engaged” in a project. This assessment is also relevant where GSU researchers only receive deidentified subject data for ongoing studies at collaborating institutions and have no interaction with research subjects. To promote compliance with requirements that GSU researchers must obtain IRB approval or an exempt determination before engaging in human subjects research, the IRB Compliance Office offers formal assessments of whether a proposed activity constitutes engagement therein (via the Not Engaged in Research application in iRIS).

### 3.4 PUBLICLY AVAILABLE DATA SETS

The research use of publicly available deidentified data sets generally does not constitute human subjects research. The use of specific public data sets **may** constitute human subjects research requiring IRB review if either of the following activities occur:

- a. Merging public data sets in such a way that individuals may be identified; or
- b. Enhancing a public data set with identifiable, or potentially identifiable, data.

Researchers using publicly available deidentified data sets must complete the Application for Designation of Not Human Subjects Research to obtain a formal and independent determination from the IRB Compliance Office that the project is “not human subjects research.” Contact the IRB Compliance Office with any questions regarding the use of publicly available data.

#### 3.4.1 PRE-APPROVED PUBLICLY AVAILABLE DATA SETS

Research involving only the analysis of data from public data sets pre-approved by the IRB Compliance Office does not require a determination from the IRB Compliance Office that the project is “not human subjects research.”
subjects research.” Researchers may conduct this research without submitting any application or other materials to the IRB Compliance Office. The pre-approved list is available at https://ursa.research.gsu.edu/human-subjects/#manuals under the Policy for Publicly Available, Archival, and Secondary Data heading. To request adding a data set to this pre-approved list, researchers should submit the request form available via https://ursa.research.gsu.edu/document/archival-and-secondary-data-request.

3.5 STUDENT PROJECTS

Student work involving human subjects at GSU generally falls into one of two categories:

a. Research practica - research activities, such as class projects or research conducted for presentation at the Georgia State Undergraduate Research Conference, with the goal of providing research experience to students. By definition, research practica are not intended to add to generalizable knowledge and thus do not meet the federal regulatory definition of research. That is, the product from the practicum will not be submitted for presentation or publication at the time of the activity or in the future. Since they do not contribute to generalizable knowledge, research practica do not usually require IRB submission. However, the faculty of record bears the responsibility to ensure that students engaged in these practica behave according to the highest standards of professional ethics and in accordance with the policies and procedures of the setting in which the activity takes place. These procedures may include, but are not limited to, the use of information letters, consents, assents, and releases. Faculty of record for class projects must be especially cognizant of their responsibility and potential liability when these student projects place subjects at greater than minimal risk. Such projects may include the following:
   i. studies asking about illegal activities
   ii. studies in which a breach of confidentiality would place the subject at risk
   iii. studies that address emotionally charged subject matter.
   iv. studies that involve any aspect of deception
   v. studies involving vulnerable subjects

   Faculty of record may consult with the IRB staff for information and guidance when evaluating risks. Faculty and students involved in these activities are encouraged to complete human subjects training through CITI.

b. Research projects - faculty-directed or independent research activities (for example, honors or graduate theses, capstone projects, dissertations) with the goal of adding to generalizable knowledge. These projects must be submitted to the IRB for review and
approval (or other applicable determination) prior to initiation.

3.6 **ORAL HISTORIES**

The purpose of oral histories is to preserve primary source information about the past to be used by others. Oral history is a method of gathering and preserving historical information that is authentic, useful, and reliable. It is done by recording interviews with subjects about people, places, or events in their lives in the form of recollections, reminiscences, and memories of the subject about their past as requested and recorded by an interviewer. Oral histories are primary sources recorded in the person's own words with no interpretation, analysis, or aggregation by another person.

Assessing whether oral history or other activities solely consisting of open-ended qualitative type interviews are subject to IRB oversight requires consideration of the definitions of Human Subjects and Research. For GSU researchers, the assessment often hinges upon whether the person is engaged in the creation of “Generalizable Knowledge.” Oral history documents specific historical events through the individual perspective of the narrator and is not typically designed to contribute to generalizable knowledge; as such, it should not be considered “human subjects research.” Oral history research activities undertaken in furtherance of a dissertation project are considered generalizable knowledge per GSU IRB policy. Questions of whether an oral history project involves “human subjects research” should be addressed to the GSU IRB Compliance Office.

3.7 **CELL LINES AND CULTURES**

*In vitro* research using cell lines that are already derived and established, from which the identity of the donor cannot readily be ascertained by the investigator, is not considered human subjects research and therefore is not governed by 45 CFR 46. IRB review is not required for such research, and it is not necessary to obtain a research determination.

Research involving cells that have already been derived and established, where the donor may be identified, including cells that retain links (such as a code) to identifying information, is considered to be human subjects research and therefore requires submission, review and approval by the IRB. A permissible exception to this would only be cases in which the investigator obtains a written agreement from the holder of the identifiable private information (e.g., the originator of the cell line) that such information will not be released to the investigator or, if applicable, a consultant, under any circumstances, and that the research will be conducted within the terms of the applicable Assurance by all parties engaged in the research.

Please contact the IRB Compliance Office if you are unsure if your research with coded specimens is human subjects research.
3.8 LITERATURE REVIEW
Literature reviews using only published data are not considered human subjects research. Literature reviews where additional unpublished data are obtained from the author or others for meta analyses and other activities may be considered human subjects research. Please contact the IRB Compliance Office if you have any questions about a literature review.

3.9 COURSE EVALUATIONS
Student course evaluations of faculty are not considered human subjects research unless the evaluation results will be used for research purposes (see definition of Research).
Section 4: General Policies and Procedures

4.0 Policy
4.1 Purpose
4.2 General IRB Guidance
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4.4 Composition of the Board and Term of Appointment
  4.4.1 Evaluations
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4.15 IRB Advisory Committee (Senate Research Sub-committee)
4.16 Human Research Protection Program (HRPP) Complaints, Feedback, Concerns, and Issues
4.17 Research Agreements Involving Human Subjects
4.0 POLICY
The governing regulations for GSU’s IRB are 45 CFR 46, 21 CFR 50, 21 CFR 56, and HIPAA.

4.1 PURPOSE
The purpose of this policy is to provide general information on the functionality of GSU’s IRBs and their interaction with researchers.

4.2 GENERAL IRB GUIDANCE
GSU’s Federalwide Assurance (FWA #00000129) with OHRP specifies that the Assurance applies whenever GSU becomes engaged in human subjects research conducted or supported by any U.S. federal department or agency that has adopted the U.S. Federal Policy for the Protection of Human Subjects (the Common Rule, appearing at 45 CFR 46) unless the research is otherwise exempt. For compliance purposes, GSU also applies the Common Rule (including its exempt provisions) to guide the IRB’s protection of human subjects for research not conducted or supported by a U.S. federal department or agency, with the exception of requirements for single IRB review of cooperative research. FDA regulations at 21 CFR 50 and 21 CFR 56 are observed in the review of FDA-regulated studies. The purpose of the IRB is to protect the rights, welfare and safety of human subjects participating in research under the auspices of the institution with which it is affiliated. The IRB fosters review by a peer group not involved in the study protocol under consideration. In order to provide an open discussion regarding human subjects’ protection from risks, the IRB maintains a commitment to involve a diverse group, sufficiently qualified through experience and expertise for reviewing research protocols based on regulations, applicable laws and standards of professional conduct.

All IRB Policies and Procedures are accessible to researchers on the University Research Services and Administration website. Any modifications to current policies and procedures are announced on the website.

GSU’s IRBs utilize an electronic submission system, iRIS, for all submissions to the IRB.

4.3 DESIGNATION AND AUTHORITY
GSU has two designated IRBs responsible for conducting initial and continuing review and providing oversight for all non-exempt research involving the use of human subjects performed by faculty, staff, students or agents of GSU.

The Institutional Official (IO) grants the IRBs authority relative to the protection of human subjects:
   a. Determine whether activity is human subjects research;
   b. Review, approve, require modifications (to secure approval), or disapprove all human subjects
research activities;

c. Require reports for continuing review;

d. Observe, or have a third party observe the consent process and the conduct of the research;

e. Restrict, suspend or terminate approval of research that is not being conducted in accordance with IRB requirements or has been associated with serious unexpected risk to subjects;

f. Require all IRB members to disclose any conflict of interest at the beginning of each IRB meeting and review;

g. Document confidentiality agreement for all IRB members.

Research that has been approved by the IRB may be subject to further appropriate review and approval or disapproval by officials of the Institution. However, those officials may not approve the research if it has not been approved by the IRB.

4.4 COMPOSITION OF THE BOARD AND TERM OF APPOINTMENT

Each IRB (one Full board and one Expedited) consists of a minimum of five members and includes at least one member not affiliated with GSU, apart from his or her committee membership, who represents the interest of the surrounding community. Each IRB includes at least one member whose primary concerns are in the scientific area and at least one member whose primary concerns are in the non-scientific areas. Each IRB is diverse in its membership, considering representation of multiple professions, ethnic backgrounds, and includes members from both genders. Each IRB includes at least one member with knowledge of GSU commitments, knowledge about federal and state privacy laws, and knowledge and experience with vulnerable participants.

The IRB members are appointed annually on July 1, and as vacancies occur, by the VP for Research and Economic Development for a three-year term, conditioned upon renewal each year. IRB members may serve no more than three consecutive three-year terms. Term limits may not apply to the IRB Chair. Vacancies occurring during a term will be filed for the unexpired term in the same manner in which members are initially appointed. Nominations are sought from a variety of sources, including previous and current board members, research faculty, compliance administrators, various public groups, community groups, and organizations. Individuals who are responsible for business development for GSU cannot serve as IRB members or be involved in day-to-day operations of the review process. Scientific members of each IRB generally possess the training, background, and occupation that would incline them to view scientific activities from the standpoint of someone within a behavioral or biomedical research discipline and are usually recruited from GSU faculty. Non-scientific members possess the training, background, and occupation that would incline them to view research
activities from a standpoint outside of any behavioral or biomedical scientific discipline, and may also be recruited from GSU faculty. In addition, they may reflect professional expertise in areas such as law or ethics. There are also members who are not affiliated with GSU to offer the perspective of the community and participants. The unaffiliated member, the member representing the general perspective of subjects, and the non-scientific member may be the same person or they may be represented by two or three different persons. No member of the IRB will participate in University activities (e.g. GSU Research Foundation) that pose or appear to pose a conflicting business interest with the ethics review function.

IRB members are expected to attend at least seventy-five (75) percent of regular meetings of the IRB each Fiscal Year, July 1 to June 30. IRB member performance is evaluated on such performance measures as: attendance at meetings; communication with IRB Compliance Office; completion of reviewer reports and checklists; and contributions verbally and in writing during the IRB meeting. Current Curriculum Vitae are maintained on each IRB member. A list of IRB members is maintained by the IRB Compliance Office. The list includes each member's name, earned degrees, representative capacity, experience, licenses, board certifications, employment and any other relationships or affiliations members may have with GSU. These documents are updated on a regular basis. Non-affiliated IRB members must provide written confirmation that neither they nor their immediate family members (spouse and dependents) have a present affiliation with GSU. The IRB membership is governed by 45 CFR 46.107 and 21 CFR 56.107.

Alternate members are also appointed by the VP for Research and Economic Development. They have qualifications comparable to the applicable regular member. They may review expedited IRB applications, make recommendations on IRB application approvals as well and participate fully in all IRB meetings. Alternates are encouraged to attend convened IRB meetings, receive all materials for meetings and general updates. An alternate member may only vote in the IRB meeting or count toward quorum when replacing a designated member of the IRB. When acting in accordance with their official duties, committee members are protected from liability to the extent of the terms of the Georgia Tort Claims Act and the State Board Form Insurance.

Consultants may be asked to evaluate the scientific soundness of the research protocol, make fair and accurate determination of the risk-benefit ratio, review the cultural appropriateness of the informed consent, and offer additional expert advice. If the IRB, primary reviewer, or IRB staff determine they do not have sufficient expertise to conduct a sound review, they may, at their discretion, invite individuals (consultants) with competence in special areas to assist in the review of issues which require expertise
beyond or in addition to that available on the IRB. Consultants are independent of the IRB and selected by the IRB Chairman according to scholarly and scientific expertise. However, consultants cannot vote with the IRB; they may only offer guidance.

The IRB staff will document in the IRB application file and distribute to all IRB members all guidance received from consultants prior to the formal IRB application and protocol review. Consultants are required to either attend meetings to present their comments or to provide their comments to the IRB in a written report. If consultants attend a meeting, a summary of their findings will be described in the minutes. If consultants provide a written report, a copy of the report will become part of the IRB application file. GSU's IRBs do not use consultants that have disclosed a conflict of interest, based on the University's Conflict of Interest Policy.

Each Chair is an experienced member of the IRB, fully capable of managing the Board and concerns brought before it with impartiality. Each IRB Chair has served a minimum of three years on the IRB or other similar committee. The IRB Chairs understand the federal, state and local laws governing human research. The IRB chairs are recommended by the Associate Vice President of Research Integrity and must be experienced in human subject research, knowledgeable in federal and state regulations, GSU policy, and ethics. Appointment of IRB chair is made by the VP for Research and Economic Development. There is no term limit for the length of service of the IRB chair.

Vice Chairs are also chosen from the IRB. The IRB may have multiple Vice-Chairs. Whenever the Chair is not available, one of the Vice Chairs assumes the responsibilities during their absence.

4.4.1 EVALUATIONS

Annually, each IRB member completes a self-evaluation. The IRB member self-evaluation is reviewed by the IRB Chair, IRB Compliance Staff, and the Associate Vice-President for Research Integrity. IRB Members also complete an anonymous evaluation of the IRB Chair and the compliance staff. The evaluations are reviewed by the Associate Vice-President for Research Integrity and shared with the VP for Research and Economic Development. Evaluations (excepting self evaluations) are kept anonymous and only de-identified data is presented to the Chairs of the IRBs to ensure IRB member confidentiality.

Annually, each IRB member meets with the IRB Chair and IRB compliance staff to provide feedback on evaluations and to ascertain if any resources are needed to provide timely and quality reviews. The Chairs and Vice Chairs of the IRBs participate in a similar evaluation with the Associate Vice-President for Research Integrity.
4.4.2 ADDITIONAL EXPERTISE
The IRBs have good rapport with GSU representatives in the areas of Compliance and Safety to provide expert guidance at any time, either formally or informally during the review of a new or ongoing study and/or non-compliance cases. A representative from Legal Affairs provides expert counsel on interpretation of 45 CFR 46 as it pertains to State of Georgia law.

4.5 FUNCTIONS AND RESPONSIBILITIES

4.5.1 THE HRPP
GSU's program on human research protection is based on the three basic ethical tenets of respect for persons, beneficence, and justice, and the application of these tenets set forth in the Belmont Report. GSU’s HRPP applies these tenants to all human subjects research, regardless of sponsorship.

The HRPP at GSU supports:

a. the right of persons to choose whether to participate in research,
b. fundamental and sacred dignity of human subjects who participate in research,
c. the presumption of investigator integrity and ethical behavior,
d. alignment of federal regulations with proposed research,
e. professional growth and education to augment the conduct of research,
f. tracking and monitoring of human research activities, and
g. ongoing education in the field of human research.

4.5.2 THE IRB
Protecting the rights and welfare of human subjects participating in research activities regardless of sponsorship is primarily the responsibility of the institution. In order to provide sufficient discharge of institutional responsibility, engagement in non-exempt research activity involving human subjects that is under the jurisdiction of GSU cannot take place without IRB review and approval (for information about GSU’s jurisdiction, see Section 7.2).

The IRB review provided will ensure that the Criteria for IRB Approval of Research are satisfied (see Section 7.3.6).

4.5.3 PRINCIPAL INVESTIGATORS
While protection of human subjects in research is the shared responsibility of Principal Investigators (“PIs”), sponsors, and the IRB, the ultimate responsibility for the safety and welfare of subjects rests with the PI.

GSU’s policy for Principal Investigator eligibility on sponsored projects can be found at
https://ursa.research.gsu.edu/proposals-awards/prepare-proposal/#principal-investigator-project-director-eligibility.

For human subjects research studies without an external sponsor, the following may serve as Principal Investigators:

a. Faculty holding full-time tenure track and full-time non-tenure track positions and staff holding full-time, non-temporary positions (“permanent full-time”).

b. Individuals employed by GSU but not on a permanent full-time basis IF a permanent full-time faculty or staff member is named as Co-Principal Investigator. Affiliate and adjunct appointees are not eligible to serve as PIs under this provision.

Exceptions to this policy can be made and require approval of the appropriate Department Chair, College Dean, and the Vice President for Research & Economic Development.

In developing research studies, PIs must:

a. Design studies that are scientifically sound and that will yield valid results.

b. Submit the IRB application along with the research protocol to the IRB for review and approval prior to beginning any research activity.

c. Be appropriately qualified to conduct the research.

d. Comply with federal, state, and local laws and GSU policies.

e. Properly obtain and document consent before research is initiated, if applicable.

f. Conduct the study according to the IRB application and protocol approved by the IRB and with the highest ethical standards.

g. Ensure that the research is conducted responsibly and that all research personnel are adequately supervised.

h. Disclose to the appropriate administrator(s) any potential conflict of interest.

i. Report any new information, modification, non-compliance with the protocol or IRB policies and procedures, or unanticipated events or problems involving risks to subjects or others promptly.

j. Submit requested materials in a timely manner for continuing review of ongoing research activities or required status checks.

k. Ensure that the rights of subjects are protected.

l. Make adequate provisions to protect the privacy of subjects and maintain confidentiality of data.

m. Honor all agreements made as a part of the approved research (e.g. reimbursement to subjects, results of research to subjects).

n. Submit a Study Closure Form upon completion of the research activities.
o. Ensure that there are adequate resources to carry out research safely. This includes, but is not limited to, sufficient investigator time, appropriately qualified research team members, equipment, and space.

p. Ensure that research staff are qualified (e.g. including but not limited to appropriate training, education, expertise, credentials, and, when relevant, privileges) to perform procedures assigned to them during the study.

4.5.4 FACULTY ADVISORS

In student research, the Faculty Advisor (FA) is named as the PI and provides supervision and guidance to the student researcher (the Student PI).

When a faculty member agrees to be a Faculty Advisor, at a minimum he or she agrees to the following responsibilities, in addition to those described in Section 4.5.3:

   a. Oversees the design and conduct of the study
   b. Ensures that the student/staff member assuming duties are well-trained and competent
   c. Reviews IRB application and protocol prior to submission to the IRB
   d. Provides guidance in the protection of research subjects
   e. Assures timely submission of continuing review, amendments, and reporting to the IRB
   f. Works with student/staff researcher to identify revisions warranted by unexpected events/circumstances
   g. Is accessible to student during the active research phase
   h. If applicable, advises and assists students with presentations and manuscript preparation

4.5.5 FACULTY SPONSORS

If a non GSU researcher wishes to conduct research on this campus, the researcher may seek out a GSU faculty sponsor. The Faculty Sponsor serves as the local PI for this study. The non GSU researcher will be named as Co-Investigator. In addition to those described in Section 4.5.3, the roles and responsibilities of the GSU faculty sponsor are as follows:

   a. Reviews IRB application and protocol prior to submission to the IRB
   b. Assures that the researcher is competent
   c. Provides guidance on institutional policy and procedures
   d. Assures proper application and reporting to the IRB

In most cases, however, a non GSU researcher wishing to conduct research on campus presents a situation of GSU not being engaged, as an institution, in the research (See Engagement in Research).
4.5.6 DEPARTMENTAL CHAIRS

At GSU, department chairs or their designees are responsible to review and attest to a protocol’s scientific validity before it is submitted to the IRB for review and approval. The review and attestation at the department level should be undertaken with care, and chairs are encouraged to utilize expertise within the department to ensure appropriate peer review of a protocol before it is submitted to the IRB. Departmental chairs or their designees are required to:

a. Review all IRB applications and their research protocols submitted by all faculty, staff, students, and agents through their department;
b. Assure the IRB that applications meet IRB minimum requirements;
c. Attest that the proposed research is scientifically valid and appropriate; and
d. Sign-off on the IRB application indicating departmental/school approval and forward to the IRB for review and approval.

IRB applications cannot be accepted without the departmental chair or head sign-off unless the IRB chair or designee has given special permission. This is granted on a case-by-case basis.

Scientific validity and appropriateness refers to the following: “Scientific review for both biomedical and behavioral/social science research considers the soundness and worth of the hypothesis, the procedures used to test the hypothesis and the adequacy of the analysis to be employed. For both behavioral and biomedical research, it is important that scientific rigor be maintained because, as the Belmont Report indicates, exposing subjects to any risk is unethical if valid scientific results are not possible” (Protecting Study Volunteers in Research, Second Edition, Chadwick and Dunn, p. 47). Further, putting more participants at risk than is necessary to adequately answer the research question would also be considered unethical. Finally, the data collected during the research must be complete and accurate. Inaccurate or faulty data can lead to misleading or faulty conclusions, putting participants at risk with no potential offsetting benefit.

4.6 TYPES OF RESEARCH CONDUCTED AT GSU

The majority of research conducted at GSU is social-behavioral. GSU does not conduct: planned emergency use research; FDA-regulated research of drug products requiring an Investigational New Drug (“IND”) application; FDA-regulated research of significant risk medical devices requiring an Investigational Device Exemption (“IDE”) application; or classified research.

4.6.1 CATEGORIES OF RESEARCH SUBJECTS

Research subjects at GSU include adults and children and individuals within populations considered vulnerable. The vulnerable populations most commonly included in research at GSU are children,
prisoners, and decisionally impaired adults.

4.7 MEETINGS
The Full IRB holds one regularly scheduled meeting per month, at a time and place to be pre-
determined and posted on the IRB web site. The IRB may invite researchers to attend the IRB meetings. Invited researchers are asked to leave the meeting during discussion and all votes. The IRB compliance staff typically make all agenda items available through the electronic submission program (iRIS) at least 5 business days prior to each scheduled meeting date. All materials are made available to all Full Board IRB members including alternates. The agenda also states any educational items or topics that will be discussed at the meeting.

Full board research protocols (all protocols other than exempt or expedited) and IRB applications will be reviewed only at convened meetings of the full IRB at which quorum has been established and includes at least one non-scientific member. Quorum is defined as greater than half of the voting IRB members. If quorum fails during a meeting, such as due to a lack of a majority of IRB members being present or an absence of a non-scientific member, including because members are recused due to a conflicting interest (See Section 4.9), the IRB will not take further votes until the quorum is restored. The IRB compliance staff monitor quorum at each meeting, determine vote counts, and record IRB discussion points for the minutes. When the IRB reviews research involving prisoners, a prisoner representative will be present. A non-affiliated member and a member whose primary interest represents the general perspective of participants will attend most meetings (at least 10 of 12 meetings per year) and their attendance is documented in the IRB minutes. The unaffiliated member, the member representing the general perspective of subjects, and the non-scientific member may be the same person or they may be represented by two or more different persons.

Prior to each full board meeting the IRB compliance staff or the IRB chair will review the agenda of IRB applications (full board) and will assign a primary and secondary reviewer knowledgeable about or experienced in working with the research subject matter. Studies involving vulnerable populations will have a primary and/or secondary reviewer knowledgeable about or experienced with the subject population. Should the IRB membership not have the appropriate expertise, relevant consultation (See Section 4.4) will be obtained. Reviews will be made available to IRB members at the convened meeting. If the primary or secondary reviewer is not available at the meeting his/her review will be read to the board.
4.8 CONFIDENTIALITY OF THE REVIEW PROCESS

During the process of initial or continuing review of a research activity, material provided to the IRB and IRB compliance staff is considered privileged information, and the Board shall ensure the confidentiality of the information provided. Hence, each IRB member, IRB compliance staff or anyone with access to submitted materials is required to sign a Confidentiality Agreement to:

   a. Maintain in confidence all confidential information and agree not to disclose such confidential information to third parties without prior written permission of GSU;

   b. Use the confidential information only for the purpose of reviewing research proposals submitted to the IRB for review and approval, and

   c. Disclose the confidential information only to those persons having a need to know for the purpose stated above and that such persons shall be advised of the obligations set forth in the written Confidentiality Agreement and shall be obligated in like manner.

4.9 CONFLICTS OF INTEREST

GSU’s Policy on Financial Disclosures in Sponsored Projects requires researchers to disclose to the University information on certain outside financial interest(s) related to the researcher’s responsibilities at GSU. The policy also sets forth the procedures for the review and management of conflicts of interest in research.

In addition to the disclosures required by such policy, the IRB requires investigators to respond to specific questions related to significant financial conflicts of interest with each application submitted to the IRBs for review. If the response to those questions posed to the investigator is affirmative, the Conflicts of Interest Officer is notified; and, the Disclosure of Significant Financial Interest Form must be completed and submitted.

The Disclosure of Significant Financial Interest Form will capture the outside interests of each researcher and his or her spouse and dependents. The Disclosure Form must be resubmitted when the details of any previously disclosed outside interest change. IRB members also complete the Disclosure of Significant Financial Conflict of Interest Form on a yearly basis. IRB members will not review a submission in which they have a conflict of interest. IRB members disclose conflicts of interest with the review of new studies, continuing reviews, modifications to previously approved research, unanticipated problems involving risks to participants or others, and non-compliance before each IRB meeting and will not participate in the review of those research submissions. Investigators and research staff will declare whether they have a financial or other conflict of interest with each application they submit for review, and when their financial interests change. All consultants must also complete the Disclosure Form prior to beginning a consultation. Consultants with a conflict of interest will not be used.
Disclosure of Significant Financial Conflict of Interest Forms will be reviewed by the GSU Conflict of Interest Officer, and, where applicable, the Conflict of Interest Committee. If the Conflict of Interest Officer and/or the Committee determines that there is a conflict of interest that must be managed, the Conflict of Interest Committee will work with the researcher to design a plan to manage the conflict (a “Management Plan”). The COI Committee determines if a conflict of interest is related to the research based on the URSA Procedures for Compliance with the GSU Policy on Financial Disclosures in Sponsored Projects. The results of the evaluation including the Management Plan are provided to the IRB Chair or a Vice Chair for their review. The Management Plan is also included as a part of the IRB submission. The IRB reviewer will review the Management Plan and the IRB will make a determination as to whether the IRB application can be approved with the Management Plan.

The IRB reviewer will determine:

a. Whether the activity creating a conflict of interest, as managed, will adversely affect the protection of participants in terms of the criteria for IRB approval of research.

b. Whether the activity creating a conflict of interest, as managed, will adversely affect the integrity of the research.

The IRB reviewer may add requirements to the Management Plan but may not delete any requirements. The IRB reviewer may also make the determination that the conflict cannot be adequately managed, and thus, deny the application as submitted. The Management Plan and IRB determination will be documented in the IRB minutes. The IRB has the final authority to decide whether the interest and its management, if any, allows the research to be approved. The study will not be approved until the management of the conflict of interest is acceptable to the IRB.

When disclosing financial conflicts of interest the investigator, staff, or IRB members must include his/her “Immediate Family” defined as the investigator’s, staff’s, or IRB member’s spouse or domestic partner and dependent children or stepchildren.

The following is considered significant financial interest and must be disclosed:

a. Ownership interest, stock option, or other financial interested related to the research. Unless it meets the following four tests:
   i. Less than $5000 when aggregated for the immediately family
   ii. Publicly traded on a stock exchange
   iii. Value is not affected by the outcome of the research
   iv. Less than 5% interest in any one single entity aggregated for the immediate family.

b. Compensation related to the research. Unless it meets the following two tests:
   i. Less than $5000 in the past year when aggregated for the immediately family
   ii. Amount will not be affected by the outcome of the research.
c. Proprietary interest related to the research including by not limited to a patent, trademark, copyright, or licensing agreement.

d. Board or executive relationship related to the research regardless of compensation. Any reimbursed travel or sponsored travel related to Institutional responsibilities (including purpose of trip, sponsor/organizer, destination, and duration). NOT required to disclose travel that is reimbursed or sponsored by a federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education. The Institution will determine if any travel requires further investigation, including determination or disclosure of the monetary value.

The following is excluded from disclosure of significant financial interest:

a. Income from seminars, lectures, or teaching engagements sponsored by and service on advisory or review panels for a federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

b. Income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles.

The GSU Policy on Institutional Financial Interests in Research Involving Human Subjects can be found at the following link:

4.10 IRB MINUTES, CONVENED BOARD

Minutes of the IRB meeting are created by the IRB compliance staff. The IRB Chair or his/her designee and HRPP Director will review, monthly, each set of minutes to evaluate the accuracy of determinations and subsequent justifications. The IRB compliance staff may refer to the Minutes Checklist to ensure compliance. Minutes are distributed monthly to all IRB members (chair, members, and alternates), at the IRB meeting. A vote for approval of those minutes takes place at the convened meeting. The final version of the minutes is posted on a secure website, IRIS. The approval of the minutes is documented in the minutes of the next convened IRB meeting. IRB minutes may not be altered once approved by the IRB unless the IRB votes on approval of the revised minutes. Copies of minutes are provided to the IO quarterly to inform the IO of all actions taken by the convened IRB.

Minutes include:

1. Overall attendance at the meeting, including all members present for any aspect of the meeting. The minutes document when an alternate member replaces a primary member.
2. A list of all full board studies with the respective information:
   a. Actions taken and decisions made by the Committee:
      i. Approved
      ii. Approved, pending required modifications
      iii. Deferred
      iv. Disapproved
   b. Votes will record the total number of members voting for, against, and abstaining. If a member was recused due to a conflicting interest, it is documented in the minutes and indicates the member was absent from the room for the discussion and vote. The minutes will indicate if members leave or enter the meeting.
   c. Required modifications to the research proposal or consent documents or any basis for disapproving the research proposals;
   d. A summary of the discussion of controverted issues and their resolution;
   e. Minutes will also document determinations required by the regulations along with project specific findings that justify each determination. These determinations include those for waiver or alteration of consent, waiver of consent documentation, research involving children, prisoners, pregnant women, or fetuses.
   f. For initial and continuing review, the approval period.
   g. When research appearing in an expedited review category(ies) is reviewed by the convened board, IRB minutes include the rationale for the reviewer’s determination that the research is more than minimal risk.
   h. When following FDA requirements, IRB minutes document the rationale for significant risk/non-significant risk device determinations.

3. A list of all actions taken on behalf of the convened IRB (such as expedited reviews) that were taken during the previous month outside of the IRB meetings by the board.

Minutes include separate deliberations, actions, and votes for each IRB submission by the convened IRB. In order to document the continued existence of a quorum, vote totals for each action will be recorded in the minutes. In order for the IRB application to be approved, it must receive the approval of a majority of members present at the meeting and eligible to vote. The IRB minutes list all suspended and terminated studies that occurred during the previous month.

When a reliance agreement is in place and the IRB is providing oversight for an external organization engaged in the research, the materials provided for IRB review will include documentation specifying the responsibilities that the relying organization and GSU’s IRB will undertake to ensure compliance with the requirements of the Common Rule.
4.11 EXPIRATIONS AND INACTIVE NOTICES

The iRIS system sends email notices to investigators at 60, 30 and 15 days prior to the study expiration date. Notices provide:

a. Name of Principal Investigator
b. Protocol Number
c. Title
d. Expiration Date
e. Continuing Review Instructions
f. Study Closure Instructions

PIs desiring to continue research beyond the expiration date must submit a continuing review request (Section 9.0). There is no grace period for the PI to submit a request for continuing review. Only if the IRB finds an over-riding safety concern or ethical issue involved such that it is in the best interest of the individual research subject is a study allowed to continue without the PI having submitted and approved request for continuing review.

The iRIS system sends investigators an expiration notice on the day the study expires. The expiration notice states that all work on the research must cease immediately. The notice also provides information on who to contact if it is believed that IRB records are incorrect. GSU IRB lists the study as Expired and stores it accordingly.

4.12 IRB APPLICATION FILES

IRB application files are maintained electronically in iRIS. Studies created before the implementation of iRIS were migrated into the system and are also maintained electronically on a University Research Services Administration drive, with encryption protection. The files are assigned a protocol number that is parallel to those in the online database, iRIS. A corresponding electronic file is maintained with iRIS.

Each IRB application file contains the following:

a. A copy of the IRB application
b. A copy of the research protocol
c. Any supplementary forms
d. Correspondence with the IRB related to the research
e. Complete Reviewer Checklists including determinations, justifications and findings of the IRB. (For initial and continuing review of expedited studies, Reviewer Checklist includes the specific permissible category. For initial review of exempt studies, the specific exempt category is documented.)
f. Official notification of the IRB action
g. Any changes made to the official research proposal, as requested by the IRB, (if any)
h. A stamped copy of the approved consent form, (if applicable)
i. Applications for continuing review and all correspondence and records related to that review, (if any)
j. Applications to amend a protocol and all correspondence and records related to that review, (if any)
k. Reports of unanticipated events or problems involving risks to subjects or others, (if any)
l. Any IRB action regarding non-compliance and related correspondence, (if any)
m. Copies of scientific evaluations, (if any)
n. Reports of injuries to participants, (if any)
o. Statements of significant new findings provided to participants, (if any)
p. Recruitment materials, (if any)
q. Progress reports submitted by researchers, (if any)
r. Data and safety monitoring reports (if any).

4.13 RECORD RETENTION

a. IRB records. While federal regulations require IRB records be retained for at least three (3) years, the University System of Georgia (USG) Records Retention Manual requires IRB minutes to be retained five (5) years. The IRB Compliance Office records are kept electronically in iRIS or in a securely locked area, designated specifically for IRB records. The IRB compliance staff and administrators are the only individuals with access to this area.

b. Research Records. Generally, the University System of Georgia (USG) Records Retention Manual requires research records to be retained three (3) years after completion of research. The USG Records Retention Manual includes additional requirements depending on the type of research that is conducted, including human subjects research. Researchers should be familiar with the requirements of the USG Records Retention Manual, as all detail is not included here. Also, there may be additional record retention requirements of the sponsor, funding agency, or regulatory authority that must be followed in addition to these requirements.

- Records relating to funded research grant proposals, and research activity associated with grant-funded projects, must be retained for seven (7) years after the closing of the grant. The final research report should be retained permanently.
- If a research project involves human subjects and the interventional activities of the project or the outcome of the project has potential long-term effects to human subjects, the USG Records Retention Manual requires records to be retained for seventy (70) years after completion of the project. Additionally, if the project is of major national or international significance, interest or controversy, or where the PI has a widely acknowledged influence on
the area of scholarship, the records must be retained permanently.

- GSU requires researchers to maintain, in a specified location that ensures security, privacy and confidentiality, all records pertaining to research which is conducted. Records may be kept in hardcopy, electronic, or other media form. All research records must be accessible for inspection and copying by authorized representative (e.g. IRB, HHS, FDA, Sponsors) at reasonable times and in a reasonable manner. Records maintained that document compliance or non-compliance with the Department of Defense (DoD) requirements shall be made accessible for inspection and copying by representatives of the DoD at reasonable times and in a reasonable manner as determined by the supporting DoD component.

- If the PI should leave GSU prior to the record retention period, the PI is responsible for initiating a mutually satisfactory arrangement with his/her department and GSU administration as to the disposition of the executed subject consent documents and research related files.

- If a protocol is cancelled without participant enrollment, IRB records are maintained for at least three (3) years after cancellation.

4.14 UNDUE INFLUENCE OF IRB MEMBERS OR HUMAN RESEARCH PROTECTION STAFF

The IRB is independent and does not answer to individuals, departments, or units that rely on the IRB for the review of their research. The IRB has the final authority for all decisions regarding the protection and welfare of humans participating as subjects in research activities. Institutional officials may not approve the research if it has not been approved by the IRB.

Inappropriate attempts to influence the IRB process, individual IRB members, or IRB staff will be documented and reported in writing to the Vice President for Research and Economic Development, who is also the Institutional Official (IO). The IO will formally review the information and at his discretion may convene a meeting to obtain additional information if deemed necessary. The IO will respond to and stop any attempt at inappropriate influence and has the authority to limit or remove an investigator’s privilege to conduct research.

4.15 IRB ADVISORY COMMITTEE (Senate Research Sub-committee)

The members include the IRB Chair, the IRB HRPP Director, the Associate Vice-President for Research Integrity, and three to four faculty members. The determination of Chair of the Advisory Committee is made by the Senate Research Committee. This Committee is given the charge to ensure the workload for members of IRB is equitable, assisting in identifying individuals with necessary expertise, and make recommendations regarding the number of faculty members from each College serving on the IRB based
on the number of new IRB applications received from each College.
The Advisory Committee meets annually and as needed to review concerns and suggestions made by investigators.

4.16 HUMAN RESEARCH PROTECTION PROGRAM (HRPP) COMPLAINTS, FEEDBACK, CONCERNS AND ISSUES

All complaints, feedback, concerns, or related issues about the IRB compliance staff or IRB actions should be directed to the Associate Vice-President of Research Integrity. Complaints about participation in research should be directed to the IRB compliance staff. Please consult Section 1.4 for contact information or report anonymously at https://ursa.research.gsu.edu/human-subjects/#survey or https://ursa.research.gsu.edu/human-subjects/#community-participant-information.

All allegations of non-compliance should be directed to the IRB compliance staff in accordance with Section 20 and resolution sought. All other complaints will be directed to the IRB Chair. The Chair can direct the IRB to review the complaint, appoint a sub-committee of the IRB, or meet with the involved parties and to reach a satisfactory resolution. Complaints are documented with resolution and noted as formal actions in the IRB application file.

Unanticipated problems are to be reported to the IRB using the unanticipated problem procedure, Section 21.

IRB compliance staff field calls from research participants including questions, concerns, offering input, obtaining information, or suggestions about the study. They also field calls when participants have questions or concerns about their rights in this study. The compliance staff can review the study file to obtain information that may be helpful to the participant. If any further action is needed, it is handled on a case by case basis.

4.17 RESEARCH AGREEMENT INVOLVING HUMAN SUBJECTS

The Assistant General Counsel is responsible for ensuring that any research agreement involving human subjects uses the appropriate Research Agreement. The Assistant General Counsel also ensures that elements of the research agreement that pertain to the protection of human subjects include the following if applicable:

1. Indicate who will provide care and who is responsible to pay for the care.

2. Specify time frame for prompt reporting by the sponsor to GSU of any findings that could:
   a. Affect the safety of participants.
b. Influence the conduct of the study or alter the IRB’s approval to continue the study.

3. Specify the time frame for providing routine and urgent data and safety monitoring reports to GSU as indicated in the data and safety monitoring plan approved by the IRB.

4. Require sponsor to follow GSU’s policies and procedures regarding the publication of findings from sponsored research.

5. Describe the steps followed to communicate findings from a closed research study to the researcher or GSU when those findings directly affect participant safety. Contracts or other funding agreements specify a time frame after closure of the study during which the Sponsor will communicate such findings.
Section 5: Training in the Protection of Human Research Subjects

5.0 Policy

5.1 Purpose

5.2 Background

5.3 Georgia State University Policy for Required Training

5.4 Training for IRB Members

5.5 Training for IRB Staff

5.0 POLICY

Training on the protection of human subjects is a critical component of all research endeavors. Therefore, training is required of all researchers as well as IRB members and IRB compliance staff.

5.1 PURPOSE

The purpose of this policy is to describe the training and educational requirements for all individuals involved in human subjects research.

5.2 BACKGROUND

October 1, 2000, the National Institutes of Health required education on the protection of human research participants for all investigators submitting NIH applications for grants or proposals for contracts or receiving new or non-competing awards for research involving human subjects. (NIH Policy) GSU has adopted the policy to cover all research involving human subjects, regardless of sponsorship.

5.3 GEORGIA STATE UNIVERSITY’S POLICY FOR REQUIRED TRAINING

All researchers who interact with human subjects to collect data or who handle data must complete a required educational program on ethics and procedures for the use of human subjects in research before the IRB may approve a proposal. This requirement does not apply for projects that do not constitute “human subjects research” (see Section 3.2 Definitions). GSU has selected the Collaborative Institutional Training Initiative (CITI) as the best and most efficient mechanism for delivering education to GSU researchers involved with human subjects research. CITI is an on-line educational training course that provides relevant, up-to-date information on the protection of human research subjects in the format of instructional modules. The modules are divided into two groups, social/behavioral or biomedical. The researcher may select the more appropriate group of modules based upon the type of
research being conducted. Each module of training, developed by experts in the national IRB community, requires mastery of an associated quiz. Certification is provided upon completion of the modules and the GSU administrator is automatically notified of successful completion of each module. This certification is valid for three years. At that time, it is necessary to complete a refresher course. Documentation of completion is entered into the iRIS database by the IRB compliance staff.

The training is required for the PI, Co-Investigators, Student PI, and other key personnel who are responsible for the design and/or conduct of the study. The requirement also applies to department chairs/division head who sign-off on IRB applications, sub-contractors, consultants, individual fellowship applicants, study coordinators, and persons who conduct procedures or conduct surveys or interviews. Any person who is collecting data from human subjects, including providing explanations or answering questions about the research or data gathering instruments, is required to complete the training program. Study personnel who handle data or complete activities such as making transcripts must complete the training program. Individuals providing only technical services such as setting up a room or handing out and collecting survey instruments without providing explanations or answering questions about the research or data-gathering instruments are not covered by this requirement; however, they should receive instruction on maintaining privacy and confidentiality of data. The PI is responsible for ensuring that all personnel are properly trained.

For individuals coming from other institutions to become faculty, staff or students at GSU, current (not expired) human subjects CITI courses completed at previous institutions will apply toward GSU’s CITI training requirements; individuals must “affiliate” with GSU in the CITI interface and use their “.gsu” email address as their primary contact in CITI for this to occur. These individuals may have to complete additional CITI modules if GSU’s CITI requirements differ from those of their prior institution. For study personnel who are not faculty, staff or students at GSU, these individuals can provide current (not expired) certifications of human research protections programs completed per the requirements of their own institution. GSU personnel who interact with human research subjects are required to complete the Social Behavioral (“Group 2”) or Biomedical (“Group 1”) human subjects CITI training. The assigned IRB reviewer ensures training is current before the IRB application is approved. If education requirements are not fulfilled, a submission will not be approved by the IRB.

5.4 TRAINING FOR IRB MEMBERS

IRB members charged with the responsibility of reviewing, approving, and overseeing human subjects research receive detailed training in the regulations, guidelines, ethics and applicable policies related to human subject research.
In addition to completion of the CITI Training, all new IRB members undergo a two-part orientation session. The purpose of the orientation is to provide general information and familiarize the member with the iRIS system as an IRB reviewer. Members are provided with Regulations and Guidance on the Protection of Human Subjects (45 CFR 46 and 164; 21 CFR 50 and 56) historical documents that help to shape the current federal regulations (Belmont Report, Nuremberg Code, and Declaration of Helsinki), Policies and Procedures Manual for the IRB, and directed to the GSU IRB website. IRB Compliance staff provide periodic training at IRB meetings by presenting articles or discussion on current topics in human research protection. Each member of the IRB is asked to fulfill six training opportunities per year, which may include in-service trainings. These initiatives are undertaken to fulfill the mandate to protect the rights and welfare of research subjects.

5.5 TRAINING FOR IRB STAFF

Senior IRB compliance staff maintain certifications as IRB professionals. As such, they are constantly engaged in educational opportunities germane to their responsibilities and duties. The compliance staff also completes the CITI IRB reference course and any optional modules applicable to the functionality of the IRB.

IRB Members and IRB compliance staff are encouraged to attend workshops and other educational opportunities that focus on IRB functions. GSU supports such activities as appropriate to the responsibilities of IRB members and staff. Training records for the IRB members and staff are maintained and housed by the IRB HRPP Director.
Section 6: Recruitment and Participation

6.0 Policy
6.1 Purpose
6.2 General Recruitment Guidelines
6.3 Advertisements
6.4 Recruitment of Students
6.5 Recruitment of Employees
6.6 Snowball Sampling
6.7 Subject Pools
6.8 Site Authorization/Permission
6.9 Compensation
   6.9.1 IRB Regulations
   6.9.2 Nonresident Alien Payment
6.10 Lotteries, Raffles and Other Games of Chance
6.11 Finder Fees and Bonus Payments
6.12 Peer Recruitment
6.13 Certificates of Confidentiality

6.0 POLICY
GSU requires that all recruitment materials used to enroll research subjects for studies be prospectively reviewed by the IRB.

6.1 PURPOSE
The purpose of this policy is to provide guidance on the types of recruitment that are allowed and outline the process for receiving prospective IRB review and approval of these recruitment methods.

6.2 GENERAL RECRUITMENT GUIDELINES
Recruitment of subjects is considered the start of the consent/assent process. Therefore, it is important for researchers to consider how study subjects will be recruited before the study is initiated.
Recruitment of research subjects should be equitable and non-discriminatory. There are many questions in the IRB application that must be answered to describe the proposed study population to be recruited for the research.
For studies under IRB review, all materials used to recruit subjects must be submitted to and approved by the IRB. This includes materials such as flyers, posters, brochures, media advertisements (e.g. audio
or video taped), and recruitment letters. The IRBs must review the final copies of all recruitment materials and not draft versions. For printed advertisements or audio video advertisements, the IRBs must review the final version prior to use. Researchers must also state the amount of reimbursement given to subjects to compensate for their time, parking, travel, etc.

6.3 ADVERTISEMENTS

The IRB must review and approve the information presented in all advertisements that will be used to recruit potential research subjects and the method used to communicate the information. Advertisements must present information that is adequate, accurate, and balanced so that potential subjects can make an informed decision about possible participation. An appropriate advertisement should:

a. Provide straightforward and honest information
b. Specify the project is research
c. Provide ages and other requirements for eligibility
d. Clearly state the purpose
e. Include benefits, if any
f. State time or other commitment required of subjects
g. Provide a contact person’s name and identify the institution
h. Indicate where the research will take place

Researchers should be careful to avoid creating advertisements that:

- Focus on the amount of reimbursements (e.g. payment amount should not be in bold or larger print);
- Use exculpatory language through which the subject or the legally authorized representative is made to waive or appear to waive any of the subject’s legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence; or promise favorable outcomes. The use of the GSU logo is permitted. However, researchers should be aware that the GSU logo is a registered trademark protected by Federal law. Use of the GSU seal is not permitted. For additional guidance of use of the GSU logo, contact the Division of University Relations.

When following FDA requirements, the IRB reviews advertisements to ensure they do not:

a. Make claims, either explicitly or implicitly, about the drug, biologic, or device under investigation that are inconsistent with FDA labeling.
b. Use terms, such as “new treatment,” “new medication,” or “new drug,” without explaining that the test article is investigational.
c. Allow compensation for participation in a trial offered by a sponsor to include a coupon good for a discount on the purchase price of the product once it has been approved for marketing.
6.4 RECRUITMENT OF STUDENTS

Students are entitled to the same protections and considerations granted to other research subjects. However, there are some considerations such as the perception of coercion to participate or undue influence. Researchers who plan to recruit their own students to participate in research should consider:

a. The study could be completely anonymous.
b. The Researcher/Professor can collect the data and not use it for research until the course has ended and grading is complete.
c. The consent form must state the students will have no penalty for refusing to participate.
d. The study should be introduced by a colleague or someone who has no association with the study.

6.5 RECRUITMENT OF EMPLOYEES

In cases where employees participate as volunteers in research projects conducted by their supervisors or in which their supervisors are doing the recruiting, they represent a vulnerable population subject to coercion or undue influence. Researchers must ensure that all personnel who participate, even in studies that are minimal risk, do so entirely voluntarily. Special care should be taken when school employees or laboratory personnel participate as subjects in research.

6.6 SNOWBALL SAMPLING

Some studies propose using "snowball sampling" in which current subjects are asked to put the researcher in touch with other potential subjects. If this method is used, the researcher should ask the research subject to provide the contact information of the researcher to potential subjects and have these potential subjects contact the researcher directly (rather than asking the subject for the name or contact information of potential subjects).

In some circumstances, the researcher may feel it is necessary to obtain contact information for future subjects directly from current subjects. In this case, the researcher must justify why this approach is necessary for the research and how privacy and confidentiality will be ensured.

6.7 SUBJECT POOLS

Subject pools, commonly utilized in social and behavioral research, are a tool used by some departments in academic settings as a registry of individuals who may be interested in volunteering to participate in research studies. Subject pools may serve to provide researchers with a group from which to recruit.
student participants for their studies and may be beneficial in familiarizing students with the research process as subjects.

Web-based human subject pool management software programs are available and SONA Systems are utilized by some GSU departments. Students can log on to the system, and view all available studies and the times they may participate in those studies. Researchers may choose to provide students with incentive for participating (usually extra credit for the course). Alternative opportunities to earn the same extra credit must be available for those not wishing to participate in the research (For more information, see Section 6.9).

Researchers are encouraged to obtain IRB authorization for subject pools to ensure that activities embodied therein align with human subject protections for research recruitment. The Office for Human Research Protections has issued a guidance titled Student Subject Pools and Use of Penalties for Students Who Fail to Show up for Scheduled Research Appointments; it should be reviewed by researchers planning to utilize subject pools as part of a research recruitment plan.

6.8 SITE AUTHORIZATION/PERMISSION

The location or facility at which research will be conducted must be appropriate for the procedures. Prior to beginning research study, the researcher may be required to obtain written documentation of permission from the location or facility owner, if not owned or leased by GSU or a public location. There is not a specified template for a site permission letter; however, typically the letter will be written on letterhead from the site or will be sent from an official email address. The letter should contain the name of the study and the researcher(s), it should briefly state what study activities will take place at the study site, and it will state that permission is granted to conduct the research at the study site. The signature, name and role or the person granting permission should also be included.

a. If recruitment of participants is conducted off GSU’s campus, additional permission may be required.

b. A written letter of permission from a person in authority at the site should be provided if researchers plan to recruit by direct contact with potential participants.

c. When the proposed research activity includes school settings, the IRB requires approval of school district (s). To avoid delay in IRB approval, it is recommended that submissions to both the IRB and the school district (s) be submitted to the respective entities simultaneously. Copies of the district (s) approval letters should be uploaded via iRIS with other required documents.

d. If flyers or materials are to be posted or provided at a non-public site, the nature of the materials and the sites will be taken into consideration by the IRB. A letter of permission
may be necessary. In some cases, a letter describing the study may be provided by the researcher to the appropriate person at the site, and he or she can then give verbal permission.

e. If recruitment is conducted through online posting, such as on a message board or a blog, permission may be necessary from the website administrator. Administrator permission may not be required if the researcher can show that posting the materials would be acceptable according to the website’s user agreement policy.

f. All materials, including those that are posted off-site or online, must be reviewed and approved by the IRB (See Section 6.3).

If the research participant is a person in authority at a site and their agreement to participate in the research effectively authorizes the researcher’s use of the site, additional documentation of site permission may not be necessary.

6.9 COMPENSATION
Requirements for compensation to research subjects are outlined below:

a. Compensation to research participants is generally used as a means to offset inconvenience for the participant. It cannot be considered a benefit of the research.

b. The IRBs will review the compensation to be sure it is fair, is not coercive, and does not present an undue influence.

c. The IRB application and, where applicable, the informed consent form, should contain the amount, method, and terms of any compensation.

d. The amount of compensation must be reasonable and commensurate to the time and effort required of the participant.

e. Proration of compensation is reasonable when participants will be required to come for several sessions or stay for long periods of time. The entire payment should not be contingent upon a participant completing the entire study in these cases.

f. If the researcher could withdraw the participant during the study, the application must describe how compensation will be handled.

g. When extra credit is presented as a means of compensation to students, an alternative assignment of equal time and effort must be provided to students who do not wish to participate in the research.

h. If a lottery or raffle is used as a means of compensation, the investigator must observe State of Georgia law as referenced in this policy at Section 6.10.

i. Records regarding the compensation should be maintained by the PI along with other research
6.9.1 IRS REGULATIONS

In order to comply with Internal Revenue Service (IRS) regulations, GSU must report payments to human subjects totaling $600 or more paid to an individual during a calendar year. This total is from all payments paid, not just payments associated with an individual research project. To comply with this IRS regulation, information needs to be recorded on individuals paid for their participation in a research project. This covers payment via check, cash, cash equivalents, coupons, giveaways, food, and drawings. It is the PI’s responsibility to contact the applicable GSU units/departments regarding providing the IRS with form 1099-MISC. If necessary, the researcher should advise the participant to consult his/her tax consultant to learn of any tax liabilities that could arise from receiving compensation. The researcher and his/her department are responsible for ensuring compliance with this regulation.

6.9.2 NONRESIDENT ALIEN PAYMENTS

US tax laws require that payments made to non-resident aliens (including foreign students) are subject to withholding and reporting rules that require tax withholding at the time of payment. Payments to individuals who are non-resident aliens are subject to 30% withholding unless exempt under some provision of law or a tax treaty. Payments made to Human Subjects who are nonresident aliens must be paid by check and are reported on Form 1042-S, Foreign Person’s U.S. Source Income Subject to Withholding, regardless of the dollar amount. The PI must be mindful of this issue and alert any potential subject who may be a non-resident alien to the tax withholding requirement. In the event that a research protocol is specifically targeting international students and/or non-resident aliens for recruitment, this disclosure must be in the informed consent document. Researchers anticipating payments to Non-Resident Aliens should contact GSU’s Tax Accountant in the Office of Disbursements (x3-3056) for guidance prior to making any such payments. The researcher and his/her department are responsible for ensuring compliance with this regulation.

6.10 LOTTERIES FOR RESEARCH, RAFFLES AND OTHER GAMES OF CHANCE

The State of Georgia closely regulates the operation of lotteries, raffles, and other games of chance (collectively, “raffles” for purposes of this Policy). In Georgia, a raffle is defined as “any scheme or procedure whereby one or more prizes are distributed by chance among persons who have paid or promised consideration for a chance to win such prize.” O.C.G.A. § 16-12-22.1(b)(3). This definition is very broad and includes any procedure whereby a prize is given away, as long as the participant is required to provide something of value (i.e., “consideration”) in exchange for the chance to win.
Consideration can include an individual buying a raffle ticket or giving up his/her time in order to participate in a research study. It is a misdemeanor of a high and aggravated nature, and in some instances a felony, to conduct a raffle (or aid in the operation of a raffle) without a license issued by a county sheriff in Georgia.

However, raffles may be conducted if persons are allowed to participate in the raffle without having to provide any consideration. For example, in the research context, any person should be able to participate in the raffle, even those persons not participating in the research study itself, in order for the raffle to satisfy state laws. Accordingly, in a rare circumstance where a raffle may be conducive to a research study, the GSU IRBs would need to review and approve the procedures underlying the raffle (as well as the protocol generally).

Due to concerns related to fairness and the potential for coercion and undue influence, the IRB generally discourages the use of raffle as a mechanism for participant compensation. However, the IRBs recognize that such raffles may provide useful and meaningful participant engagement in certain specific research studies. Accordingly, the IRBs may consider protocols utilizing raffles as a means for participant compensation on a case-by-case basis, with appropriate justification provided by the PI.

Specifically, if a PI would like to utilize a raffle as a means for participant compensation, he/she must comply with the following:

a. The research must not include activities that are more than minimal risk (i.e., the IRB application must be reviewed in the “Exempt” or “Expedited” categories).

The raffle considered by the PI must be open to all individuals, whether they participate in the research or not. The PI must provide the IRB with a comprehensive plan for how the public will learn of the research study, how the public may participate in the raffle, how the prize will be selected (i.e., date and time of the drawing, person who will conduct the drawing, etc.), how the recipient will be notified, how persons involved in the raffle may ultimately discover who received a prize, and other relevant information pertaining to the raffle.

b. Any raffle should only be open to those eighteen (18) years of age and older and who reside within the United States.

c. The PI must provide the IRB with information concerning the amount(s) and number of prizes involved in the raffle. Both the amount(s) and number of prizes must not be coercive or exert an undue influence on participants, and the disparity between subjects should be considered (i.e., it is preferable to have several lower value prizes than one higher prize because the disparity between subjects is lower).
d. Except on rare occasion, and upon explicit indications otherwise, all persons who elect to participate in the raffle, must have the same chance of winning the prize(s). The PI must include statements that entry into the raffle is not contingent on participation in the research and that a person may remain eligible for the raffle even if he/she withdraws from a study or does not complete every question.

e. The PI, any persons named in the IRB application, immediate family members (spouse, parents, siblings, and children) of such persons, and any other persons with a direct interest in the research study should be excluded from participation in the raffle.

f. Records regarding the raffle should be maintained by the PI along with other research-related documents.

g. The IRB’s policy on Compensation as found in Section 6.9 must also be followed.

### 6.11 Finder’s Fees and Bonus Payments

Finder’s fees and bonus payments are generally associated with clinical trials and are offered by the sponsor of the research as an incentive to enhance subject recruitment. The IRB at GSU does not permit the payment of finder’s fees and/or bonus payments (monetary or in kind) in any form, because such a practice has the potential to cause undue influence and borders on unethical recruitment of subjects. Further, several professional associations and groups have stated that this practice is unethical (for an example, see Ethical Principles and Code of Conduct of the American Psychological Association).

### 6.12 Peer Recruitment

Peer or network recruitment known as respondent-driven sampling or participant driven research may be useful for reaching hidden or hard-to-reach populations. Often the method has a dual incentive structure where individuals who participated in the research project receive remuneration (monetary or in-kind) for their participation and they may receive additional remuneration if they successfully recruit their peers to participate in the research project.

Due to concerns related to the potential for coercion and undue influence when remuneration is provided to participants for recruiting their peers to participate in the research project, the HRPP generally discourages the use of remuneration as a mechanism for recruitment.

However, the HRPP may consider protocols utilizing this type of remuneration on a case-by-case basis, with appropriate justification provided by the PI.

The following safeguards should be included to protect against coercion, undue influence and any ethical violations.
a. The PI must justify why the remuneration is needed and why the research cannot be conducted without providing such remuneration.

b. The PI must describe all safeguards, including privacy safeguards, that are in place to avoid any coercion or undue influence a recruiter may have on a potential participant.

c. There must be a fixed referral quota to limit the number of participants each recruiter can recruit to participate in the research project. This is to restrict potential influence of any one recruiter on the study sample and cap potential remuneration to recruiters. The chosen limit must be justified.

d. The PI must justify the level of remuneration for both the payment amount of original participation in the research project and for recruitment of peers into the research project.

e. The recruiters and recruits must not share a clinical or consulting relationship and must not have a financial or professional conflict of interest.

f. The research team members (not the peer recruiter) must obtain informed consent in order to minimize any pressure, coercion or undue influence.

g. In some cases, researchers may be required to ask participants why they participated in the study to evaluate any potential undue influence on participants regarding their recruitment into the research project.

h. The research project should only be open to those eighteen (18) years of age and older. No minors should participate as a recruiter or participant in the research project.

i. All safeguards outlined in the Section 6 on Recruitment, including snowball recruitment, must be followed.

The IRBs will evaluate the research protocol based on these factors as well as the protections provided, risks and benefits of the research project to determine approval status of the research project.

6.13 CERTIFICATES OF CONFIDENTIALITY

Effective October 1, 2017, NIH updated its policy for issuing Certificates of Confidentiality (“CoC”) as detailed in its Notice of Changes to NIH Policy for Issuing Certificates of Confidentiality (NOT-OD-17-109). Pursuant to the 21st Century Cures Act., the Secretary of the U.S. Department of Health and Human Services issues CoCs to persons engaged in NIH-funded or conducted biomedical, behavioral, clinical or other research, in which identifiable, sensitive information is collected. These CoCs protect the privacy of the subjects by limiting the disclosure of identifiable, sensitive information.
All research commenced on or after December 13, 2016 and funded wholly or in part by the NIH (whether supported through grants, cooperative agreements, contracts, other transaction awards, or conducted by the NIH Intramural Research Program) that collects or uses identifiable, sensitive information is deemed to be issued a CoC.

For the purposes of this policy, the term “identifiable, sensitive information” means information about an individual that is gathered or used during the course of biomedical, behavioral, clinical, or other research, where the following may occur:

- An individual is identified, or
- For which there is at least a very small risk, that some combination of the information, and other available data sources could be used to deduce the identity of an individual.

NIH considers research in which identifiable, sensitive information is collected or used to include:

- Human subjects research as defined in the Common Rule, including exempt research, except for exempt research where the information obtained is recorded in such a manner that subjects cannot be identified, or identities readily ascertained, directly or through identifiers linked to the subjects;

- Research involving the collection or use of biospecimens that are identifiable to an individual or for which there is at least a very small risk that some combination of the biospecimen, a request for the biospecimen, and other available data sources could be used to deduce the identity of an individual;

- Research that involves the generation of individual level, human genomic data from biospecimens, or the use of such data, regardless of identifiability as it is described in the Common Rule; or

- Any other research that involves information about an individual for which there is at least a very small risk, as determined by current scientific practices or statistical methods, that some combination of the information, a request for the information, and other available data sources could be used to deduce the identity of an individual (as defined in §301(d) of the Public Health Service Act).

To determine if NIH’s CoC policy applies to research conducted or supported by NIH, investigators will need to ask and answer the following question:

- Is the activity biomedical, behavioral, clinical, or other research?
  
  If the answer to this question is “no,” then the activity is not issued a CoC.
  
  If the answer is “yes”, then investigators will need to answer the following questions:
− Does the research involve human subjects as defined by 45 CFR Part 46?
− Is the investigator collecting or using biospecimens that are identifiable to an individual as part of the research?
− If collecting or using biospecimens as part of the research, is there a small risk that some combination of the biospecimen, a request for the biospecimen, and other available data sources could be used to deduce the identity of an individual?
− Does the research involve the generation of individual level, human genomic data?

If the answer to any one of these questions is “yes,” then NIH’s CoC policy applies to the research.

When NIH’s CoC policy applies, organizations and investigators (‘recipients of the CoC’) may not:

− Disclose or provide in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding, the name of subjects or any such information, document, or biospecimen that contains identifiable, sensitive information about the individual and that was created or compiled for purposes of the research unless the subject provides consent for the disclosure; or
− Disclose or provide to any other person not connected with the research the names of subjects or any information, document, or biospecimen that contains identifiable, sensitive information about a subject and that was created or compiled for research purposes.

Disclosure is permitted only when:

− Required by Federal, State, or local laws (e.g. reporting to FDA, reporting communicable diseases to health departments) excluding proceedings as noted above;
− Necessary for the medical treatment of the subject, with consent of the subject;
− Made with consent of the subject; or
− Made for the purposes of other scientific research that is in compliance with applicable Federal regulations governing the protection of human subjects in research.

The protection offered by a CoC is not absolute. CoCs do not restrict voluntary disclosures. For example, CoCs do not prevent PIs from voluntarily disclosing to appropriate authorities such matters as child abuse, a subject threatening violence to self or others, or reportable communicable diseases.

Where PIs intend to make such disclosures, it should be clearly stated in the consent form (See Section 8.4.p). Where informed consent is sought from subjects, they should be notified of the protections (and limitations of protection) afforded by a CoC issued by NIH under this policy.
For non-federally funded research, NIH will also consider requests to issue CoCs in accordance with the guidelines applied to funded studies; such requests must be submitted to NIH directly by GSU's Institutional Official (Vice President of Research and Economic Development) rather than by a PI or research team member. See NIH's Notice of Transition to New System for Issuing Certificates of Confidentiality for Non-NIH Funded Research (NOT-OD-20-075) and resources on How to Get a Certificate of Confidentiality.
Section 7: Initial IRB Review

7.0 Policy
7.1 Purpose and Regulatory Guidance
7.2 Research Activity within GSU’s Jurisdiction
7.3 IRB Review at a Convened IRB Meeting
  7.3.1 Data Safety and Monitoring Plan (DSMP)
  7.3.2 Assignment of Primary and Secondary Reviewers
  7.3.3 Distribution of Submitted Materials
  7.3.4 IRB Meeting Schedule
  7.3.5 Presentation and Discussion of IRB Applications
  7.3.6 Criteria for IRB Approval of Research
  7.3.7 Scholarly and Scientific Review
  7.3.8 IRB Application Determinations
  7.3.9 Notifications
  7.3.10 Length of Approval Period
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  7.4.1 Submission Review Schedule
  7.4.2 Submission Requirements and Materials Reviewed
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  7.4.5 Criteria for Approval
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  7.4.7 IRB Application Determinations
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  7.4.10 Reporting of Expedited Review to the IRB
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  7.5.1 Submission Schedule
  7.5.2 Submission Requirements and Materials Reviewed
  7.5.3 Exemption Determination
  7.5.4 Subject Protections
  7.5.5 Modifications to Exempt Research
7.0  POLICY
The IRBs are appropriately constituted and formally designated to review and monitor research and to protect the rights and welfare of human subjects participating in research. The IRBs also provide oversight of such protections. In accordance with the Common Rule, the IRBs have the responsibility for approving, requiring modifications to obtain approval, or disapproving research.

7.1  PURPOSE AND REGULATORY GUIDANCE
All research proposals involving human subjects must meet certain criteria before related study procedures can be initiated. These criteria are based on the principles of the Belmont Report which are justice, beneficence, and respect for persons. Regulatory guidance for the IRBs is 45 CFR 46, 21 CFR 50, 21 CFR 56, and 21 CFR 312.

The IRBs, consistent with their purpose, will evaluate each proposed human subject research submission on an individual basis to determine if the investigator is adequately protecting the rights and well-being of human subjects participating in the research activity.

7.2  RESEARCH ACTIVITY WITHIN GSU’S JURISDICTION
Research covered by any one of the following elements is within GSU’s jurisdiction:

a. Research conducted by or under the direction of any employee or agent of GSU in connection with his or her institutional responsibilities (regardless of the location of the project).

b. Projects wherein GSU is “Engaged in Human Subjects Research” as defined in Section 2.

GSU is not considered engaged in the research if its employees or agents only “inform prospective subjects about the availability of the research; provide prospective subjects with information about the research (which may include a copy of the relevant informed consent document and other IRB approved materials) but do not obtain the subject’s consent for the research or act as a representative of the investigator; provide prospective subjects with information about contacting investigators for information or enrollment; and/or seek or obtain the prospective subjects’ permission for investigators to contact them.”

GSU is not considered engaged if only its facility or equipment is being used by non-GSU
personnel. However, IRB approval from one’s home institution is required and approval by GSU personnel with authority to grant permission and/or use of facility or equipment.

GSU properties and facilities include:

i. Georgia State University

ii. Language Research Center

iii. Georgia Perimeter College


d. Studies that receive funding through GSU.

If an activity requires IRB review or an exempt determination, proper IRB approval/determination is necessary before the project can begin. Re-approval, in the format of a renewal application, is necessary at least annually for full board studies and for some expedited board studies. Most expedited and exempt projects are extended a three year determination period; no activity is allowed to continue past the determination period unless a status check is submitted and the determination period renewed.

7.3 IRB REVIEW AT A CONVENED IRB MEETING

IRB applications that are considered to be more than minimal risk must be reviewed at the convened IRB meeting. The full IRB will evaluate each submission on an individual basis to determine if the investigator is providing adequate protection for the research subject. The determination is based on the initial IRB application which includes applicable documents listed in this section.

Submission deadlines and IRB meeting dates for the convened board are listed on the University Research Services and Administration/Human Subjects website at: https://ursa.research.gsu.edu/human-subjects/#committee. All submissions to the IRB are performed electronically via the iRIS system, and must include the following:

a. The research protocol. A complete original IRB application with electronic signatures of the PI, and the Department Head or Dean or his/her designee.

b. Documented human subjects training for all members of the research team (Section 5.3).

c. Informed consent documents (assents, parental permission, etc.) in all applicable languages.

If applicable, the following should also be included:

d. Site permission letters.

e. Recruitment materials (e.g. flyers, posters, email messages, etc.).

f. Copies of all instruments, if the study involves the use of questionnaires, surveys or similar instruments. If a survey tool such as Qualtrics or REDCap will be used, this should
be described in the protocol and application.

g. Data and Safety Monitoring Plan (Section 7.3.1)

h. Copy of the grant.

i. Other required approvals [e.g. Radiation Protection Committee (RPC), Institutional Biosafety Committee (IBC), Institutional Animal Care and Use Committee (IACUC). Note that researchers may need to obtain approval by the Survey Coordinate Committee (SCC) for some survey distributions but this approval documentation is not a required component of IRB submissions.

j. The complete DHHS-approved protocol (when one exists) and the DHHS-approved sample consent document (when one exists).

7.3.1 DATA AND SAFETY MONITORING PLAN (DSMP)

Research studies in which subjects are at a greater than minimal risk of experiencing physical or psychological injury (behavioral studies that deliver an intervention to subjects) must consider how study data will be monitored and unanticipated problems addressed to assure the ongoing safety and well-being of subjects during the study. In these types of studies, a Data and Safety Monitoring Plan (DSMP) that addresses the following must be submitted.

a. The type of data or events that are to be collected or recorded in the study. The monitoring provisions should be tailored to the expected risks of the research, the subject population under study, the nature and size of the study, and the complexity of the research protocol.

b. Frequency of assessments of data or events to be collected or recorded in the study (e.g. at certain time frames in the study or after enrollment of a certain number of subjects).

c. Person responsible for monitoring the data collected, including data related to the research protocol deviations and unanticipated events and the respective roles with the research activity (e.g. investigators, study coordinators, statisticians).

d. Procedures for analysis and interpretation of data.

e. Time frames for reporting research protocol deviations and unanticipated events.

f. Definition of specified triggers or stopping rules that will dictate when action is required and what the range of that possible action is.

g. Reporting mechanisms/procedures for communicating and reporting to the IRB or other appropriate offices regarding the outcome of the review of data safety and monitoring.
7.3.2 ASSIGNMENT OF PRIMARY AND SECONDARY REVIEWERS
The IRB compliance staff assign primary and a secondary reviewer to each IRB application submitted requiring full board review. Primary and secondary reviewers are assigned based on their scholarly expertise with the proposed research and/or the subject populations to be enrolled. IRB applications are not assigned to reviewers who have a conflict of interest (COI). The primary and secondary reviewers may contact the PI, the Co-Investigators (Co-I), other IRB members, or outside sources as necessary to ensure a thorough evaluation of the risk and benefits of the proposed research. If the convened IRB determines that there is not sufficient expertise to review the study for scientific or scholarly validity, the IRB chair or the chair’s designee will consider who in GSU faculty or community has sufficient expertise to serve an expert consultant to conduct an in-depth review of the study (See Section 4.4).

7.3.3 DISTRIBUTION OF SUBMITTED MATERIALS
All IRB application submission information is available to all IRB members approximately 5 business days prior to the scheduled meeting via iRIS. The primary and secondary reviewers are expected to review all materials for their assigned submission(s). IRB members who are not assigned as primary or secondary reviewers are expected to be well-versed with the application and related materials (i.e. informed consent documents, request to include vulnerable populations, recruitment materials, copies of instruments, etc.) for the research being considered at the meeting.

7.3.4 IRB MEETING SCHEDULE
The IRB is generally scheduled to meet on the third Thursday of each month. The full IRB meeting scheduled may be viewed on the University Research Services and Administration/Human Subjects website at: www.gsu.edu/irb

7.3.5 PRESENTATION AND DISCUSSION OF IRB APPLICATIONS
IRB applications undergoing initial and continuing review at the convened meeting are presented individually to the full IRB by the primary and secondary reviewers. The IRB compliance staff will assure members with appropriate expertise, local knowledge, and other expertise specific to the research protocols are present at the full IRB meeting. When research involving subjects who are vulnerable to coercion is to be reviewed, the IRB compliance staff will also ensure that at least one member who is knowledgeable or experienced in working with vulnerable subjects is present at the meeting. If the IRB compliance staff determines that there is not appropriate expertise, knowledge or experience working
with a particular vulnerable population cannot be present at the meeting, the IRB Chair or the Chair’s
designee will be notified to obtain a consultant. If needed, the consultant can provide a written report
as an evaluation of the research protocol. If there is not at least one member of the full IRB or a
consultant with appropriate scientific, scholarly, other expertise, or knowledge to conduct an in-depth
review, the study will be deferred to another meeting. Proper presentation and discussion requires a
quorum of the members (which must include a non-scientist and a prisoner representative if research
including prisoners is discussed) must be present for the entire presentation, discussion, and
deliberation. A non-affiliated member and a member whose primary interest represents the general
perspective of participants will attend most meetings (at least 10 of 12 meetings per a year) and their
attendance is documented in the IRB minutes. The unaffiliated member, the member representing the
general perspective of subjects, and the non-scientific member may be the same person or they may be
represented by two or three different persons. Members not present for a substantial part of the
discussion and deliberation should abstain from voting. For those IRB applications undergoing initial
review, the following are discussed in detail:

a. Regulatory criteria for IRB approval of research at 45 CFR 46.111.
b. Research setting.
c. Whether the research uses procedures consistent with sound research design and to
   not unnecessarily expose the subjects to risk.
d. Whether the research is designed to answer the proposed research question.
e. The importance of the knowledge reasonably expected to result from the research.
f. If applicable, scientific and ethical justification for including vulnerable populations
   (children, prisoners, decisionally impaired adults, pregnant women, fetuses)
g. Analysis of procedures to minimize risks.
h. Procedures to be used to ensure protection of subject’s privacy and data confidentiality.
i. Scientific qualifications and experience of the investigators and their research staff.
j. Human subjects training of investigators and their research staff.
k. Disclosed or potential investigator conflict of interest.
l. If applicable, written consultant reports, DSMP, justification for excluding classes of persons
   from the research.

7.3.6  CRITERIA FOR IRB APPROVAL OF RESEARCH

In order to approve research, the IRB will provide ethical and scientific review of all human subject
research to the extent necessary to determine that all of the requirements of 45 CFR 46.111 Criteria
for IRB approval of research are satisfied. To ensure that all regulatory requirements for review have
been met, a reviewer checklist is utilized. The reviewer checklist becomes a part of the permanent
Criteria for IRB Approval of Research:

a. Risks to subjects are minimized:
   i. By using procedures that are consistent with sound research design and that do not unnecessarily expose subjects to risk, and
   ii. Whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

b. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (e.g., the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

c. Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted. The IRB should be particularly cognizant of the special problems of research that involves a category of subjects who are vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons.

d. Informed consent is sought from each prospective subject or subject’s legally authorized representative.

e. Informed consent will be appropriately documented or waived.

f. When appropriate, the research makes adequate provision for monitoring the data collected to ensure the safety of subjects.

g. When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

h. When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.
7.3.7 **SCHOLARLY AND SCIENTIFIC REVIEW**

The scientific and scholarly review will be conducted by the assigned primary and secondary reviewer performing the review. The review will include an evaluation of the following:

a. The research uses procedures consistent with sound research design and do not unnecessarily expose the subjects to risks,

b. The research is designed to answer the proposed research question, and

c. The importance of knowledge reasonably expected to result from the research.

7.3.8 **IRB APPLICATION DETERMINATIONS**

The IRB, at the convened meeting, can render one of the following determinations regarding a submitted IRB application.

a. Approved: The study activity may start as soon as approval is received, if all other GSU requirements relevant to the activity have been met. The IRB approval is necessary, but not always sufficient for a study to proceed.

b. Approved Pending Required Modifications: Approval of the IRB application can be granted by the IRB Chair or his/her designee after reviewing the response to the contingencies that were identified by the IRB during the convened meeting. Return to the convened board may not be required if these contingencies are minor and do not impact the criteria for IRB approval of research.

c. Deferred: The IRB application required extensive modifications and must be re-submitted to the IRB for reconsideration by the convened board after modifications are made.

d. Disapproved: The activity may not be conducted as proposed. The researcher will be provided with written documentation of reasons for the IRB’s decision. A new IRB application may be submitted for reconsideration after being revised to address the reasons for disapproval.

The PI may appeal the IRB’s decision by responding in writing to the Chair and the Office of HRPP. This written response is not required to contain the entire rationale for the appeal but must be received within 30 days of notification. It must state that the PI wishes to appeal the decision. Upon receipt of a written response, the issue will be added to the next “open” IRB meeting agenda. If the response is received after the agenda for the next meeting is closed, the PI may be required to wait until the following month’s meeting to present the appeal.

Once the item has been placed on the agenda, the PI will be notified and will be given the opportunity to attend the meeting and present information in person. Copies of the written response of the PI will be provided to all members of the IRB (not just the primary reviewer).

The IRB carefully and fairly evaluates the PI’s response in reaching their final decision. The IRB
compliance staff notifies the PI in writing of the IRB’s final decision. If the study is disapproved, the reason for the disapproval is included in the PI’s notification letter. Any PI is encouraged to contact the IRB through this mechanism to provide other types of feedback. However, other types of investigator feedback are accepted without this process.

7.3.9 NOTIFICATIONS
Within seven days after each IRB meeting, the Principal Investigator of each IRB application is notified via iRIS of the IRB’s determination. If the study is determined to be approved pending required modifications, the notification giving approval with specific required modifications will be in a list format, and the PI will not receive final approval until all of the required modifications have been met. In addition to the IRB determination, the IRB will determine whether the PI’s responses to the required modifications will need to be reviewed for appropriateness and completeness at another convened meeting or by the IRB Chair or a designated reviewer. Responses to clarifications and/or required modifications that are directly relevant to regulatory criteria must be reviewed by the convened IRB. For those IRB applications that are deferred, the PI will be notified via the iRIS system, with the reasons outlining why the IRB application was deferred. The IRB application and research protocol must be revised as needed and resubmitted. The PI may also be invited to attend the IRB meeting. The PI of the IRB application that is disapproved will receive a letter that outlines the reasons for disapproval. If the IRB determines that the study can be approved, the PI will receive an approval letter via iRIS. If the PI does not respond to required modifications within 90 days of receiving notification from the IRB, the submission may be withdrawn from IRB consideration. Reconsideration of the IRB application will require a complete resubmission.

7.3.10 LENGTH OF APPROVAL PERIOD
The interval for the continuing review of the research will be determined by the IRB. The degree of risks that will be experienced by the research subject is considered when determining the length of the approval period. The interval for continuing review will be at least once per year for studies requiring full board review but may be shorter. If the IRB application was approved or approved with minor modifications, the expiration date is calculated from the date of the convened meeting. IRB applications that have not undergone continuing review will expire at 9:00 p.m. on the expiration date. Research activities may not continue after 9:00 p.m. of the expiration date. IRB applications involving the conditions below may require review more often than annually.
a. High degree of risk to subjects.
b. Proposed research has many unknown risks.
c. Proposed procedures have not been used in humans.
d. Documented instances of serious or continuing non-compliance.
e. The IRB member believes more frequent review is required.
f. Other reasons provided by the IRB that require closer monitoring.

7.4 EXPEDITED REVIEW

The expedited procedure may not be used where 1) identification of subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal, 2) research involves prisoners, 3) research is classified, or 4) research is greater than minimal risk.

Research activities that meet the above criteria and involve only procedures listed in one or more of the specified categories below may be approved for expedited review.

1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met.
   a. Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)
   b. Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

2. Collection of blood samples by finger stick, heel-stick, ear stick, or venipuncture as follows:
   a. From healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or
   b. From other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

3. Prospective collection of biological specimens for research purposes by noninvasive means.
   Examples: (a) hair and nail clippings in a non-disfiguring manner; (b) deciduous teeth at time of
exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gum-base or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and sub-gingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.) Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject’s privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. This listing refers only to research that is not exempt.)

6. Collection of data from voice, video, digital, or image recordings made for research purposes.

7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. This listing refers only to research that is not exempt.)
8. Continuing review of research previously approved by the convened IRB as follows:
   a. where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or
   b. where no subjects have been enrolled and no additional risks have been identified; or
   c. where the remaining research activities are limited to data analysis.

9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

7.4.1 SUBMISSION REVIEW SCHEDULE
IRB applications submitted for expedited review may be submitted at any time. The IRB request that if the proposed research activity qualifies for review under an expedited category, the researcher should allow 7 business days for initial response from the IRB.

7.4.2 SUBMISSION REQUIREMENTS AND MATERIALS REVIEWED
If the IRB application meets the requirements for expedited review, the following applicable documents must be submitted electronically via the iRIS system.
   a. A complete original IRB application with electronic signatures of the PI, and the Department Head or Dean or his/her designee
   b. The research protocol.
   c. Documented human subjects training for all members of the research team (Section 5.3).
   d. Informed consent documents (assents, parental permission, etc.) in all applicable languages.
If applicable, the following should also be included:
   e. Site permission letters.
   f. Recruitment materials (e.g. flyers, posters, email messages, etc.).
   g. Copies of all instruments, if the study involves the use of questionnaires, surveys or similar instruments. If a survey tool such as Qualtrics or REDCap will be used, this should be described in the protocol and application.
   h. Data and Safety Monitoring Plan (Section 7.3.1)
   i. Copy of the grant.
   j. Other required approvals [e.g. Radiation Protection Committee (RPC), Institutional Biosafety Committee (IBC), Institutional Animal Care and Use Committee (IACUC). Note that researchers may need to obtain approval by the Survey Coordinate Committee (SCC) for
some survey distributions but this approval documentation is not a required component of IRB submissions.

7.4.3 ASSIGNMENT OF EXPEDITED REVIEWER

The Full Board IRB conducts the expedited review of amendments, continuing reviews and other actions for those previously reviewed by members of the IRB for the Full Board. The Expedited Board conducts reviews of new expedited studies and subsequent amendments, periodic reviews, and other actions for those expedited studies.

Upon processing the IRB application, the compliance staff will perform a pre-review to verify the submission is appropriate for expedited review. The compliance staff will also work with the PI to assure all required documents have been uploaded and the IRB application is complete.

Once the pre-review process has been completed, the expedited review submission undergoes a subsequent review by a designated IRB member qualified by experience or expertise (professional competence) to conduct the review. The IRB Chair decides which IRB members can conduct reviews using the expedited procedure. Only experienced IRB members may conduct reviews using the expedited procedure. IRB members are defined as experienced when they have completed human subjects training in CITI and individual training with IRB compliance staff and attended at least two convened IRB meetings or have prior experience as an IRB member. The review assignment is made by the IRB compliance staff based on IRB member expertise. If the assigned reviewer does not have adequate expertise, he or she will inform the IRB compliance staff and another reviewer will be assigned. Submissions are not assigned to IRB members with a conflict of interest.

Approval of the expedited submission is granted by the IRB Chair or their designee.

7.4.4 REVIEWER CONSIDERATIONS

IRB submissions undergoing expedited review are reviewed to assure:

a. The research is in one of the eligible categories for review using the expedited procedure in Section 7.4, and the research meets the following applicable criteria:
   i. The research procedures present no more than minimal risk to subjects.
   ii. The standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review, expedited or convened, utilized by the IRB.
   iii. The identification of subjects or their responses will not reasonably place them at risk of criminal or civil liability or be damaging to their financial standing, employability, insurability, reputation or be stigmatizing, unless reasonable and appropriate
protections will be implemented so that the risks related to invasion of privacy and breach of confidentiality are no greater than minimal.

iv. The research is not classified.

b. The regulatory criteria for IRB approval are met.
c. Researchers and their staff have appropriate and sufficient qualifications and training to conduct the proposed research.

If the assigned reviewer determines that the IRB application does not meet the applicability criteria or does not fall into one of the eligible categories of research that may be reviewed using expedited procedures, the reviewer returns the submission to the IRB Compliance Office to arrange for full board review.

7.4.5 CRITERIA FOR APPROVAL

See Criteria for IRB Approval of Research, above. In addition, IRB applications that may be minimal risk but are not included on the list of activities that may undergo expedited review are reviewed at a convened meeting of the IRB. The convened IRB may then designate that the submission is minimal risk and determine that the IRB application may undergo an expedited review process under Category 9 during its subsequent reviews for continuation.

7.4.6 SCIENTIFIC AND SCHOLARLY REVIEW

The scientific and scholarly review will be conducted by the Department Chair. The review will include an evaluation of the following:

a. The research uses procedures consistent with sound research design and does not unnecessarily expose the subjects to risks;
b. The proposed sample size contains the number of participants large enough to result in reliable, replicable results;
c. The research is designed to answer the proposed research question;
d. The research questions are aligned with the proposed data collection and analysis; and
e. The study has the potential to contribute to the field or add to the existing body of knowledge.

7.4.7 IRB APPLICATION DETERMINATIONS

Upon completion of the pre-review by the compliance staff, the application is forwarded to the IRB chair or designee. On any application requiring expedited review action, the decisions available to the reviewer(s) are:
a. Approved: Approval of the IRB application can be granted by the IRB Chair or their designee if all of other GSU requirements relevant to the activity have been met.

b. Approved Pending Required Modifications: Approval of the IRB application can be granted by the Chair or their designee after additional information or removal of contingencies that were identified by the reviewer.

c. Referral to Full Board: There are enough unanswered questions or concerns, that a reviewer may refer the application to the convened board.

An IRB application reviewed using the expedited procedures may not be disapproved. If the reviewer feels an IRB application may need to be disapproved it must be referred to the convened board for review.

7.4.8 NOTIFICATIONS

Within five business days after the IRB application is reviewed by a designated reviewer, the PI will receive notification of the IRB determination.

For those IRB applications that are deferred or require changes, the PI will be notified via the iRIS system outlining the necessary modifications.

The PI will be notified by an approval letter when the research study has been approved. The approval letter will state the approval period (if applicable).

If notification of approval is requested by an organizational office (e.g. Institutional Biosafety Committee, Radiation Protection Committee, Institutional Animal Care and Use Committee, the approval letter will be provided as appropriate via email.

The Associate Vice President for Research and the IO are provided with a copy of the minutes each quarter.

Due to the large number of IRB applications received by the IRB for review, any submission for which the PI does not respond to required modifications within 90 days may be withdrawn from IRB consideration. Reconsideration of the IRB application will typically require a complete re-submission.

7.4.9 LENGTH OF APPROVAL PERIOD

When a study is determined to constitute research that may be reviewed through an expedited review procedure, it is typically assigned an expiration date in three years and Investigators must provide a Status Check Form prior to expiration. The expiration date is calculated from the date of review and approval by the IRB Chair, Vice Chair or designated reviewer. If the protocol was approved pending modifications, the expiration date is calculated from the date that the reviewer extended approval. Investigators also have the obligation to report certain events such as unanticipated problems and
protocol deviations.

Annual (or more frequent) continuing review of research eligible for expedited review is not required unless the IRB explicitly determines so for a specific study.

Protocols that have not undergone a status check or continuing review will expire at 9:00 p.m. on the expiration date. All research activities must cease at that time. At the completion of the research, the PI should submit a Study Closure Form.

7.4.10 REPORTING OF EXPEDITED REVIEWS TO THE IRB
The Expedited Board is primarily a virtual board. However, there are two scheduled meetings annually to provide status updates, which include the number of expedited studies submitted, the number approved, and mean/median turnaround times, and educational training. Expedited Board members receive a monthly report listing research proposals that have been approved by the expedited procedure in the prior period.

7.5 EXEMPT REVIEWS
Exempt reviews may be conducted by IRB Compliance Office staff or IRB members, while projects requiring limited IRB review must be reviewed by IRB members. Research activities within exempt categories must be submitted to the IRB office for a formal and independent determination; researchers cannot make such determinations on their own behalf.

Proposed research activities qualifying for exempt status must be in accordance with GSU’s ethical standards. The IRB recognizes the following categories qualifying for exemption as set forth by the federal regulations in 45 CFR 46.104(d).

1. Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students’ opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

2. Research that only includes interactions involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:
   i. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through
identifiers linked to the subjects;

ii. Any disclosure of the human subjects’ responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, educational advancement, or reputation; or

iii. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a Limited IRB Review to make the determination required by 45 CFR 46.111(a)(7).

3. Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following is met:

   i. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects; OR

   ii. Any disclosure of the human subjects’ responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, educational advancement, or reputation; OR

   iii. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subject, and an IRB conducts a Limited IRB Review to make the determination required by 45 CFR 46.111(a)(7).

Note: For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.
Note: If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

4. Secondary research for which consent is not required: secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following is met:
   i. The identifiable private information or identifiable biospecimens are publicly available,
   ii. Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;
   iii. The research involves on information collection and analysis involving the investigator’s use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E (HIPAA), for the purposes of “health care operations” or “research as those terms are defined at 45CFR46.164.501 or for “public health activities and purposes” as described under 45CFR164.512(b) or
   iv. The research is conducted by, or on behalf of, a federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and if applicable the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 501 et seq.

5. Research and demonstration projects conducted or supported by a federal department or agency or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to
study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.

Note: Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.

6. Taste and food quality evaluation and consumer acceptance studies,
   i. if wholesome foods without additives are consumed or
   ii. if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

7. *Storage or maintenance for secondary research for which broad consent is required.

8. *Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use where defined criteria are met.

The researcher makes a preliminary assessment that the submission is eligible for exemption based on the proposed research activities, by considering whether it falls into one or more of the categories specified in the federal regulations. The IRB member or the IRB compliance staff makes the final determination regarding whether a protocol is eligible for exemption.

*GSU has not adopted the practice of broad consent and does not classify research as exempt using exempt categories 7 or 8.
Limited IRB Review

Limited IRB review is a condition of exemption for exempt categories 2 and 3, as referenced above. Projects requiring limited IRB review must be reviewed by an IRB member. The limited IRB review to support exempt categories 2 and 3 requires that the following criterion for approval detailed at 45 CFR 46.111(a)(7) is met:

− When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

Note, regulations provide for additional conditions of limited IRB review performed in support of exempt categories 7 or 8. Because GSU has not adopted the practice of broad consent, the limited IRB review required to support those categories is not detailed herein.

7.5.1 SUBMISSION SCHEDULE

Submissions for exempt determination may be submitted at any time. The researcher should expect a response within 7-10 business days.

7.5.2 SUBMISSION REQUIREMENTS AND MATERIALS REVIEWED

The following applicable documents must be submitted electronically via the iRIS system.

a. A complete original IRB application with electronic signatures of the PI, Department Head or Dean, the Faculty Sponsor, the Student PI.

b. Research protocol, grant application or prospectus.

c. Documented human subjects training for all members of the research team (Section 5.3).

d. Exempt consent documents in all applicable languages

e. Copies of all instruments, if the study involves the use of questionnaires, surveys or similar instruments. If a survey tool such as Qualtrics or REDCap will be used, this should be described in the protocol and application. Note that researchers may need to obtain approval by the Survey Coordinate Committee (SCC) for some survey distributions but this approval documentation is not a required component of IRB submissions.

Site permission letters are not a required component of exempt submissions, but it is the PI’s responsibility to secure any permissions necessary to conduct research at the selected site(s).

7.5.3 EXEMPTION DETERMINATION

Upon processing the submission, the IRB member or the IRB Compliance Office staff will verify the request is appropriate for exemption. The Compliance Office staff will also work with the PI to assure all required documents have been uploaded and the submission is complete.
7.5.4 SUBJECT PROTECTIONS

Exempt research must meet the same ethical standards as non-exempt research and must protect human subjects. The following subject protections must be considered for exempt status:

a. The research involves no more than minimal risk to subjects.
b. Selection of subjects is equitable.
c. If there is recording of identifiable information, there are adequate provisions to maintain the confidentiality of the data.
d. If there are interactions with subjects, the reviewer will determine whether there should be a consent process that will disclose such information as:
   i. The activity involves research.
   ii. A description of the procedures.
   iii. Participation is voluntary.
   iv. The PI’s name and contact information.
   v. There are adequate provisions to maintain the privacy interest of the subjects (see also Limited IRB Review).
e. Subjects will be provided additional protections if appropriate.

7.5.5 MODIFICATIONS TO EXEMPT RESEARCH

Researchers should notify the IRB Compliance Office by submitting an amendment application before any proposed modification is implemented. The IRB Compliance Office staff will determine whether the proposed modification(s) permits the research to continue to qualify for exemption or changes the review category, (e.g. to expedited or convened board). If the proposed modification changes the review category, a new IRB submission is required for review and subsequent approval.

If notification of determination is requested by an organizational office (e.g. Institutional Biosafety Committee, Radiation Protection Committee, Institutional Animal Care and Use Committee), the determination letter will be provided as appropriate via email.

7.5.6 IRB EXEMPTION DETERMINATIONS

On any application qualifying for exemption, the following determinations are available to the reviewer(s):

a. Determined to be Exempt: The activity may start as soon as approval for exempt status is received if all other GSU requirements relevant to the activity have been met.
b. Referral to the convened board or expedited review: The study does not meet exempt status review. The proposed research activity must either undergo review by the convened...
board or expedited review.

c. Changes Required: clarifications and updates are necessary before the determination can be made.

7.5.7 NOTIFICATIONS
Within five business days after the submission is determined to qualify for exemption, the PI will receive notification of the determination. Notification indicating required modifications are needed, must be addressed by the PI. Once the PI has responded appropriately and completely to the IRB Compliance Office addressing all required modifications, a determination can be made. The PI will be notified by letter that a determination has been made.

7.5.8 DETERMINATION PERIOD
When a study is determined to be exempt, it is extended a three year determination period; no study activity is allowed to continue past the determination period unless a Status Check Form is submitted and the determination period renewed. Investigators also have the obligation to report certain events such as unanticipated problems and protocol deviations. At the completion of the research, the PI should submit a Study Closure Form.

7.5.9 REPORTING OF EXEMPTIONS TO THE IRB
The protocol number, title, PI name, determination date, and the category for each protocol approved using an exempt procedure where limited IRB review is conducted is reported to the IRB at the next scheduled meeting in the activity reports section of the minutes. The Associate Vice President for Research and the IO are provided with a copy of the minutes quarterly.
Section 8: Informed Consent of Research Participants

8.0 Policy
8.1 Purpose
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8.11 Waiver of Authorization for the Use and Disclosure of Protected Health Information (PHI)
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8.0 POLICY
GSU and the IRBs require that prospective and properly executed informed consent be obtained from all human subject research participants unless the process or any portion of the process has been approved for waiver by the IRB.

8.1 PURPOSE
The purpose of this policy is to provide guidance in the development of consent documents and to describe the requirements for obtaining and documenting informed consent.

8.2 INFORMED CONSENT GENERAL INFORMATION
The informed consent is a process that should give the potential subject all the information that he/she may need to make a decision whether to participate in the study. It is important to understand that the informed consent is a process of communication that occurs between the potential subject and the researcher(s) throughout the study. The information provided should be factual, complete, and
accurate. The informed consent document facilitates the process of informed consent. To ensure potential subjects understand, the information provided should be written at an 8th grade reading level, and in a language that is understandable to the potential subject or representative. (Section 8.5.1 –Non-English Language Consent) The researcher should give the potential subject an opportunity to consider being in the study on an initial and ongoing basis. While researchers are required to obtain legally effective consent prior to enrolling any subject in the research activity, the requirement should also be viewed as an ethical obligation.

A consent form used to enroll subjects in a research study must be reviewed and approved by the IRB prior to enrollment. No consent process or consent form used to obtain and document consent may include exculpatory language through which the subject waives any of their legal rights or releases, or appears to release the researcher, sponsor, institution or its agents from liability for negligence.

Further, the IRB may request to observe the informed consent process to ensure adequate consent when the research is deemed high risk or involves populations deemed vulnerable. Researchers should be aware of the setting in which informed consent is sought. Consideration should be taken to ensure there is sufficient privacy for the communication process to take place. The setting should also not invoke undue influence.

8.3 ELEMENTS OF INFORMED CONSENT

A current model informed consent document, with required language, may be found on the IRB webpage at: https://ursa.research.gsu.edu/human-subjects/#informed-consent-process. A researcher should choose either the Expedited/Full Consent or Exempt Consent, whichever is appropriate for the study. The following are the basic required elements based on federal regulations at 45 CFR 46.116:

Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research. There are five elements that cover key information: (1) The fact that consent is being sought for research and that participation is voluntary; (2) The purposes, the expected duration of participation, and the procedures to be followed; The reasonably foreseeable risks and discomforts to the prospective subject; (4) The benefits to subjects or others that may reasonably be expected; and (5) Appropriate alternatives, if any that might be advantageous.

a. A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject’s participation, a description of the procedures to be followed, and the identification of any procedures which are experimental;
b. A description of any reasonably foreseeable risks or discomforts to the subject;

c. A description of any benefits to the subjects or to others which may reasonably be expected from the research;

d. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

e. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained.

f. For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

g. An explanation of whom to contact for answers to pertinent questions about the research and research subjects’ rights, and who to contact in the event of a research-related injury to the subject; and

h. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:

i. Identifiers might be removed and the de-identified information or biospecimens used for future research without additional informed consent from the subject; or

j. The subject’s information or biospecimens will not be used or distributed for future research studies even if identifiers are removed.

When appropriate, one or more of the following additional elements of information shall also be provided to each subject:

a. A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;

b. Anticipated circumstances under which the subject’s participation may be terminated by the investigator without regard to the subject’s consent;

c. Any additional costs to the subject that may result from participation in the research;
d. The consequences of a subject’s decision to withdraw from the research and procedures for orderly termination of participation by the subject;
e. A statement that significant new findings developed during the course of the research which may relate to the subject’s willingness to continue participation will be provided to the subject;
f. The approximate number of subjects involved in the study;
g. A statement subject’s biospecimens, (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit.
h. A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so under what conditions.
i. For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e. sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen.
j. In addition, studies that offer compensation for participation should include the amount and timing of payments in the consent forms.

*Broad Consent*

Broad consent may be obtained in place of informed consent in accordance with the basic and additional elements, but only with respect to the storage, maintenance, and secondary research uses of identifiable private information and identifiable biospecimens. This is not a waiver, but an alternative. Broad consent is permissible only for storage, maintenance, and secondary research. Federal regulations do not permit IRBs to omit or alter any of the required broad consent elements because each element is considered essential. Broad consent is allowed either for a specific type of specified future research (e.g. prostate cancer research) or a broader scope of research (e.g. any biomedical research). The PI is responsible for tracking those participants who consent for the research but do not consent to broad consent.

*Note: GSU has not adopted the practice of broad consent.

The informed consent requirements in this policy are not intended to pre-empt any applicable federal, state or local laws which require additional information to be disclosed in order for informed consent to be legally effective. Nothing in this policy is intended to limit the authority of a physician to provide medical care, to the extent the physician is permitted to do so under applicable federal, state, or local law.
8.4 ADDITIONAL CONSENT INFORMATION FOR DIFFERENT TYPES OF STUDIES

a. Studies involving blood samples: The consent form should contain a statement such as, “blood samples will be obtained by venipuncture. This method involves inserting a needle into a vein in the arm and withdrawing a sample of blood. It is routinely used to obtain blood for physical examinations. Venipuncture is accompanied by minor discomfort at the site of needle entry and may result in minor bruising and a feeling of faintness. In this study, a trained technician will obtain a 30 ml (about 2 tablespoons full) sample of your blood that will be analyzed for....”

b. Studies involving blood, tissue or body fluid for possible genetic research: If the research involves the use of a subject’s blood, tissue or body fluid for current or future genetic research, the researcher should modify the consent form to explain subject’s rights, including:

   i. Specimen will be maintained without identifiers,
   ii. The risk level to the subject is minimal, provided they agree to participate,
   iii. Where the specimens will be stored,
   iv. Who owns the specimen, and
   v. How the specimens will be used in the future.

Studies that involve physical risk: GSU does not have a plan to provide facilities or insurance to cover research-related injuries. GSU student participants will be allowed access to the designated services available to all students through the University Student Health Clinic. If the study involves physical risk, assess the risk and add a statement such as, “If you have a question about this study or believe you have suffered any injury because of participation in this study, you may contact [Principal Investigator] at [Phone Number]. The University has no plan to provide treatment for research related injury and no plan to provide payment in the event of a medical problem.” If emergency treatment for research-related injuries is arranged by having a medical doctor available for emergency treatment, that should be stated, but a disclaimer for extended care should be put into the consent form, such as “You will be charged for continuing medical care and hospitalization for research-related injuries. The University has no plan to provide financial compensation.” If all of the participants are GSU students, it is appropriate to state, “If injuries occur as a result of the study activity, eligible University students may be treated at the usual level of care with the usual cost for services at the Student Health Clinic, but the University has no policy to provide payment in the event of a medical problem. If the research study includes both student and non-students the consent form should indicate how research
related injuries are handled for each population or the researcher may option to use two separate consent forms, one for students, and one for non-students.

c. Studies that involve risks to a fetus: The female participant must be informed of the risk and methods to be used (such as a pregnancy test) to minimize the risk.

d. Studies that involve drugs: The participant must be given a statement of known side effects, warned about possible drug interactions (including interactions with alcohol), and warned about activities that may be dangerous (such as driving with a drug that has a sedative effect).

e. Studies that involve psychological risk: The principles that apply to studies that involve psychological risk or mental stress are similar to those that involve physical risk. Participants should be informed of the risk and told that GSU has no plan to provide treatment. They should be given the names and telephone numbers of individuals or groups that may alleviate their mental concerns. If the PI or the faculty sponsor of a student PI is qualified to treat mental health problems, that person may be listed as a resource.

f. Studies that involve sensitive topics: Participants should be told that some of the questions are of a personal or sensitive nature and should be given examples of topics or questions. They should also be told that they can skip a question if they do not wish to answer it. If questionnaires or interviews may generate reports of child physical or sexual abuse, the participant must be informed that the researcher is legally required to report this information to Child Protective Services. The researcher should be aware of the requirements for mandatory reporters. Please see Section 12.10 for more information on mandatory reporting requirements. If the questionnaires or interviews may generate reports that the participant plans to harm him or herself or others, the participant must be told that the investigator may be ethically required to report that information to the local authorities. If the information/responses collected are completely anonymous, the information regarding legal obligations to report abuse and threats of harm to oneself or others may be omitted.

g. Studies that involve concealment or deception: For more detailed information on studies that involve concealment or deception, please see Section 15. Studies subject to IRB review and approval that involve concealment or deception must have a waiver of the required elements of consent justified and approved. If the study involves concealment or deception, unless a strong, specific justification is provided, the following language (or language to similar effect) must be used: “We will not tell you everything about the study in advance. When the study is over, we will tell you everything. At that time, you can choose whether
you want to allow us to use the information/responses you’ve provided.”

h. Studies that are conducted online: A waiver of documentation of consent may be appropriate for those studies conducted online because it is often not possible to obtain a signed consent. A consent form with all of the required elements should be provided for review, but no signature is obtained. The consent form should be modified to reflect what constitutes consent (e.g. “If you agree to participate in this research, please click the continue button”). The form should also instruct the participant to print a copy of the form for his/her records. The confidentiality section of the consent form must be appropriate for an online study. The participant should be informed that data sent over the Internet may not be secure. The participant should be informed of any special procedures to protect the data such as encryption or not collecting IP addresses.

i. Participants Consenting Others for Research: Some research may involve participants taking pictures (often referred to as Photovoice), video or audio taping, or interviewing other people. These people who are photographed, audio/video taped, or interviewed are considered participants in the research. Therefore, proper procedures to ensure confidentiality and informed consent are necessary. The best method to ensure that participants who consent other people know and understand confidentiality, research ethics, and proper informed consent procedures is to have them complete human subjects training in CITI. If CITI training is not practicable, the researcher can justify using another strategy to be sure participants are properly trained. This training must be detailed in the application. When appropriate and justified by the federal regulations, the IRB may consider granting a waiver of consent for some studies. Special caution must be taken when the research involves subjects that may be vulnerable or topics that are higher risk. Some of these topics will include photographing children, photographing criminal activity, or photographing gay or lesbian individuals who may not have disclosed this to others. The IRB may have additional requirements depending on the nature of the study. Whenever possible, the researcher should consider having participants photograph things representing people instead of the actual people. For example, a playground could represent children playing or graffiti could represent gan members.

j. Studies that involve the use of MRI scans: An MRI (or magnetic resonance imaging) scan is an imaging technique that uses magnetism, radio waves, and a computer to produce images of body structures. For minimal information that must be included in the consent document utilizing MRI scans, please see the model informed consent template at https://ursa.research.gsu.edu/human-subjects/#informed-consent-process.
k. Health Information Portability and Accountability Act (HIPAA): HIPAA requirements mandate certain language be included in the informed consent document (For more information, please see Section 8.10).

l. Studies that utilize mobile applications (apps) that require the user to agree to Terms of Use, Privacy Policies and License Agreements:
   i. If the use of the app is required in order for the participant to take part in the research study, the following information must be included in the informed consent document:
      1. “As part of this research study, you will need to use the (name of app) app. When downloading the app, you will be asked to agree to the Terms of Use (or something similar) which will appear on your mobile device’s screen when you begin using the app. If you do not agree to the Terms of Service, you should not take part in this research study.”
   ii. If the use of the app is optional in the research study, the following information must be included in the informed consent form:
      1. “As part of this research study you will have the option to use the (name of the app) app. In order to use the app, you will be asked to agree to the Terms of Use (or something similar) which will appear on your mobile device’s screen when you begin using the app. If you do not agree to the Terms of Service, you may choose not to use the app and still participate in the research study.

m. DEXA Scans: This body scan is a method approved by the National Institutes of Health and FDA. It is often used for body fat and bone measurements. You will lie down on the body scan table for approximately 15 minutes. A low dose twin-beam X-ray will measure your body fat and bone health. There is a minimal risk of radiation from the body scan (less than that received from a microwave oven). The radiation exposure from these tests is considered small and is not likely to cause any health problems. However, the effects of radiation add up over a lifetime. It is possible that having several of these tests may add to your risk of injury or disease. When deciding to enter this study, think about your past and future contact with radiation. Examples of contact with radiation include x-rays taken for any reason or radiation therapy for cancer treatment.

n. Studies that involve a screening process: Studies that involve screening to determine eligibility may also require the participant to be consented prior to the screening process, this is known as a Screening Consent. A Screening Consent is separate from the Consent Document. It allows researchers to collect information from possible participants to determine their eligibility to participate in the study. Screening Consents are appropriate for
studies where the researchers will collect identifiable information about the potential research participants. A Screening Consent is not necessary if the information collected during the screening process:

1. is not identifiable
2. is not sensitive
3. is not embarrassing
4. does not put the potential participant at risk

If a Screening Consent is necessary, it must contain all of the required elements of informed consent (see the model informed consent). A Waiver of Documentation of Consent may be requested and granted if appropriate as determined by the IRB.

As an alternative to a screening consent, the researchers may execute the following procedures:

To determine a potential participant’s eligibility for a study, the researchers may ask all relevant inclusion and exclusion criteria. Should the potential participant meet those criteria and qualify for the study, the researcher may then provide the screening consent to the potential participant. If the potential participant agrees, the researcher may then collect the participants’ necessary identifying information.

o. For studies implementing a Certificate of Confidentiality, the following language should be used: To help us protect your privacy, we have a Certificate of Confidentiality from the National Institutes of Health (NIH). With this Certificate, we can’t be forced by a court order or subpoena to disclose information that could identify you in any civil, criminal, administrative, legislative or other proceeding.

There are circumstances where the Certificate doesn’t protect against disclosure of your personally identifiable information:

− When the US government is inspecting or evaluating federally-funded studies
− When information must be disclosed to meet FDA requirements
− If you give someone written permission to receive research information or you voluntarily disclose your study information
− If the researcher reports that you threatened to harm yourself or others
− In cases of child abuse reported by the researcher
− If the investigator reports cases of contagious disease (such as HIV) to the state

p. All NIH funded studies that qualify as clinical trials must add the following statement to consent forms: “A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not
8.5 DOCUMENTATION OF THE INFORMED CONSENT

Federal regulations governing the use of human subjects in research activities require written documentation of informed consent (handwritten signature of the subject or electronic equivalent) unless the research qualifies for the criteria of waiver of documentation 45 CFR 46.117. The subject and the researcher or the researcher’s staff conducting the consent process should sign and date the IRB approved consent form. The following are deemed acceptable methods for documenting informed consent of human research subjects at GSU.

a. The IRB must be made aware of the person(s) who will be obtaining consent of the participant. These faculty/staff members/students should be listed in the IRB application and on the informed consent form, unless indicated otherwise, are the only personnel allowed to obtain consent.

b. The process of obtaining consent (e.g. mail or in-person) must be appropriate for the data collection method and the study population to be recruited.

c. Each subject (or their legally authorized representative) must be provided adequate time to read and review the consent form, in addition to being advised of the procedures, risk, potential benefits, alternatives to participation, etc. This is frequently accomplished by using the consent form as guide for the process.

d. After completing the consent process and assuring that the subject (or their representative) has no further questions and agrees to participate in the research activity, the individual obtaining consent should instruct the subject (or their representative) to sign and date the consent form in the appropriate places.

e. The individual obtaining the consent should then sign and date the consent form in the appropriate places (PI or designee). It is assumed that in most cases all persons signing the consent form will do so at the conclusion of the consenting process.

f. Each subject (or their representative) should be given a copy of the signed consent form. The original consent form should be filed in such a manner as to ensure immediate retrieval when required by auditing entities (e.g. IRB, federal entities, sponsors).

g. The regulations are clear that written documentation of informed consent is required, unless a waiver is approved by the IRB. Therefore, obtaining consent from an authorized third party via telephone is not acceptable unless the IRB waives the
requirement to document the informed consent process.

h. The regulations also include provisions for approval of a waiver or amendment of part or all of the consent process. The IRB will consider written request for waiver or amendment of the process when accompanied by sufficient justification.

i. Obtaining informed consent from subjects must be accomplished prior to performing the research activity and using only the IRB approved, stamped consent form. Written request for amendments to an existing consent form must be approved prior to implementation, at which time the IRB Compliance Office will provide a formal approval letter of the amendment to the consent form.

j. Upon receipt of the IRB approved consent form, all old versions should be discarded to prevent inadvertent use of an outdated consent form. Copies of the most recently approved consent form may be made and should be used unless replaced by an amended consent form.

k. Consent forms for exempt studies are not stamped.

8.5.1 NON-ENGLISH LANGUAGE INFORMED CONSENT
It is generally not ethical or justifiable to exclude potential subjects in a research study solely on the basis of language spoken, nor is it ethical or justifiable to obtain consent of subjects who do not have a clear understanding of the consent document or who do not have the opportunity to freely ask and receive answers to their questions. Without this understanding and opportunity, consent may not be truly informed and may not be legally effective. In order to address these considerations, when enrolling subjects who do not speak English in research, the potential subject must be provided with the following:

a. A written consent document in a language understandable to them.

b. An interpreter fluent in both English and the subject’s spoken language.

All consent forms must be provided to and approved by the IRB in English. To provide objectivity and transparency in all human subjects research projects, informed consent documents requiring translations into another language must provide a certified translation. If a certified translation is not possible for reasons that are acceptable to the IRB, the IRB may consider a back translation provided by a third party unaffiliated with the research project. This is solely at the discretion of the IRB and depends on circumstances adequately representing that the objectivity of the informed consent process is not compromised. The IRB recognizes that consent forms may not be word for word translations, therefore the IRB must review the back translation to assure that the study is accurately reflected in tone and intent. Translated versions of other (non-consent) study materials/instruments previously
approved by the IRB in English will be accepted by the IRB without a back translation.

8.5.2 SHORT FORM OF CONSENT DOCUMENTATION

Federal regulations require that the informed consent process be presented in language understandable to the research subject, and in most instances, that informed consent be documented in writing (45 CFR 46.116 and 45.117).

When informed consent is documented in accordance with 45 CFR 46.117 (b)(1), the written consent document should embody language understandable to the subject, all the elements necessary for legally effective informed consent. Subjects who do not speak English should be presented with a consent document written in a language understandable to them. This procedure is preferable. Alternatively, 45 CFR 46.117 (b)(2) permits oral presentation of the informed consent information in conjunction with a short form written consent document (stating that the elements of consent have been presented orally) and a written summary of what was presented orally. A witness to the oral presentation is required, and the subject must be given copies of the short form document and summary.

When this procedure is used with subjects who do not speak English, the oral presentation and the short form written document should be in a language understandable to the subject, the IRB-approved English language informed consent document may serve as the summary, and (the witness should be conversant in both English and the language of the subject.

To allow the use of the short form of consent documentation, the IRB will determine the following:

a. The consent document states that the elements of disclosure required by regulations will be presented orally to the participant or the participant’s legally authorized representative.

b. A written summary embodies the basic and required additional elements of disclosure.

c. There will be a witness to the oral presentation.

d. For participants who do not speak English, the witness is conversant in both English and the language of the participant.

e. The participant or the participant’s legally authorized representative will sign the consent document.

f. The witness will sign both the short form and a copy of the summary.

g. The person actually obtaining consent will sign a copy of the summary.

h. A copy of the signed short form will be given to the participant or the legally authorized representative.

i. A copy of the signed summary will be given to the participant or the legally
authorized representative.

8.6 CHILD ASSENT/PARENTAL PERMISSION
If the research involves minors (those under the age of 18 years in Georgia), federal regulations typically require the assent of the child or minor and permission of the parent(s) 45 CFR 46.408. While children may be legally incapable of giving informed consent, they may have the ability to provide assent. The assent process should involve taking the time to explain to the child, at whatever age they can begin to understand, what is going on in the proposed study, why the study is being conducted, what will happen to them, and explain that they can object. Assent means the potential subject’s affirmative agreement to participate in the research. Also, see Child Assent Procedure Details at https://ursa.research.gsu.edu/human-subjects/#informed-consent-process. For additional information on Research Involving Children, see Section 12.5.

8.7 LEGALLY AUTHORIZED REPRESENTATIVES AND SUROGATE CONSENT
Unless otherwise approved by the IRB, informed consent must be obtained directly from the individual subject. Under appropriate conditions and IRB approval, however, researchers may also obtain informed consent from a Legally Authorized Representative of the subject.

If an adult or emancipated minor cannot give informed consent, and the research involves lawful surgical or medical treatment which may be recommended, prescribed or directed by a duly licensed physician, then the following apply:

- Any adult may delegate to another adult the authority to give consent for him/herself by a lawful Advanced Directive for Health Care or other appropriate legal document.
- Any married person, whether an adult or minor (defined as between the ages of 16 and 18), may provide consent on behalf of his/her spouse.

In the event that an adult cannot consent for him/herself and in the absence of any person to consent under the provisions in set forth above, then the following persons may sign informed consent documents in the following order of priority:

- Any adult offspring for his/her parents
- Any parent for his/her adult offspring
- Any adult for his/her brother or sister
- Any grandparent for his/her grandchild

If an adult or emancipated minor cannot give informed consent and the research does not involve surgical or medical treatment which may be recommended, prescribed or directed by a duly licensed physician, then only a person who is authorized pursuant to the terms of an appropriate power of
attorney may provide consent for the research subject.

The provisions set forth in this section apply only to subjects in the State of Georgia. Researchers should contact the Office of Legal Affairs for assistance with other jurisdictions.

8.8 **WAIVER OF DOCUMENTATION OF INFORMED CONSENT**

The IRB can approve a waiver of documentation of informed consent. The waiver of the requirement for a signed document, however, does not mean that the IRB waives the requirement for an informed consent process. Researchers desiring to not have a signed consent form must still provide participants with a consent document with all of the required elements necessary for informed consent. The IRB encourages researchers to utilize the model informed consent form and remove the signature section. According to 45 CFR 46.117 and/or 21 CFR 56.109 (c)(1) the IRB may waive the requirement for the researcher to obtain a signed consent form for some or all subjects if it finds either:

a. That the research presents no more than minimal risk of harm to the subjects and involves no procedures for which written consent is normally required outside of the research context. (for studies regulated per the Common Rule or FDA)

b. That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality.

Each subject would be asked whether the subject wants documentation linking the subject with the research and the subject’s wishes will govern; (for studies regulated per the Common Rule) or

c. If the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained. (for studies regulated per the Common Rule)

A waiver of documentation of consent may be requested in the IRB application within the iRIS system.

The IRB can approve a research proposal in which an investigator will obtain information or biospecimens for the purpose of screening, recruiting, or determining the eligibility of prospective subjects without the informed consent of the prospective subject or the subject’s legally authorized representative, if either of the following conditions are met:

a. The investigator will obtain information through oral or written communication with the prospective subject or legally authorized representative, or
b. The investigator will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens.

IRB consideration of screening/recruitment/eligibility procedures under this condition is distinct from IRB review of a request for waiver of documentation of consent or waiver of consent. See 45 CFR 46.116(g).

FDA regulations do not provide a corresponding allowance.

8.9 WAIVER OF CONSENT OR WAIVER/ALTERATION OF THE REQUIRED ELEMENTS OF CONSENT

The IRB may waive the requirements for obtaining informed consent or approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent listed in Section 8.3, provided the IRB finds and documents the following:

a. The research involves no more than minimal risk to subjects;

b. The research could not practicably be carried out without the waiver or alteration;

c. If the research involves the use of identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format;

d. The waiver or alteration will not adversely affect the rights and welfare of the subjects;

e. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

f. The research is not FDA regulated.

OR

The research is a Public Demonstration Project and the IRB finds that:

a. The research is conducted by or subject of the approval of state or local government officials.

b. The research or demonstration project is designed to study, evaluate, or otherwise examine:
   – Public benefit or service programs.
   – Procedures for obtaining benefits or services under those programs.
   – Possible changes in or alternatives to those programs and procedures.
   – Possible changes in methods or levels of payment for benefits or services under those programs.

c. The research cannot practicably be carried out without the waiver or alteration.

d. The research is not FDA regulated.

These same criteria can be used for the waiver of parental permission. In addition, parental permission
can be waived if:

Permission is not a reasonable requirement and the IRB finds that:

a. The research is designed for conditions or for a participant population of which parental or guardian permission is not a reasonable requirement to protect the participants.
b. An appropriate mechanism for protecting the children who will participate as participants in the research is substituted:
c. The research is not FDA regulated.

8.10 AUTHORIZATION TO USE OR DISCLOSE PROTECTED HEALTH INFORMATION (PHI)
The authorization section of the consent form must include the following specified, required information set forth in the Privacy Rule:

a. A description of the information to be used or disclosed that identifies the information in a specific and meaningful fashion.
b. The name or other specific identification of the person(s), or class of persons, authorized to make the requested use of disclosure.
c. The name or other specific identification of the person(s), or class of persons, to whom the covered entity may make the requested use or disclosure.
d. A description of each purpose of the requested use or disclosure. The statement, “at the request of the individual” is a sufficient description of the purpose when an individual initiates the authorization and does not, or elects not to, provide a statement of the purpose.
e. An expiration date or an expiration event that relates to the individual or the purpose of the use or disclosure.
f. A statement of the individual’s right to revoke, together with a description of how the individual may revoke the authorization.
g. The statement, “end of the research study,” “none,” or similar language is sufficient if the authorization for a use or disclosure of protected health information for research, including the creation and maintenance of a research database or research repository.
h. Signature of the individual and date. If the authorization is signed by a personal representative of the individual, a description of such representative authority to act for the individual must also be provided.

In addition to the elements above the authorization must also include statements that inform the individual of the following:
a. The individual’s right to revoke the authorization in writing, and either
b. The exception to the right to revoke and a description of how the individual may revoke the authorization, or
c. To the extent that the information included in the above section is included in the notice by §164.520, a reference to the covered entity’s notice.
d. The ability or inability to condition treatment, payment, enrollment or eligibility for benefits on whether the individual signs the authorization when the prohibition on conditioning applies, or
e. The consequences to the individual of a refusal to sign the authorization, the covered entity can condition treatment, enrollment in the health plan, or eligibility for benefits on failure to obtain such authorization.
f. The potential for information disclosed pursuant to the authorization to be subject to re-disclosure by the recipient and no longer be protected by this subpart.

As with the informed consent document, the authorization must be written in a language that is understandable to the proposed research participant.

The researcher must provide the participant with a copy of the signed authorization.

8.11 WAIVER OF AUTHORIZATION FOR USE AND DISCLOSURE OF PROTECTED HEALTH INFORMATION (PHI)

In order to use or disclose PHI without an authorization signed by the research subject, the researcher must obtain one of the following:

a. Documentation that an amendment or waiver of the researchers’ authorization, for use/disclosure of PHI has been approved by the IRB. The provision of the rule might be used, for example, to conduct records research when researchers are unable to use de-identified information; or
b. Where researchers present:
   i. That the research is only for purposes of preparing a research protocol or similar uses preparatory to research.
   ii. That he or she will not remove any PHI from the covered entity and
   iii. That PHI is necessary for the research purpose; or
c. To disclose PHI of decedents, where the researcher represents that the use or disclosure of PHI is:
   i. Solely for research on PHI of decedents,
   ii. Necessary for the research, and
iii. Documentation of the death of the individuals about whom PHI is sought and provided.

8.12 RE-CONSENTING SUBJECTS
Researchers have the responsibility to inform subjects of any new information that might affect subjects’ willingness to continue participation in research. Amended consent forms or consent form addenda delineating the findings and the changes to research risk/benefits must be reviewed and approved by the IRB. The subjects should then be briefed on the changes, asked if they wish to continue participation, and signify their willingness to continue participation; where documentation of informed consent is required, subjects will sign the amended consent form or addendum. For minor changes to the consent form that do not change risk/benefit, re-consent of enrolled subjects is generally not required.

8.13 RECORD RETENTION REQUIREMENTS FOR SUBJECT CONSENT FORMS
The PI shall maintain, in a designated location, the original copy of all executed subject consent forms. The signed consent forms, along with all research-related files, are to be available for inspection by authorized officials of University Administration, the IRB, regulatory entities (FDA, DHHS), and sponsors generally for a period of three (3) years after the completion of the study (See Record Retention).
Section 9: Continuing Review, Status Checks

9.0 Policy
9.1 Purpose
9.2 Requirements for Continuing Review
9.3 Submission Materials
9.4 Continuing Review of Research Activities, Expedited Review
9.5 Reviewer Considerations
9.6 Possible IRB Considerations
  9.6.1 Length of Approval
  9.6.2 Notification to the IRB of Expedited Reviews
9.7 Notifications
9.8 Continuing Review at the IRB Convened IRB Meeting
9.9 Distribution of Submitted Materials to IRB Members
9.10 Status Checks

9.0 POLICY
The IRB conducts continuing review of research taking place within its jurisdiction at intervals appropriate to the degree of risk but not less than once per year.

9.1 PURPOSE
The purpose of this policy is to describe the continuing review process for approved research before expiration of the study.

9.2 REQUIREMENTS FOR CONTINUING REVIEW
Any research activity that has received initial review by the convened Board, and any study for which a continuing review requirement was imposed after an initial review using an expedited procedure, is subject to continuing review. The intervals for reviews are made at the discretion of the IRB but shall occur at least annually. A study must continue to satisfy the Criteria for IRB Approval of research to be approved at continuing review.

Once the study is complete, a Study Closure Form must be submitted to and approved by the IRB to officially close the study.

As a courtesy, email notifications are sent to Researchers at 60, 30, and 15-day intervals prior to the expiration date of the study.
Researchers must submit for continuing review when a) no research has begun; b) enrollment is closed, no new subjects will be enrolled, but interaction with existing subjects may occur; c) enrollment is closed, no interaction with subjects will occur but data analysis is ongoing; or (d) research involving human subjects is ongoing and will continue beyond the current expiration date, new subjects will be enrolled in the upcoming year. If only data analysis of de-identified data is occurring, the researcher can close the study. However, if the researcher later finds that any additional data is needed, a new study would need to be submitted to and approved by the GSU IRB before research begins.

Research activities initially reviewed by the full board must be reviewed by the full board at continuing review unless:

a. The study has been modified and is now eligible for expedited review as defined by federal regulation (e.g. change in risk to minimal) or
b. The study meets one of the conditions below:
   i. No research has begun,
   ii. The research is permanently closed to enrollment; no interaction with subjects will occur but data analysis is ongoing, or
   iii. The remaining research activities are limited to data analysis.

If the IRB determines that a study eligible for expedited approval must undergo continuing review, the continuing review may be conducted using an expedited review unless the research activities no longer meet the expedited criteria for review and approval. Research activities that previously met the criteria for expedited review may change with the review and approval of amendments, such that review by the convened board may be required.

Note: In response to the updated regulations for human subjects research that went into effect on January 21, 2019, GSU implemented a two-year period to transition all studies initially reviewed via an expedited review procedure into compliance with the new regulations. In order to comply with the new regulations, if data collection or analysis of identifiable data will continue past such a study’s expiration date in 2021, a new study application must be submitted in order to continue research; exceptions are considered on a protocol-by-protocol basis. PIs are informed of this as the study’s expiration date approaches and are advised to submit a new application in advance of the expiration date to ensure that IRB approval does not lapse.

9.3 SUBMISSION MATERIALS

All Continuing Review Submission Forms must be submitted in iRIS. Continuing review applications must be substantive and meaningful. Full board, expedited, and exempt studies require the following be submitted for consideration of renewal. (Note: Because of the electronic system, reviewers have access to all currently approved documents, including all questionnaires, recruitment materials, and scripts that
are currently being used).

a. Completed Continuing Review Submission Form
   i. Status of human subject involvement (e.g. enrolling subjects, data analysis only)
   ii. Number of subjects accrued
   iii. Summary of unanticipated events/adverse events involving risks to subjects or others
   iv. Number of subjects withdrawn from the research and reasons for the withdrawal
   v. Complaints about the research since the last IRB review
   vi. Summary of interim findings and amendments or modifications to research since last IRB Review
   vii. Publications or presentations resulting from research
   viii. Audit reports
   ix. Any relevant recent literature

b. If applicable, current approval letters from cooperating IRBs

c. Current site permission letters

d. Consent Forms/Parental Permissions/assents if applicable:
   i. Current version being used without stamped, dated insignia at the bottom of the page so that it can be stamped as approved for the upcoming year.
   ii. If study is closed to enrollment, the most current version, with IRB stamp and date.

e. Any revisions to the currently approved study must be submitted as an Amendment (See Section 10, Amendments).

If no Continuing Review Submission Form and associated documents are submitted via iRIS for review and consideration and approved by the IRB, the study will expire (See Section 9.6.1).

9.4 CONTINUING REVIEW OF RESEARCH ACTIVITIES, EXPEDITED REVIEW

Submissions for expedited studies are reviewed by the IRB compliance staff for completeness and consistency with the currently approved protocol. A determination is also made to see if studies previously reviewed by the convened board now qualify for an expedited type review.

9.5 REVIEWER CONSIDERATIONS

When conducting research under an expedited review category, the IRB Chair, Vice Chair or a designee conducts the review on behalf of the board, using the same criteria for continuation as written in Section 9.2 of this manual. One major question posted to the IRB reviewer is whether the study remains ethical in light of changes that have occurred since the last review, such as the emergence of
new information about risks, a change in anticipated benefits, or a shift in the alternatives to participation. If the reviewer feels that there has been a change in the risks or benefits, he or she may refer the study to the full board for review or require subjects to be re-consented.

9.6 POSSIBLE IRB DETERMINATIONS
The determination of the continuing review or status check will depend on the review type. Please see the following sections for the available determinations:

a. Reviewed by the Convened Board: 7.3.8
b. Expedited: 7.4.7
c. Exempt: 7.5.6

9.6.1 LENGTH OF APPROVAL
For human research studies where continuing review is required, the GSU IRB must review at intervals appropriate to the degree of risk, but at least annually to comply with federal regulations (45 CFR 46.109e and 21 CFR 56.109(f). These regulations do not allow approval for periods of more than one year. At each continuing review, the review period will be determined. Protocols that have not undergone continuing review will expire at 9:00 pm of the expiration date. All research activities must cease at that time. If an IRB application expires within 7 days of the IRB meeting, the Board will consider the submission at the convened meeting, but no research activities can take place during that time. Exempt determinations and approvals of research eligible for expedited review (unless the IRB determines otherwise) are valid for three years.

9.6.2 NOTIFICATION OF BOARD ACTIVITY
a. Convened Board
A list of protocols approved for continuing review by the expedited review procedure are listed in the activity report which is provided to the IRB members at each meeting.

If notification of continuing review is requested by an organizational office (e.g. Institutional Biosafety Committee, Radiation Protection Committee, Institutional Animal Care and Use Committee), the approval letter will be provided as appropriate via email.

All continuing reviews are listed in the activity reports section of the minutes. The Associate Vice President for Research and the IO are provided with a copy of the minutes quarterly.

b. Expedited Board
A monthly activity report is provided to members of the Expedited Board.
9.7 NOTIFICATIONS
Notification will be made according to the appropriate review category of continuing review. See Sections 7.3.9 for continuing reviews reviewed by the full board and 7.4.8 for expedited continuing reviews.

9.8 CONTINUING REVIEW AT THE IRB CONVENED MEETING
Upon receipt, the IRB compliance staff assigns each protocol to the full board IRB members as primary and secondary reviewers based upon the expertise or experience of the reviewer. The primary reviewer should conduct an in depth review of all documents provided with the request for continuing review application and be prepared to present the review of the protocol at the convened meeting. The secondary reviewer presents findings to the Board as well. The convened board discusses the protocol. Unless a conflict of interest exists, all members are expected to participate in the discussion and vote of the protocol.
If the convened IRB does not have the appropriate expertise to review the study for scientific or scholarly validity, the IRB Chair will consider who in GSU faculty or community has the appropriate expertise to serve as an expert consultant (For more information, please see Section 4.4).

9.9 DISTRIBUTION OF SUBMITTED MATERIALS TO IRB MEMBERS
The continuation review materials listed in Section 9.3 are available to all IRB members approximately 5 business days prior to the scheduled meeting via iRIS. The primary and secondary reviewers are expected to review all materials for their assigned protocol(s). IRB members who are not assigned as primary and secondary reviewers are expected to be well-versed with the application and related materials (i.e. informed consent documents, request to include vulnerable populations recruitment materials, copies on instruments, grant applications) for the research being considered at the meeting.

9.10 STATUS CHECKS
Research eligible for expedited review in accordance with 45 CFR 46.110 (if no continuing review requirement is imposed by the IRB) and research determined to qualify for “exemption” are assigned a three-year expiration date. If such a study will continue beyond three years, a Status Check Form must be submitted to and approved by the IRB. All Status Check Forms must be submitted in iRIS. If no Status Check Form and associated documents are submitted via iRIS for review and consideration and approved by the IRB, the study will expire and study activities must cease.
Section 10: Amendments of Human Subject Research Activities

10.0 Policy
10.1 Purpose
10.2 Requirements for Amendments
10.3 Submission Requirements
10.4 Assignment of Expedited Reviewer
10.5 Review of Amendment Request
10.6 Possible IRB Determinations
10.7 Criteria for Approval of Amendments
10.8 Length of Approval Period
10.9 Notifications
10.10 Notification to the IRB of Expedited and Exempt Amendments Reviewed
10.11 Exempt Amendments

10.0 POLICY

Proposed changes to approved research may not be initiated without prior review and approval by the GSU IRB, except when necessary to prevent apparent immediate harm to research subjects. In such cases, the researcher must notify the IRB of the change within 72 hours.

10.1 PURPOSE

The purpose of the policy is to describe the requirement for the review of proposed changes to approved research.

10.2 REQUIREMENTS FOR AMENDMENTS

When the GSU IRB approves an activity, it is with the expectation that that activity will be carried out exactly as it was approved. With the advent of new information or hindsight, it may be necessary to modify the protocol, consent forms, or procedures for all remaining work. All modifications to an approved protocol must be submitted to and approved by the necessary IRB prior to initiating any changes.
10.3 SUBMISSION REQUIREMENTS
All amendments must be submitted through the iRIS process. The requirements for amendments are:
  a. Complete the amendment application.
  b. Requests must describe what modifications are desired, justification for the changes, and if changes pose any additional risk.
  c. Where applicable, revise the protocol, consent document or other study activity or procedures.
  d. Upload revised documents, stating what the changes are in the application.

10.4 ASSIGNMENT OF EXPEDITED REVIEWER
Upon receipt of the amendment request, the IRB compliance staff will verify the amendment is appropriate for expedited review. They will work with the PI to assure all required documentation has been uploaded and the amendment request is complete. When appropriate, the amendment is sent to one of the board members for review. The amendment is then reviewed by the IRB Chair, Vice-Chair or IRB Chair appointed designee. The IRB Chair and HRPP compliance staff assign reviewers based on scientific expertise or experience. The reviewer receives a copy of the documents submitted by the researcher (i.e. amendment request form, and any revised documents).
If the amendments changes the risk level of the study to more than minimal risk, the study must be reviewed by the convened board.

10.5 REVIEW OF AMENDMENT REQUESTS
Minor changes (those which involve minimal risk, do not increase the risk or decrease the potential benefit to the subject, or those that are also included on the Categories 1-7 of the Expedited list) may be approved through an expedited review process. Typical changes considered to be minor include a change in personnel, non-significant changes in sample size, an addition of a questionnaire that does not include sensitive or controversial questions, a change in compensation schedule, an addition of a site, etc. Reviewers using the expedited review process must consider the following:
  a. The amendment is a minor modification to previously approved research,
  b. The regulatory criteria for IRB approval of research are met.
At the reviewer’s discretion, the amendment may be referred to the convened IRB. All amendments reviewed through an expedited process are reported, as a list included with the minutes of the next convened meeting.
Changes considered more than minor must be reviewed at a convened meeting of the IRB. When amendments are reviewed by the convened IRB, all IRB members will be provided with a copy of all documents submitted by the researcher. Members receive materials for review 5 business days prior to the meeting. Each amendment to be considered will be assigned and presented by the assigned primary and secondary reviewers. IRB compliance staff assures that appropriate scientific expertise, local knowledge, and other expertise specific to the protocol(s) are present at the IRB meeting. If there is not at least one member of the IRB or a consultant with appropriate scientific, scholarly, other expertise, or knowledge to conduct an in-depth review, the amendment will be deferred to another meeting.

10.6 POSSIBLE IRB DETERMINATIONS
Either the IRB Chair or an assigned reviewer will render one of the following determinations for each amendment:

a. Approved: It is approved as written and submitted, with no conditions
b. Approved pending modifications: The amendment is approved with explicit modifications.
c. Deferred: The information in the submitted documents has deficiencies that prevent accurate determination of risk and benefits. The deficiencies are identified to the PI, who must address all concerns in a written response.

A designated expedited reviewer may not render a decision of disapproval. Amendment disapprovals may only be rendered by the IRB at a convened meeting.

10.7 CRITERIA FOR APPROVAL OF AMENDMENTS
In order to approve an amendment to research activities, the IRB will confirm that the criteria for IRB approval of research continue to be satisfied.

10.8 LENGTH OF APPROVAL PERIOD
Amendment approvals do not change the approval period of the protocol. Therefore, the expiration date will remain the same as was determined for the study at the time of initial or continuing review.
10.9 NOTIFICATIONS
Notification will be made according to the appropriate review category of amendment. See sections 7.3.9 for amendments reviewed by the full board, 7.4.8 for expedited amendments, and 7.5.7 for exempt amendments.

10.10 NOTIFICATION TO THE IRBs OF EXPEDITED AND EXEMPT AMENDMENTS REVIEWS

a. Convened Board
A list of amendments approved by the expedited or exempt review procedure is provided to IRB members at each meeting in the activity report.

If notification of approval of an amendment is requested by an organizational office (e.g. Institutional Biosafety Committee, Radiation Protection Committee, Institutional Animal Care and Use Committee), the approval letter will be provided as appropriate via email.

All amendment approvals are listed in the activity reports section of the minutes. The Associate Vice President for Research and the IO are provided with a copy of the minutes quarterly.

b. Expedited Board
A monthly activity report is provided to members of the Expedited Board.

10.11 EXEMPT AMENDMENTS
A designated IRB reviewer will review amendments submitted to an exempt study. The reviewer will determine if the amendment modifies the exempt status of the study.
Section 11: Study Closure

11.0 Policy

11.1 Purpose

11.2 General Information

11.3 Closure Determination

11.4 Administrative Action

11.0 POLICY

The completion of a study is a change in activity and must be reported to the IRB. Although subjects will no longer be “at risk” under the study, a final report allows the IRB to close its files.

11.1 PURPOSE

The purpose of this policy is to describe the requirements for the Researcher to close the study.

11.2 GENERAL INFORMATION

PIs have the responsibility of informing the IRB when a study has been completed. A research study is considered to be open and active until the investigator has submitted the study closure report to the IRB or the study expires. If the researcher allows the study to expire, a notification is sent to indicate all work on the protocol must cease immediately and to submit the study closure form to file the final report.

As a courtesy, investigators will be notified by the IRB Compliance Office as described in Section 4.11. At these notification intervals, investigators are to submit either a continuing review request, status check or a study closure report. However, the study closure report may also be submitted at any time, if closure determination criteria are met (See Section 11.3). Investigators will be notified by the IRB Compliance Office when their continuation or final reports have been received.

Faculty advisors for student research have the obligation to ensure study closure reports are filed with the GSU IRB in a timely fashion.

When a PI terminates employment or other association with GSU, he or she is obligated to submit a study closure report to the IRB or formally transfer the protocol to another PI via an Amendment Request which is reviewed and approved by the IRB.
11.3 CLOSURE DETERMINATION

The PI or the IRB may close an approved study under certain conditions.

The PI is responsible for promptly closing the study if any of the following exist.

a. All research activities including data analysis and reporting are complete;

b. The research was never initiated and will not be initiated;

c. Subject enrollment is finished, all data collection is complete, and the only remaining activity is analysis of the data if all data are de-identified and there are no identifying links or codes to the de-identified data; or

d. The PI plans to leave GSU and intends to continue the research activities at another institution.

The PI cannot close a study if the following exist:

a. Data collection is ongoing;

b. Subjects are still being followed; or

c. Identifiable data (including data with codes with links to identifiers) are being analyzed.

11.4 ADMINISTRATIVE ACTION

The IRB Chair, Vice Chair, expedited reviewer, other designated IRB member or IRB Compliance Office staff reviews and accepts the study closure report. The IRB Compliance Office staff will prepare a study closure letter and send it to the PI after processing the request.
Section 12: Vulnerable Populations and Additional Requirements

12.0 Policy

12.1 Purpose

12.2 Research Involving Neonates and Fetuses

12.3 Research Involving Pregnant Women

12.4 Research Involving Prisoners
   12.4.1 Requirements by Category
   12.4.2 Measures to take when a Current Research Participant Becomes a Prisoner
   12.4.3 Documentation and Certification of Research Involving Prisoners

12.5 Research Involving Children
   12.5.1 Requirements by Category for Research Involving Children
   12.5.2 Assent Requirements for Research Involving Children
   12.5.3 Requirements for Parental Permission
   12.5.4 Requirements for Parental Signature on Parental Permission Forms
   12.5.5 When a Child Reaches the Age of Consent While Enrolled in a Study

12.6 Wards

12.7 Research Involving Decisionally Impaired Individuals

12.8 Economically or Educationally Disadvantaged

12.9 Additional Vulnerabilities to be Considered

12.10 Mandatory Reporting to Law Enforcement Agencies
   12.10.1 Child Abuse
   12.10.2 Abuse of Disabled Adults or Elder Persons
   12.10.3 Spousal Abuse
   12.10.4 Communicable Disease Reporting

12.0 POLICY

GSU’s IRB realizes that vulnerability of certain populations makes consideration of involving them as research subjects particularly important. To safeguard their interests and to protect them from harm, special ethical and regulatory considerations are in place when reviewing research that involves vulnerable populations.
12.1 PURPOSE
The purpose of this policy is to outline the considerations that must be taken into account when reviewing research that involves the use of vulnerable populations as research subjects. Some individuals participating in research activities such as pregnant women, prisoners, children, and decisionally impaired adults are considered vulnerable populations. Therefore, additional safeguards are required in the study to protect their rights and welfare as research subjects. In addition to the duties and responsibilities outlined for the designated IRB under 45 CFR Part 46, Subpart A, the IRB shall also follow the procedures specified in Subparts B, C, and D with respect to pregnant women, fetuses, neonates of uncertain viability, prisoners, and children.

12.2 RESEARCH INVOLVING NEONATES AND FETUSES
Research with fetuses, neonates of uncertain viability, and non-viable neonates is not performed at GSU.

12.3 RESEARCH INVOLVING PREGNANT WOMEN
Research activities that wish to include pregnant women may be undertaken if all of the following requirements, consistent with 45 CFR 46.204, are met.

a. Where scientifically appropriate, pre-clinical studies, including studies on pregnant animals and clinical studies, including studies on non-pregnant women, have been conducted and provide data for assessing potential risks to pregnant women and fetuses;

b. The risk to the fetus is caused solely by intervention or procedures that hold out the prospect of direct benefit for the woman or the fetus; or if there is no such prospect of benefit, the risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means;

c. Any risk is the least possible for achieving the objectives of the research;

d. If the research holds out the prospect of direct benefit to the pregnant woman, the prospect of benefit for the pregnant woman or the fetus when the risk is not greater than minimal and the purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means, her consent is obtained in accord with the informed consent provisions of Subpart A of 45 CFR 46, or unless altered or waived in accordance with 45 CFR 46.116(f);
e. If the research holds out the prospect of direct benefit solely to the fetus, then the consent of the pregnant woman and the father is obtained in accordance with the informed consent provisions of 45 CFR 46, Subpart A, except that the father’s consent need not be obtained if he is unable to consent because of non-availability, incompetence or temporary incapacity or the pregnancy resulted from rape or incest;

f. Each individual proving consent is fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate;

g. For children as defined in 45 CFR 46.402(a), who are pregnant, assent and permission are obtained in accordance with the provisions of 45 CFR 46, Subpart D. Generally, in the State of Georgia, if the research is related to the pregnancy, only the child’s assent/consent is needed. If the research is on the pregnant minor and is not related to the pregnancy, parental permission and child assent/consent is required;

h. No inducements, monetary or otherwise, may be offered to terminate pregnancy for the purposes of the activity;

i. Individuals engaged in the research will have no part in any decisions as to timing, method, and procedures used to terminate a pregnancy, and

j. Individuals engaged in the research will have no part in determining the viability of the neonate.

k. If the research is greater than minimal risk, a Data and Safety Management Plan (DSMP) to monitor participants must be established.

On occasion, some low risk research may involve pregnant women (e.g. survey research) even though pregnant women are not the target population of the research activity. This research would pose no additional risk to pregnant women or the fetus. Research activities that are approved to include pregnant women as the target population of the research must be documented in the IRB minutes.

12.4 RESEARCH INVOLVING PRISONERS

The special vulnerability of prisoners makes consideration of involving them as research subjects particularly important. Prisoners may be under constraints because of their incarceration, which could affect their ability to make a truly voluntary and un-coerced decision whether or not to participate as subjects in research. To safeguard their interests and to protect them from harm, special ethical and regulatory considerations apply for reviewing research involving prisoners.
None of the exemption categories listed in Section 7.5 apply for research involving prisoners. In addition, even though it is not prohibited by 45 CFR Part 46, Subpart C, research requesting inclusion of prisoners as subjects will not be reviewed by an expedited review process. All such protocols will be reviewed at a convened meeting with at least one IRB member who is a prisoner or a prisoner representative with appropriate background and experience to serve in that capacity. A majority of the convened IRB (exclusive of prisoner members) have no association with the prison involved, apart from their membership on the IRB. The prisoner representative is a voting member of the IRB. The prisoner representative will review all studies involving prisoners, focusing on the requirements in Subpart C or equivalent protections. The prisoner representative will receive all review materials pertaining to the research (same as primary reviewer). A prisoner representative must be present at a convened meeting when the research involving prisoners is reviewed. If a prisoner representative is not present, research involving prisoners cannot be reviewed or approved. The prisoner representative may attend the meeting by phone, video-conference, or web, as long as the representative is able to participate in the meeting as if they were present in person at the meeting. The prisoner representative must present his/her review either orally or in writing at the convened meeting of the IRB when the research involving prisoners is reviewed.

Therefore if a protocol involves the use of prisoners as subjects, in addition to the duties and responsibilities outlined for the IRB under 45 CFR Part 46, Subpart A, the IRB shall also follow the procedures specified in Subpart C. Research activities that wish to include prisoners may be undertaken if all of the following requirements, consistent with 45 CFR 46.305(a) are met.

a. Any possible advantages accruing to the prisoner through his or her participation in the research, when compared to the general living conditions, medical care, quality of food amenities and opportunity for earnings in prison, are not of such a magnitude that his or her ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison is impaired.

b. The risks involved in the research are commensurate with the risks that would be accepted by non-prisoner volunteers.

c. Procedures for the selection of subjects within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners. Unless the PI provides the IRB with justification in writing for following some other procedures, control subjects must be selected randomly from the group of available prisoners who meet the characteristics needed for that particular research project.
d. The information is presented in language that is understandable to the subject population.

e. Adequate assurance exists that parole boards will not take into account a prisoner’s participation in the research in making decision regarding parole, and each prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole.

f. Where the IRB finds there may be a need for follow-up examination or care of participants after the end of their participation, adequate provisions has been made for such examinations or care, taking into account the varying lengths of individual prisoner’s sentences, and for informing participants of this fact.

12.4.1 REQUIREMENTS BY CATEGORY

Permitted research involving prisoners as subjects is only approvable based on the categories below:

a. The study of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects.

b. The study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects.

c. Research on conditions particularly affecting prisoners as a class (e.g., vaccine trials and other research on hepatitis which is much more prevalent in prisons than elsewhere; and research on social and psychological problems such as alcoholism, drug addiction, and sexual assaults), provided that the study may proceed only after the Secretary of HHS has consulted with appropriate experts including experts in penology, medicine, and ethics, and published notice, in the Federal Register, of his/her intent to approve such research.

d. Research on practices, both innovative and accepted, that have the intent and reasonable probability of improving the health or well-being of the subject. In cases in which those studies require the assignment of prisoners, in a manner consistent with the protocols approved by the IRB, to control groups that may not benefit from the research, the study may proceed only after the Secretary of HHS has consulted with appropriate experts including experts in penology, medicine, and ethics, and published notice, in the Federal Register, of his/her intent to approve such research.
12.4.2 MEASURES TO TAKE WHEN A CURRENT RESEARCH PARTICIPANT BECOMES A PRISONER

If a subject becomes a prisoner while enrolled in a research study that was not reviewed according to requirements outlined in sections 12.4 and 12.4.1 above, the PI should:

a. Confirm the subject meets the definition of a prisoner (as defined by DHHS).
b. Report this event immediately to the IRB in writing.
c. Terminate enrollment or review the research study under Subpart C if it is feasible for the subject to remain in the study.
d. If the participant’s enrollment is not terminated, the full, convened IRB will review the current research protocol in which the participant is enrolled, taking into special consideration the additional ethical and regulatory concerns for a prisoner involved in research.

12.4.3 DOCUMENTATION AND CERTIFICATION OF RESEARCH INVOLVING PRISONERS

For all research activities that are approved for the inclusion of prisoners as subjects, it must be documented in the IRB minutes that the approved research has been reviewed and meets criteria for approval. Further if the research is funded by DHHS, the IRB compliance staff will ensure a certification letter to OHRP is submitted that states the following:

a. The IRB has been constituted according to the regulations,
b. The IRB has considered and made the seven findings set forth in 45 CFR 46.305, and
c. The IRB finds that Category A, B, C and/or D of 46.306 permits the research to go forth with prisoners as human subjects. The certification letter should also provide a brief description of the research sufficient to allow OHRP to determine whether or not to concur with the IRB’s findings or whether to consult with appropriate experts and publish a Federal Register notice.

Please Note: The requirement for a letter does not apply if the study is not funded by DHHS.

12.5 RESEARCH INVOLVING CHILDREN

The special vulnerability of children makes consideration of involving them as research participants particularly important. To safeguard their interests and to protect them from harm, special ethical and regulatory considerations apply for reviewing research involving children. The designated IRB may approve research involving children only if special provisions are met. The designated IRB must classify research involving children into one of four categories and document their consideration of the risks and
benefits of the research study. The four categories of research involving children that may be approved by the IRB are based on degree of risk and benefit to individual subjects.

12.5.1 REQUIREMENTS BY CATEGORY FOR RESEARCH INVOLVING CHILDREN

a. Research not involving greater than minimal risk (45 CFR 46.404).
   i. Adequate provisions need to be made for soliciting the assent of the children.
   ii. Adequate provisions are made to obtain permission of their parents or legal guardians (parental permission form).

b. Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects (45 CFR 46.405)
   i. The IRB must find that the risk is justified by the anticipated benefit to the subject.
   ii. The relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches.
   iii. Adequate provisions are made for soliciting the assent of the children
   iv. Adequate provisions are made for obtaining permission of their parents or guardians (parental permission form).

c. Research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject’s disorder or condition (45 CFR 46.406).
   i. The risk represents a minor increase over minimal risk.
   ii. The intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations.
   iii. The intervention or procedure is likely to yield generalizable knowledge about the subjects’ disorder or condition which is of vital importance for the understanding or amelioration of the subject’s disorder or condition.
   iv. Adequate provisions are made for soliciting assent of the children and
   v. Adequate provisions are made for obtaining permission of their parents or guardians (parental permission form).

d. Research not otherwise approvable which presents an opportunity to understand, prevent or alleviate a serious problem affecting the health or welfare of children (45 CFR 46.407).
The IRB must find that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children.

The Secretary, after consultation with a panel of experts (e.g. science, medicine, education, ethics, law) and following opportunity for public review and comment has determined either of the following:

1. That the research in fact satisfies the conditions of 45 CRF 46.404, 46.405 or 46.406 as applicable to the following:
   a. The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children.
   b. The research will be conducted in accordance with sound ethical principles
   c. Adequate provisions are made for soliciting the assent of children
   d. Adequate provisions are made for obtaining permission of their parents or guardians (parental permission form).

### 12.5.2 ASSENT REQUIREMENTS FOR RESEARCH INVOLVING CHILDREN

Adequate provisions must be made for requesting the assent of child participants when the children are capable of providing assent. In determining whether children are capable of assenting, the age, maturity, and psychological state of the children involved must be considered. This judgment may be made for all children to be involved in research under a particular protocol or for each child, as deemed appropriate. The child should be given an explanation of the proposed research procedures in a language that is appropriate to the child's age, experience, maturity, and condition. To avoid coercion of the child participant, parental permission forms and child assent forms should be separate.

a. Under age 6 years: No assent is required. The IRB application should provide information about how the researcher will ensure the child is willing to participate and will not become upset.

b. Ages 6 – 10 years: Verbal assent must be obtained and documented by the PI. An assent script must be submitted to the reviewing IRB for review.

c. Ages 11-17 years: This age group must sign a separate assent document. The document will explain what will happen, and why, and any risks or benefits involved (for example,
“you can refuse to be in this study, and your parent(s)/legal guardian(s) can not force you.”) Also, a statement which would in effect say that they can stop being in the study at any time. It need not contain other standard items like alternative, cost/compensation and disclaimers, new findings, contacts, and confidentiality, unless it is appropriate for the population. Once the study is explained to the child, he or she should be asked to sign the assent, but if this is too intimidating, the consenter could indicate that the assent was obtained verbally. The assent process must be approved by a GSU IRB.

12.5.3 REQUIREMENTS FOR PARENTAL PERMISSION

a. If the research is approvable under 45 CFR 46, 404 or 46.405, the IRB may find that the permission of one parent is sufficient for research to be conducted.

b. If the research is approvable under 45 CFR 46, 406 or 46.407, both parent’s signatures are required for parental permission, unless one parent is unavailable, not competent to provide parental permission or one parent has sole custody of the child.

12.5.4 WAIVER OF PARENTAL PERMISSION REQUIREMENTS FOR RESEARCH INVOLVING CHILDREN

Generally, written documentation of parental permission is required when recruiting and enrolling subjects who are children. The documentation must signify “active” permission in which the parent specifically signs the document granting permission for the child to participate in the research. “Passive” permission, in which the researcher assumes that if the parental permission form is not returned, the parent has granted implied permission, is not allowed (unless a waiver of consent can be justified).

However, the IRB will consider a waiver of the requirement for parental permission and/or waiver of the requirement to obtain written documentation of the parental permission on a case-by-case basis. The IRB will determine if a waiver is appropriate and/or permissible under 45 CFR 46.408 (c) and document its findings and determination. One of the IRBs may determine that the research protocol is designed for conditions or for a subject population for which parental permission is not a reasonable requirement to protect the subjects and may approve the waiver. In these cases, an appropriate mechanism for protecting the children who will participate as subjects in the research is provided and the waiver is consistent with federal regulations and other mandating entities.
Please Note: The Protection of Pupil Rights Amendment (PPRA) (20 U.S.C. § 1232h; 34 CFR Part 98) applies to programs that receive funding from the U.S. Department of Education (ED). PPRA is intended to protect the rights of parents and students. Therefore, if the research will be conducted in a school setting, a waiver of parental permission and/ or waiver of documentation of parental permission may not be allowable.

**12.5.5 WHEN A CHILD REACHES THE AGE OF CONSENT WHILE ENROLLED IN A STUDY**

Informed consent should be viewed as an ongoing process of communication that occurs between the subject and the researcher throughout the duration of a research study. When a child who was enrolled in the research with parental or guardian permission subsequently reaches the legal age of consent (18 years old in the State of Georgia), he/she should be re-consented as an adult. Unless the IRB determines that the requirement for obtaining informed consent can be waived or is not necessary, the PI should seek and obtain informed consent as described in Section 8, for the now-adult subject for any ongoing interactions or interventions with the research.

**12.6 WARDS**

Children who are wards of the state or any other agency, institution, or entity can be include in the research approved under 45 CFR 46.406 or 45 CFR 407 only if such research is:

a. Related to their status as wards; or

b. Conducted in schools, camps, hospitals institutions, or similar settings in which the majority of children involved as subjects are not wards.

If the research is approved under 45 CFR 46.406 or 45 CFR 46.407 the appointment of an advocate for each child who is a ward is required, in addition to any other individual acting on behalf of the child as guardian or in loco parentis. One individual may serve as advocate for more than one child. The advocate shall be an individual who has the background and experience to act in, and agrees to act in the best interests of the child for the duration of the child’s participation in the research and who is not associated in any way, (except in the role as advocate or member of the IRB) with the research, the investigator(s), or the guardian organization.

**12.7 RESEARCH INVOLVING DECISIONALLY IMPAIRED INDIVIDUALS**

Decisionally impaired individuals may have diminished autonomy that may limit their capacity to provide informed consent or their ability to withdraw from a study. Therefore, research involving
decisionally impaired participants must be reviewed and approved through considerations of the GSU IRB policies, the Belmont Report, Federal and State regulations, and guidance documents. In all research wherein decisionally impaired individuals will be considered as participants, the Investigator must ensure that additional safeguards are provided to protect the rights and welfare of this vulnerable population who, due to impairment in their capacity to give informed consent, may be vulnerable to coercion or undue influence. The degree of impairment of the participant, the level of risk, and the prospect of benefit to the individual participant must all be considered.

General points of consideration are provided below:

a. It should never be presumed that a patient’s condition renders him/her incompetent.

b. The capacity of the potential research subject shall be assessed prior to enrollment and periodically throughout the study, through a standardized measure or consultation by another qualified professional, with no direct affiliation with the research activity.

c. Enrollment of individuals who are decisionally impaired, and unable to give consent generally should not occur if the research presents greater than a minor increment over minimal risk and does not offer a reasonable prospect of benefit.

d. Proposed subjects who are decisionally impaired should not be included in the research activity simply because of convenience.

e. Procedures are developed to ensure the subject’s legally authorized representative (LAR) is duly informed regarding the purpose and procedures of the proposed research (See Section 8.6).

When researchers are likely to approach adults who lack the ability to consent, the IRB will evaluate whether assent of the participants is a requirement and, if so, whether the plan for assent is adequate. The National Institutes of Health (NIH) offers a document entitled “Points to Consider” as guidance to assist IRBs and researchers in their efforts to protect participants who are, or may be, or may become decisionally impaired.

12.8 ECONOMICALLY OR EDUCATIONALLY DISADVANTAGED

When some or all subjects are likely to be vulnerable to coercion or undue influence, such as those individuals that are economically or educationally disadvantaged, additional safeguards must be included in the study to protect the rights and welfare of these subjects [45 CFR 46.111 (b)]. When reviewing studies that include these populations, the review of the designated IRB will assess for special risks that may be inherent to these groups.
12.9 ADDITIONAL VULNERABILITIES TO BE CONSIDERED
Other populations may have vulnerabilities although they may not be listed as such in the federal regulations. These populations include, but are not limited to, students, employees, non-English speaking, and patients. Additional information regarding how these populations will be protected and assessed for special risks that may be inherent to these populations may be required.

12.10 MANDATORY REPORTING TO LAW ENFORCEMENT AGENCIES
Georgia law requires that all GSU employees (faculty/staff) and volunteers who regularly come in contact with children as part of their duties and who have a reasonable cause to believe that a child has been abused or neglected (either on- or off-campus) have a duty to report that abuse immediately (no later than 24 hours after such belief arises).

Reporting Process: Persons should immediately report any concerns by phone to either (1) Child Protective Services or law enforcement or (2) their supervisor. A supervisor who receives such a report should immediately report such concern (without making any changes to the information) to Child Protective Services or law enforcement. Locally, the following departments/agencies may be contacted:

- Georgia State University Police 404-413-2100 (x3-2100)
- Fulton County Department of Family and Children’s Services 404-206-5600
- DeKalb County Department of Family and Children’s Services 404-370-5000
- Statewide Reporting Hotline 1-855-GACHILD

Reports made to Child Protective Services or law enforcement personnel may be made confidentially or anonymously.

Additional Licensing Requirements: Professional licensing associations may require additional reporting requirements for certain professions (e.g., teachers, social workers, daycare facilitators, etc.). University employees/volunteers holding such designations are encouraged to consult their professional licensing associations for more information.

We recommend the use of the Office of the Child’s Advocate’s online training recognizing and reporting suspected child abuse at: https://www.prosolutiontraining.com/content/?id=16. This course is at no cost the participant. The participant must create an account and will be emailed a certificate upon completion of the course.

If you have any questions about your responsibilities under the new mandatory reporting law, please contact the Office of Legal Affairs at (404) 413-0500.

The reporting requirements set forth herein apply to activities that take place within the State of Georgia. If the research activities take place in a jurisdiction other than Georgia and/or if the research
subject lives in a jurisdiction other than Georgia, the researcher should contact the Office of Legal Affairs for guidance regarding applicable law and reporting requirements.

Reporting requirements should be included in informed consent and HIPAA authorization forms (see Section 8.4).

12.10.1 CHILD ABUSE

Under Georgia law, the following persons have a duty to make a report if they have reasonable cause to believe that a child has been abused:

- All University Faculty or Staff
- Physicians licensed to practice medicine, interns, or residents;
- Hospital or medical personnel;
- Dentists;
- Licensed psychologists and persons participating in internships to obtain licensing pursuant to
- O.C.G.A. Chapter 39 of Title 43;
- Podiatrists;
- Registered professional nurses or licensed practical nurses licensed pursuant to O.C.G.A. Title 43, Chapter 24;
- Professional counselors, social workers, or marriage and family therapists licensed pursuant to
- O.C.G.A. Title 43, Chapter 10A;
- School teachers;
- School administrators;
- School guidance counselors, visiting teachers, school social workers, or school psychologists certified pursuant to O.C.G.A. Title 20, Chapter 2;
- Child welfare agency personnel, as defined pursuant to O.C.G.A. Section 49-5-12;
- Child-counseling personnel;
- Child service organization personnel; or
- Law enforcement personnel.

Child abuse means:

- Physical injury or death inflicted upon a child by a parent or caretaker other than by accidental means; provided, however, that physical forms of discipline may be used as long as there is no physical injury to the child;
- Neglect or exploitation of a child by a parent or caretaker thereof;
− Sexual abuse of a child; or
− Sexual exploitation of a child.

O.C.G.A. 19-7-5 further defines sexual abuse and exploitation, and GSU researchers should contact the Office of Legal Affairs for further guidance. Reports should be made orally as soon as possible (within 24 hours) by telephone and followed up by a written report to the State of Georgia Department of Human Resources, or, absent such agency, to the police or district attorney.

Sexual abuse as defined in the mandatory reporting law does not include consensual sex acts between minors of the opposite sex, or between a minor and an adult who is not more than five (5) years older than the minor. See O.C.G.A. Section 19-7-5(b) (3.1).

Good faith immunity protection is provided for those who report child abuse; but the knowing and willful failure to report a suspected case of child abuse is a misdemeanor crime.

12.10.2 ABUSE OF DISABLED ADULTS OR ELDER PERSONS

Under Georgia law, the following persons have a duty to make a report if they have reasonable cause to believe that a disabled adult or elder person has suffered abuse:

− Physician;
− Osteopath;
− Intern or resident;
− Other hospital or medical personnel;
− Dentist;
− Psychologist;
− Chiropractor;
− Podiatrist;
− Pharmacist;
− Physical therapist;
− Occupational therapist;
− Licensed professional counselor;
− Nursing personnel;
− Social work personnel;
− Day-care personnel;
− Coroner;
− Medical examiner;
− Employee of a public or private agency engaged in professional health related services to elder persons or disabled adults; or
− Law enforcement personnel.

For the purposes of this Section, adult abuse includes the willful infliction of physical pain, physical injury, mental anguish, unreasonable confinement, or the willful deprivation of essential services, or the neglect or exploitation of such person. O.C.G.A. § 30-5-4 and OCGA § 31-8-82 provide more detail about what constitutes adult abuse. Researchers should contact the Office of Legal Affairs for further guidance.

If a researcher who falls into one of the above-referenced categories of persons gains knowledge from the research that gives them reasonable cause to believe that a disabled adult or elder person has suffered adult abuse, then the researcher should make a report to an adult protection agency providing protective services, as designated by the Georgia Department of Human Resources or, if such agency is unavailable, to an appropriate law enforcement agency or prosecuting attorney.

The report may be made by oral or written communication. The report should include the name and address of the disabled adult or elder person and should include the name and address of such individual’s caretaker, the individual’s age, the nature and extent of injury or condition resulting from the abuse, and other pertinent information. All such reports prepared by a law enforcement agency shall be forwarded to the Director of the Division of Aging Services of the Georgia Department of Human Resources within 24 hours.

12.10.3 Spousal Abuse

There are no mandatory reporting requirements concerning spousal abuse in Georgia, unless the spouse falls within the category of disabled adult or elder person. Researchers should check with the Office of Legal Affairs regarding reporting requirements in other jurisdictions.

12.10.4 Communicable Disease Reporting

All Georgia physicians, laboratories, and other health care providers are required by law to report patients with conditions of public health concern. Both lab-confirmed and clinical diagnoses are reportable within certain time frames. (See O.C.G.A. §§ 31-12-2, 31-22-7; DHR Rules and Regulations, Notification of Disease, Chapter 290-5-3 and Chapter 290-9-8) Reporting enables appropriate public health follow-up, helps identify outbreaks, and provides a better understanding of disease trends in
Georgia. For the latest information on such reporting requirements, visit the Georgia Department of Human Resources, Division of Public Health website: https://dph.georgia.gov. Researchers should contact the Office of Legal Affairs for further guidance.
Section 13: International Research

13.0 Policy
13.1 Purpose
13.2 General Researcher Considerations
13.3 Specifics for IRB Protocol Submission

13.0 Policy
GSU is committed to upholding the standards for ethical research and informed consent expectations for all research conducted outside of the United States of America (USA). Research conducted out of the US creates areas of concern for both the investigator and the IRB. Cultural, economic, or political environments of the host country may alter the risk for participants compared to the same research conducted in the U.S. Other countries and institutions within foreign countries may have Ethics Committees or IRBs which also require review of the proposed research before the study can be conducted in that country. All policies and procedures that are applied to research conducted domestically should also be applied to research conducted in other countries as appropriate.

13.1 Purpose
The purpose of this policy is to describe the standards and considerations for review of international research.

13.2 General Researcher Considerations
It is not uncommon for researchers at this University to conduct studies outside the borders of the United States. When performing human subjects’ research in foreign countries, researchers are expected to comply with local laws and have consideration for the cultural context of the country in which the research takes place. The research must be conducted in a manner that honors the autonomy and dignity of all persons and embodies the principles of respect for persons, beneficence, and justice. Further, researchers are also expected to provide a level of human subjects protection equivalent to those provided when conducting human subjects research at GSU. This includes all research conducted on residents of foreign countries within that country regardless of where the investigator is located. For example, research done by phone or the Internet from the United States on residents of and living in a foreign country is considered international research.
General guidance on International Research has been developed by the Department of Health and Human Services (DHHS) Office for Health Research Protections. Also as a tool and resource, they provide the International Compilation of Human Research to assist IRBs and researchers to become familiar with the laws, regulations, and guidelines where the research will be conducted and to assure these standards are followed appropriately.

13.3 SPECIFICS FOR IRB PROTOCOL SUBMISSION

The information provided to the designated IRB by the researcher for approval of non-exempt research should include but is not limited to the following:

a. Provide prior approval from an appropriate local or national official.
   i. Research projects must have been approved by the local equivalent before they are presented to the GSU IRB. Where there is no equivalent board or group, researchers must rely on local experts or community leaders to provide approval. Provide the name of the contact person in the country where research is to be conducted.
   ii. Provide the agency or institutional affiliation of the contact person along with email, telephone, and/or other means to reach the contact person.

b. Demonstrate an awareness of the distinctive qualities of the local area.

c. Provide an assessment of the risks that may arise from the political and social condition of the nation.
   i. Questions asked in this country may be innocuous but may be offensive to ask in other cultures.
   ii. Breach of confidentiality could have unfavorable consequences for the research subject.

d. State if a local collaborator will be used and describe the local collaborator’s role in the conduct of the research.

e. Does the researcher speak the language of the proposed research subject? If not, provide a description of how communication with the research subject will be managed.

f. A complete description of consent procedures and issues to consider.
   i. Obtaining consent must be carried out in a manner understandable to the subjects, for example, in their primary spoken language.
   ii. The authority structure may be different.
iii. Signed consent may not be appropriate in some cultures.
   1. Subjects may become suspicious or fearful.
   2. Legal complications resulting from asking for signatures.
iv. Some words do not translate well from English to foreign languages.
v. A typical consent presumes the ability to read. Subjects may not be able to read. A study that anticipates illiterate subjects should plan alternative methods of presenting information and documenting agreement. The PI should include procedures or methods for eliciting information about literacy.
vi. A consent form translated into the appropriate language(s) with a back translation performed independent of the research team or translated by a certified translator; translated copies of other study materials/instruments

   g. If research subjects are paid, the amount and mechanism should be comparable with the local economy and custom.

   h. A description of how contact will be maintained with the Georgia State IRB and faculty advisor while abroad especially as this relates to requesting amendments or reporting unanticipated events.

   i. Confirm that a member of the research team has experience and/or specialized training in International Research.

   j. Confirm that all key personnel on the research team have completed the CITI module on International Research.

13.4 POST APPROVAL MONITORING

Post approval monitoring for international studies is conducted according to standards in Section 19. If matters are found that cannot be resolved via channels in Section 19 communications such as a teleconference will be set-up to discuss matters found, and if warranted an on-site visit will take place.
Section 14: Pilot Studies

14.0 Policy
All pilot studies require review and approval by the IRB before the initiation of the project.

14.1 Purpose
The purpose of this policy is to provide general information and review criteria for the researcher that plans to initiate a pilot study.

14.2 General Information
A pilot study is a preliminary investigation of the feasibility of a study, usually done on a small scale (usually fewer than 10 subjects) and exploratory in nature. Pilot studies are designed to help the researcher refine data collection procedures and instruments or prepare a better, more precise research design. Pilot studies are also useful in providing funding agencies with an idea of how their resources will be used. As such, the design of a pilot study can have great implications for research funding. Pilot studies are part of a research process that contributes to generalizable knowledge. All pilot studies must be reviewed and approved by the IRB.

14.3 Review Criteria
Pilot studies and feasibility studies, including those involving only one human subject, require the same scrutiny as full-scale research projects. It should be as similar to the proposed study as possible, using similar subjects, the same setting, and the same techniques of data collection and analysis. Pilot studies should be identified as such in applications to the IRB. Ordinarily, the data collected from subjects in a pilot/feasibility study are used to help refine data collection procedures and instruments or to prepare a more refined research design. It must be explained to subjects during the consent process that the research is a pilot study.
There have been cases in which information derived from pilot studies has been considered or used for research purposes. The PI preparing pilot studies is urged to weigh the likelihood that the pilot data will actually be used for research purposes. IRB review and approval is required before any research activity, including recruitment, begins. Pilot studies do not generally last more than one year.
**Section 15:  Deception and Concealment**

15.0 **Policy**

15.1 **Purpose**

15.2 **Background and Rationale**

15.3 **General Guidelines**

15.4 **Principal Investigator Requirements**

15.5 **Potential Risks**

**15.0 POLICY**

Federal regulations permit but establish limitations on the use of deception. The researcher must provide scientific and ethical justification for deceptive procedures for IRB review and approval.

**15.1 PURPOSE**

The purpose of this policy is to provide general guidelines and considerations for the researcher when conducting research that involves elements of concealment or deception.

**15.2 BACKGROUND AND RATIONALE**

Deception is the intentional misleading of subjects and concealment is the withholding of full information about the nature of the experiment. Misleading or omitted information might include the purpose of the research, the role of the researcher, or what procedures in the study are actually experimental.

Deception and concealment increase ethical concerns, because it interferes with the ability of the subject to give informed consent. However, deception and concealment are arguably necessary for certain types of behavioral research. Because humans act differently depending on circumstances, full knowledge by the subject might bias the results.

There are three situations in which researchers may not reveal to subjects in advance all details regarding the research protocol.

a. In the first situation, investigators do not reveal their hypotheses to potential subjects. This is not unusual and does not require additional scrutiny in the review process.

b. In the second situation, termed concealment, investigators do not reveal to potential subjects elements of the procedure. An example of concealment would be an experiment in
which, without their knowledge, some subjects view stimuli that highlight issues of race (and thus may prompt certain reactions), and some subjects view materials that do not. Concealment protocols may require more scrutiny in the review process.

c. In the third situation, termed \textit{deception}, investigators intentionally mislead potential subjects about some element or elements of the research procedure. An example of deception would be an experiment in which subjects are led to believe they must prepare to take an oral exam; there is no exam, but stress levels or coping will be measured.

\textbf{15.3 \textsc{General Guidelines}}

The following are general guidelines regarding the design, review and conduct of studies that involve deception or concealment:

a. The use of deception or concealment should have no adverse effects on the well-being of the subject and the relevant study activity must present no more than minimal risk.

b. The IRB must be given sufficient information to determine that the potential benefits to subjects and/or society of conducting such research outweigh the risk of waiving some aspects of full disclosure in the informed consent process.

c. The informed consent must include language indicating that some aspects of the procedure is not being described correctly or at all unless a compelling case can be made for not including such language (See \textit{Section 8.4h} for more information regarding informed consent when using deception or concealment).

d. There is no reasonable alternative to scientifically and effectively address the research question without the use of deception or concealment.

e. When appropriate, debriefing should be accomplished as soon as possible and the deception/concealment explained to the subjects. In rare instances, debriefing may not be helpful and may even be harmful. While debriefing is clearly appropriate when it contributes to subjects’ welfare (e.g. corrects painful or stressful misperceptions, or reduces pain, stress, or anxiety), there is greater uncertainty over whether it is appropriate to debrief subjects when debriefing could itself produce pain, stress, or anxiety. The IRB must be sensitive to possible harms and evaluate potential risks on a case-by-case basis.

f. During debriefing (if appropriate), the subjects should be informed of their right to withdraw their data, if they wish, and the process of withdrawing the data should be explained.

\textbf{15.4 \textsc{Principal Investigator Requirements}}

PI(s) must address the following items in the IRB submission and associated documents:
a. Explain the reason(s) for the use of deception or concealment in the study design. Specifically detail why this methodology is needed for the validity of the study.

b. Thoroughly describe the extent of the risks to the subjects.

c. Justify and discuss why there are no feasible or other valid methods that do not involve deception or concealment that would yield the same outcome.

d. Describe the methods for prompt debriefing of the subjects or provide detailed justification for not conducting a debrief.

e. Consent procedures may require modifications (See Section 8.4h)

15.5 POTENTIAL RISKS

The researchers must be aware that there are several potential risks associated with the use of deception or concealment, and these risks should be considered when designing the study:

a. If subjects had been completely informed, they may have optioned not to participate.

b. Subjects may experience embarrassment, become upset, experience inflicted insight, or even mistrust of the research process.

c. It is possible that the research may undermine the expectation in the professional standards governing human subject research.
Section 16: Internet Research

16.0 Policy

16.1 Purpose

16.2 General Information

16.3 Considerations for Principal Investigators

16.4 Amazon Mechanical Turk (MTurk), Crowdsourcing Platforms

16.5 Site Permission

16.0 POLICY

To promote innovative and scientifically valid research and protect human subjects, it is important to be cognizant of the ethical, legal and technical issues associated with Internet Research.

16.1 PURPOSE

The purpose of this policy is to provide general information and considerations for researchers when deciding to conduct or recruit subjects for research using the internet.

16.2 GENERAL INFORMATION

Internet-based research, broadly defined, is research which utilizes the internet to collect information through an online tool, such as an online survey; studies about how people use the internet, e.g., through collecting data and/or examining activities in or on any online environments; and/or uses on online datasets, databases, databanks, or repositories.

Use of the Internet proves to be an excellent resource for conducting research, but it also presents new concerns to the traditional IRB issues. There are privacy concerns that relate to whether an internet activity is identifiable and determinations on what constitutes public or private behavior. Confidentiality concerns also exist that relate to inappropriate disclosure of information. Internet research may not present any more risks to comparable research conducted through other venues. However, the nature of the risk and the researcher’s ability to assess those risks come into question.

16.3 CONSIDERATIONS FOR PRINCIPAL INVESTIGATORS

Considerations for the PI when conducting Internet research include, but are not limited to the following:
a. **Consent mechanisms:** Where documentation of consent is required, electronic signatures must be legally valid in the jurisdiction where the research is conducted. (See Section 8.4h for information related to obtaining informed consent)

b. **Methods to assure protection of privacy for subjects** (expectations of privacy; e.g. chat rooms)

c. **Provision of confidentiality of data**

d. **Quality of the data**

e. **Description of how risk will be minimized**

f. **Screening for subjects who are not considered legal adults**

g. **Reasonable security**

h. The PI is personally responsible if he/she uses an online survey company and chooses not to have a contract agreement that has been reviewed by the Office of Legal Affairs.

### 16.4 Amazon Mechanical Turk (MTurk), Crowdsourcing Platforms

Mechanical Turk (MTurk) and other crowdsourcing platforms may be used to solicit participants for research. The preview and description of the virtual task that will be used in the MTurk Human Intelligence Task (“HIT”), or equivalent virtual task on other platforms, are considered recruitment materials. The description should include at minimum the name and contact information of the researchers, the affiliation with GSU, a description of the task, and the time required for the task.

Rejected work penalizes participants by limiting virtual tasks available in the future, and blocking workers can lead to fewer virtual tasks available and account suspensions. Participants in research cannot be penalized for their participation. Therefore no work can be rejected, the PI cannot take action to block workers (including to avoid duplicate participants), and the PI cannot submit negative reports about specific users to a crowdsourcing platform. Research participants must also be given the option to skip questions.

The consent form or virtual task description are not required to state that no work will be rejected or users blocked. The consent form and virtual task description cannot falsely state that poor quality work will be rejected. Work should be approved as soon as possible, but in no more than 7 days.

The consent form should state that work performed on MTurk can be linked to the public profile page and that MTurk worker IDs will not be shared with anyone outside of the study; similar statements may be applicable for studies conducted using other crowdsourcing platforms. The compensation information, including any bonus payments, must be clearly stated. Like all compensation, bonus payments cannot be coercive or present an undue influence. Because workers on crowdsourcing
platforms have varying levels of education, the reading level of the consent form should not be higher than the 8th grade level. The consent form should be the first question on the task and participants click to indicate their willingness to participate (see the model informed consent form for more information).

Worker IDs should not be shared, and removed from the data or stored securely. Worker IDs are considered identifiable data and should not be stored with the data.

Amazon retains data collected with the MTurk data collection tool and therefore it is suggested that data be collected using other survey tools such as Qualtrics with more security.

16.5 SITE PERMISSION

If researchers plan to use an established website, forum or other on-line source for research or recruitment, additional documentation may be necessary (See Section 6.8).
SECTION 17: COMMUNITY BASED PARTICIPATORY RESEARCH

17.0 Policy
17.1 Purpose
17.2 Background
17.3 General Researcher Considerations
17.4 Reviewers Considerations

17.0 POLICY

GSU supports and recognizes the importance of actively engaging and partnering with communities in research activities.

17.1 PURPOSE

The purpose of this policy is to provide information on community-based participatory research and understand the importance of engaging the community, strengthening community linkages, and respecting community values.

17.2 BACKGROUND

Community-based participatory research is a collaborative approach to research that equitably involves all partners in the research process and recognizes the unique strengths that each may bring. The process typically starts with a topic of importance to the community and has the aim of combining knowledge with action thereby achieving change to improve health outcomes and eliminate health disparities. The community residents participate in the full spectrum of research from concept, design, conduct, data analysis, interpretation, conclusions, and communication of results. An important goal with this type research is to influence change in community health, systems, programs or policies. Academic/research and community partners join to develop models and approaches to building communication, trust and capacity, with the final goal of increasing community participation in the research process.

Community-based participatory research has emerged as an alternative research model which integrates education and social action to improve health and enhance the scientific base of knowledge in the areas of health promotion, disease prevention, and health disparities. It is regarded as an
effective method for transferring evidence-based research from clinical settings to communities that can most benefit thereby improving health.

17.3 GENERAL RESEARCHER CONSIDERATIONS

Community-based participatory research requires that the researcher follow the best practices for respectful and productive relationships. The following principles are in addition to those required for all human subjects’ research.

a. Be certain that the research topic addresses a community-defined need, question or problem.

b. Recognize research as a partnership (i.e. engagement of research projects is to be led by a team of academic and community Co-Investigators as partners).

c. Respect the community partner’s interest in the research.

d. Be open to the guidance of community’s insight and experience.

e. Maintain a balance in decision making between the researchers and community participants.

f. Provide continuous feedback to enhance the partnership and its outcomes.

g. Research findings should be disseminated to community stakeholders and participants.

h. Recognize partnerships can dissolve and therefore a plan for closure should be developed.

17.4 REVIEWER CONSIDERATIONS

Should the IRB, primary reviewer or IRB compliance staff determine that there is not sufficient expertise to conduct a sound review, a consultant with competence in the area of community-based participatory research will be obtained to assist in the review of the issues which require expertise beyond or in addition to that available on the IRB. The consultant is required to either attend the meeting to present their comments or to provide their comments to the IRB in a written report (See Section 4.4)

Reviewers should be cognizant of the following:

a. Evidence of an equitable partnership between the investigator and the community partner.

b. The Investigators have defined the relevant community or communities.

c. The investigators have identified the appropriate community or communities for the project.

d. The community Co-Investigator has identified the appropriate research partner for the project.

e. Community engagement is an integral part of the research.
f. Letters of support (from the community) are clear and well-defined.
g. There is an appropriate division of funding.
h. There is sound science.
i. There are adequate training opportunities for investigators and community member.
j. The research environment is adequate.
   i. The community benefits from the presence and implementation of the research
   ii. The research is conducted in an environment that enhances the likelihood of success
k. The research strives for positive change in the community's outcomes.
l. The research fosters long-term relationships between academic institution and the community for the benefit of both.
Section 18: Genetic Materials

18.0 Policy

18.1 Purpose

18.2 Collection and Storage of Genetic Materials

18.2.1 Stem Cells

18.3 Previously Acquired Samples

18.4 Prospectively Acquired Anonymous Samples

18.5 Identified Samples

18.0 POLICY

Use of genetic materials in research is constantly evolving. Review considerations must include confidentiality and informed consent.

18.1 PURPOSE

The purpose of this policy is to outline some specific considerations for the researcher when planning to use genetic materials in research.

18.2 COLLECTION AND STORAGE OF GENETIC MATERIALS

Genetic materials are defined as human tissues samples (blood, saliva, serum, tumor, etc.) on which genetic-related research such as identification and location of specific genes, study of gene products, inherited human traits or identification and analysis of DNA mutations, may be performed.

It should be noted that research involving genetic materials may require Institutional Biosafety Committee approval prior to beginning the research.

18.2.1 STEM CELLS

In March, 2009 previous restrictions for use of federal funding for human embryonic stem cell (hESC) derivation and research were removed and/or reduced by the President of the United States. In order to facilitate research using HESC, the National Institutes of Health (NIH) created a “Human Embryonic Stem Cell Registry” listing those cell lines that are eligible for use in NIH funded research. More recently, the NIH has released an updated document “Guidelines for Human Embryonic Stem Cell Research” that provides a set of ethical standards for conducting research with hESC. Researchers should be informed that research involving stem-cell derived materials are subject to the United States Food and Drug Administration (FDA) regulations at 21 CFR 312 and 21 CFR 812, regardless of sponsorship. The research is also subject to the FDA’s IRB and informed consent regulations at 21 CFR.
18.3 PREVIOUSLY ACQUIRED SAMPLES
Previously acquired samples and genetic material, collected without identifiers may be used for the purposes of research, without further IRB approval, if future use was indicated in the original consent form and generally discussed with the research subject.
If identifiers are present, experiments not described in the current protocols must be submitted for IRB Review.
In vitro research using cells lines that are already derived and established, from which the identity of the donor cannot readily ascertained by the investigator, is not considered human subject research and therefore is not governed by 45 CFR 46, 21 CFR 50, or 21 CFR 56. IRB submission and review are not required for such research.

18.4 PROSPECTIVELY ACQUIRED ANONYMOUS SAMPLES
For research in which samples (blood, tissue, saliva, etc.) will be prospectively acquired without identification, the following issues must be presented in the consent form and discussed with the research subjects.

a. How anonymity of the samples will be accomplished. Some basic information, such as age and gender may be retained with the sample;

b. Ownership of genetic material (usually GSU);

c. The general scope of the investigations, but new developments of the investigation in the future are permissible if this possibility is indicated and explained during the consent process;

d. Whether the sample or its genetic material will be shared with other investigators;

e. The information specific to individual subject cannot be shared due to sample de-identification. However, information that accrues from the study that is valuable to society will be shared through publications.

18.5 IDENTIFIED SAMPLES
Research utilizing samples collected with identifiers must clearly indicate as much in the consent form and also be discussed with the research subject. The following issues should be considered:
a. If genetic material is linked to the donor by specific identifiers, ownership of the materials will generally remain with GSU.

b. If a commercial use is anticipated for the genetic material, the individual must be notified.

c. If identifiers are present, new experiments (not described in the original consent form) must be submitted, reviewed and approved by the IRB. A new consent may be obtained from the research subject.

d. The PI may include a provision in the consent form for new experiments not requiring a new consent if identifiers are irrevocably removed from the samples. If the PI anticipates future experiments without identifiers, this possibility should be presented in the original consent form. The methods for removal of identifiers must be approved by the IRB.

e. A satisfactory method for sharing or withholding information gained by the research must be in the research protocol and clearly indicated in the consent form.

f. Details for sharing or not sharing the genetic material with other investigators must be present in the protocol and clearly indicated in the consent form.

g. The length of time the genetic material will be maintained must be indicated in the consent form.
Section 19: Quality Assurance

19.0 Policy
19.1 Purpose
19.2 Goals
19.3 Objective
19.4 Measures
19.5 Institutional Review Board
19.6 Investigator
   19.6.1 Routine Post Approval Monitoring
   19.6.2 For Cause Post Approval Monitoring
   19.6.3 Observations of the Informed Consent Process
   19.6.4 Observations of the Conduct of Research
19.7 Surveys

19.0 POLICY

Quality assurance measures are conducted to identify possible weaknesses and elicit process improvements in human subjects’ protections. If any deficiencies are found, corrective action such as additional training will be taken.

19.1 PURPOSE

The purpose of this policy is to provide information deemed important to the mechanics of a successful quality improvement program.

19.2 GOALS

Annual performance goals are established as part of the yearly HRPP evaluation. Annual goals include decreased turnaround time for expedited review approvals. The annual performance improvement goals are aimed at reducing review turn-around time, increasing efficiency, and improving the accuracy of IRB records and reviews.

19.3 OBJECTIVE

The objective of the Quality Assurance and Improvement program is to ensure timely review of expedited protocols is obtained, and that ethical and regulatory requirements are obtained through a proactive approach that monitors for efficiency, appropriate documentation, record keeping, data
analysis and compliance with good academic research practice.

19.4 MEASURES

The performance of the HRPP is measured through assessment tools that indicate the level of efficiency and quality across all areas of the HRPP.

The efficiency of IRB reviews is tracked by measuring the time to process expedited reviews and exempt determinations. This allows for adjustment of resources to meet demands of increased or decreased workloads. Internal processes may be modified to provide for more efficient review of protocols.

Improvement in the quality of service provided by the IRB and the experience of research participants is measured to assess areas where additional education, training, monitoring or other corrective action guidance may be required. This is measured by tracking feedback from investigators and participants through a survey process.

19.5 INSTITUTIONAL REVIEW BOARD (IRB)

The operations of the IRB will be assessed periodically to ensure human subjects are adequately protected. The IRB will be assessed quarterly by the Associate Vice-President of Research Integrity.

The minutes of the IRB meetings will be reviewed by the HRPP Director and Chair (or designee of either) to ensure completeness and compliance with federal regulations and GSU’s policies and procedures before they are circulated to IRB members.

The Associate Vice President of Research Integrity evaluates the ongoing activities of the HRPP by reviewing a minimum of three IRB files on a quarterly basis. The review includes the appropriateness of the designation of the review category, appropriateness of the designation of reviewer(s), analysis of risks, privacy and confidentiality protections, documentation of informed consent, information considered during amendment reviews, and continuing reviews. Documentation of the assessment is provided to the HRPP Director, IRB Chairs, IRB Compliance Office staff, and Institution Official.

19.6 INVESTIGATOR

The Post Approval Monitoring ("PAM") program at GSU serves to improve human research protections and the quality and integrity of research under the oversight of the GSU IRB. The PAM program has three goals:

i. Enhance the protection of all research participants,

ii. Improve the quality of human research data, and

iii. Achieve and maintain compliance with federal regulations and GSU policies involving research with
human subjects.

GSU PAM accomplishes these goals by providing ongoing study oversight and educational outreach to support GSU investigators, student investigators, research staff, and the wider GSU research community in conducting ethically sound research involving human subjects in compliance with applicable federal regulations and GSU policies. PAM may be random or for cause.

19.6.1 ROUTINE POST APPROVAL MONITORING

Routine PAM is conducted routinely as a part of human subjects protections to maintain consistency and evaluate documents that have been submitted and approved as part of the IRB review and approval process. The IRB will have the authority or may designate a third party to review at any time all research records associated with a study selected for review; PAM activities may include assessment of research taking place at institutions that have ceded review to GSU’s IRB via a reliance arrangement.

The IRB Compliance Office staff typically monitors one study per quarter. A random sampling technique may be used to identify the study for routine PAM; all active non-exempt studies currently under GSU IRB review being the population for sampling.

A routine post approval study file audit may also be directed because the IRB deemed a study of a particularly high risk or because it involves an identified vulnerable population. If such an audit is directed in a quarter, this would satisfy the routine file audit requirement for that quarter.

**PAM Process:**

1. Upon selection, the PI is notified in writing regarding the selection of their project for a GSU PAM file audit and provides a blank On-Site File Audit Form.

2. IRB Compliance Office staff and PI schedule a mutually agreeable date, time, and location to conduct the file audit and pre-audit meeting. Audits will typically be scheduled to occur on-site using a dedicated space identified for use by the PI, but may be undertaken via a remote process.

3. During the pre-audit meeting, the PI will provide prepared materials to the IRB Compliance Office staff and be available to address questions. It is in the PI’s discretion to include the other study team members in the pre-audit meeting. The PI’s presence is not required for the remainder of the audit day, but an individual should be identified who will be available to address questions during the PAM assessment.

4. The following documents may be requested and/or reviewed by the PAM program staff:
   a. Signed informed consent documents
b. Signed HIPAA authorizations (if applicable)

c. CV and CITI training documentation (or equivalent) for project staff

d. Regulatory documents

e. Participant research records including inclusion/exclusion confirmation documentation (if applicable)

f. Enrollment logs or any other relevant documents.

5. Within approximately two weeks of the PAM assessment, findings will be reported to the PI.

**PAM Outcomes:**

1. IRB Compliance Office staff documents via an audit report the outcome of PAM activities and identifies any areas of strength and/or need for improvement in research practices. This report is provided to the PI and the IRB Chair. PAM audit outcomes may also be reported to Department Chairs and/or Center Directors as appropriate.

2. If a need for improvement in research practice is identified, IRB Compliance Office staff provides education to the PI and project team (if applicable) and suggests recommendations based on existing policies and procedures.

3. If a reportable event or other unanticipated problem is discovered, the PI will be instructed to submit the appropriate form in iRIS.

4. If non-compliance is identified, it will be managed as detailed in this manual's non-compliance policy.

**19.6.2 FOR CAUSE POST APPROVAL MONITORING**

PAM designated as “for cause” or “investigator oriented” is based on known or alleged information regarding an investigator’s conduct of the study in question. For-cause PAM can result in monitoring any active study conducted by the investigator or related to the study in question. Post approval for-cause study audits can occur both at GSU and externally-based research sites when deemed necessary.

A post approval for-cause study audit may be triggered by one of the following events:

- Participant or other complaints
- Ongoing corrective action monitoring
- New reported information represents potential non-compliance
- There is concern whether the rights and welfare of participants enrolled in research are adequately protected
- There are concerns about the validity or integrity of the data collected
Reporting and Disposition:

1. The results from PAM for-cause study audits are reported to the IRB Chair.

2. If the auditing process finds that participants in a research project have been exposed to unexpected, serious harm, such findings will be promptly reported to the IRB Chair for immediate action.

19.6.3 OBSERVATIONS OF THE INFORMED CONSENT PROCESS

Observing the informed consent process in approved studies is within GSU IRB’s authority. A designee may also be appointed to observe the informed consent process, and the IRB Compliance Office may coordinate resources at participating institutions to cooperate in monitoring the informed consent process at external sites when deemed necessary.

19.6.4 OBSERVATIONS OF THE CONDUCT OF RESEARCH

Observing the conduct of approved research is within GSU IRB’s authority. A designee may also be appointed to observe the conduct of approved research. The IRB Compliance Office may coordinate resources at participating institutions to cooperate in monitoring the conduct of research at external sites when deemed necessary.

19.7 SURVEYS

Investigators are encouraged to provide feedback regarding findings of non-compliance, unanticipated problems and other issues deemed reasonable by the IRB their experience with the IRBs through completion of an online survey or direct contact with the HRPP Director or Associate Vice President of Research Integrity. Survey results are tracked by the HRPP Director and provided to the Associate Vice President of Research Integrity in monthly reports. A summary of the results is provided to the Institution Official (Vice President for Research and Economic Development) in the annual report. Research participants are encouraged to provide feedback regarding their experience as a human research participant through direct contact with the Investigator, HRPP Director or IRB Chairs. A survey is available for research participants to complete, which provides feedback of the overall experience of the participant. These results are reported as detailed above.
Section 20: Non-Compliance with IRB Policies, Procedures, or Decisions

20.0 Policy
20.1 Purpose
20.2 Reporting Non-Compliance
20.3 Procedures in Response to Allegation of Non-Compliance
20.4 Claims Determined to be Neither Serious Nor Continuing
20.5 Claims Determined to be Serious and/or Continuing
20.6 Notifications
20.7 Protocol Deviations

20.0 POLICY
All members of the research team are required to conduct research projects in accordance with the proposal approved by the IRB, and in accordance with federal regulations, state laws and University policy. Failure to do so constitutes non-compliance in the research endeavor. This policy applies to all University researchers and research personnel who conduct research involving human subjects under GSU’s jurisdiction.

20.1 PURPOSE
The purpose of this policy is to outline the process for managing issues involving reports of non-compliance with IRB policies and procedures. The following information provides a detailed explanation of the procedures in instances when GSU researchers fail to comply with IRB policies and procedures.

20.2 REPORTING NON-COMPLIANCE
In many cases, non-compliance is discovered through monitoring by the IRB Office. However, complaints of non-compliance can be made by research participants, research staff, community members, investigators, IRB staff, and employees. The IRB has an electronic complaint form on its web page (www.gsu.edu/irb). This form can be completed and electronically submitted or printed and delivered to the IRB Compliance Office. The IRB Compliance Office will also accept complaints reported anonymously by telephone, written correspondence (letters or emails), or by in-person notification. To the extent permitted by law, the IRB Compliance Office will make every effort to maintain the confidentiality of the person reporting the non-compliance, unless such person gives permission to be identified. Retaliation against an individual for reporting non-compliance is strictly prohibited and will result in disciplinary action by GSU. The following includes, but is not limited to,
examples of non-compliance:
- Results from audits
- Protocol deviations
- Complaints from researchers or research participants

20.3 PROCEDURES IN RESPONSE TO CLAIM OF NON-COMPLIANCE

When the GSU IRB compliance staff is made aware of alleged non-compliance, either through its monitoring of research or receipt of a complaint, the IRB compliance staff will determine whether there is support for a claim of non-compliance (“claim”). If the IRB compliance staff believes there is support for the claim and the alleged non-compliance is serious or continuing (based on the criteria listed below), the appropriate IRB Chair will be notified. The IRB compliance staff together with the appropriate IRB Chair will determine whether a claim of serious or continuing non-compliance is supported. If the claim cannot be handled adequately by the IRBs, it will be referred to the Associate Vice President for University Research Services and Administration.

A Claim may be considered non-serious if the action that caused the Claim:
- had no substantive effect on the safety or well-being of research participants;
- did not affect the value of the data collected (meaning the violation did not confound the scientific analysis of the results) or
- did not violate any ethical principles.

A Claim may be considered serious if the action that caused the Claim:
- posed a significant risk of substantive harm to research participants;
- caused damage to the scientific integrity of the data collected;
- violated ethical principles.
- is continuing.

A Claim may be considered continuing non-compliance if there is a pattern of non-compliance that if allowed to continue is likely to increase risk to subjects, adversely affect the rights, welfare and safety of research subjects, or adversely affect the scientific integrity of the study.

Below are specific details on how reports of non-compliance will be addressed according to their classification.
20.4 CLAIMS DETERMINED TO BE NEITHER SERIOUS NOR CONTINUING
The determination of a claim to be neither serious nor continuing is made by the appropriate IRB Chair or the IRB compliance staff. If the Claim is determined to be neither serious nor continuing, a resolution to address the non-compliance will be determined by the IRB compliance staff. Such resolution will be summarized in a written document, and forwarded to the PI, IRB compliance staff, appropriate IRB Chair, made a part of the PI’s study file, and, if deemed appropriate by the IRB compliance staff, the department chair.

20.5 CLAIMS DETERMINED TO BE SERIOUS AND/OR CONTINUING
If the IRB compliance staff and the appropriate IRB chair find that a claim of serious or continuing non-compliance is supported, the IRB Chair will appoint an IRB subcommittee to investigate the claim. The subcommittee will be composed of 2 – 4 current IRB members (with no conflict of interest). An IRB compliance staff person can serve as a member of the subcommittee. The IRB subcommittee will review the file and conduct such interviews and hearings as it determines appropriate to investigate the claim. The IRB subcommittee will prepare a written report summarizing its findings. The report will specify whether the evidence supports a finding of serious or continuing non-compliance and (if so) provide recommendations for resolution. The report will be submitted to the IRB chair and HRPP Director for review by the convened board.
The IRB will review the report at a convened meeting and can revise it as necessary. The report can be accepted or rejected by the IRB. If it is rejected, the subcommittee will revise the report and bring it before the IRB at the next convened meeting. The resolutions are dependent on the type of non-compliance. The appropriate IRB will make a determination of serious or continuing non-compliance. Once the IRB has approved the report, a notification will be prepared and sent to the PI, his/her Dean and Department Chair. Such notification will include the findings of the IRB subcommittee and an action plan for resolving the non-compliance. Receipt of the notification will be verified by email. The notification and the sub-committee’s report will be made a part of Principal Investigator’s IRB study file.

The following includes, but is not limited to, examples of possible resolutions for non-compliance:
   a. informal counseling;
   b. action plan for resolving non-compliance;
   c. audit(s) of active protocols;
d. subjects previously enrolled in the study contacted and provided with additional information and/or re-consented;

e. frequent review of compliance;

f. suspension of research protocol;

g. termination of research protocol;

h. letter(s) of reprimand;

i. suspension of sponsored research grant account;

j. notification of current participants when such information might relate to participants’ willingness to continue to take part in the research;

k. prohibit collected data from being used for publication;

l. report of non-compliance to Vice President for Research and other University administrators, the sponsor, and/or government agencies;

m. disqualification of PI from conducting research involving human subjects at GSU;

n. embargo of publications;

o. modification of the protocol;

p. modification of the information disclosed during the consent process;

q. modification of the continuing review schedule;

r. monitoring of the research;

s. monitoring of the consent process;

t. referral of the Claim to the Vice President for Research for investigation in accordance with the Policy and Procedures for Dealing with Allegations of Misconduct in Research at GSU.

If the incidents of non-compliance are serious or continuing, and/or the IRB determines that a protocol must be suspended or terminated, the incidents and IRB actions must be reported to the Institutional Official and the applicable regulating agency (See Section 22).

20.6 NOTIFICATIONS

Within five business days after the IRB application is reviewed by a designated reviewer, the PI will receive notification of the IRB determination. The PI will receive a determination letter with an explanation of the determination and any resolutions that are required. Based on the outcome of the board’s determination, appropriate notifications will be made to organizational offices and officials (See Section 23).

20.7 PROTOCOL DEVIATIONS

A protocol deviation occurs when the PI has performed activities that are different from those
described in the approved research. A deviation can occur when procedures are performed that were
not previously described in the protocol or procedures described in the protocol were not performed.
Researchers and research support staff are expected promptly to self-report deviations regardless of
whether the incident is minor, serious, sporadic, or continuing. Self-reported protocol deviations must
be submitted via iRIS.
Upon receipt, the IRB compliance staff will review the report and bring it to the attention of the
appropriate IRB chair. A review of the report will determine the seriousness of the deviation and
whether or not the deviation is an incident of non-compliance. The PI will be notified of the results of
the review and if further action is necessary (e.g., a protocol amendment) and whether the deviation
represents an unanticipated problem involving risks to subjects or others. If the action is serious or
continuing non-compliance or if it is an unanticipated problem, the procedures for those will be
followed.
Section 21: Unanticipated Problems Involving Risks to Subjects or Others

21.0 Policy

21.1 Purpose

21.2 Reporting of Unanticipated Problems

21.3 Examples of Unanticipated Problems

21.4 Responsibilities of Principal Investigator

21.5 Procedures in Response to a Submission of an Unanticipated Problem

21.0 POLICY

GSU and the federal regulations require prompt disclosure to the IRB, appropriate institutional officials, and appropriate regulatory agencies of unanticipated problems involving risks to subjects or others.

21.1 PURPOSE

The purpose of this policy is to outline procedures that ensure prompt disclosure to the IRBs, appropriate institutional officials, and appropriate regulatory agencies of unanticipated problems involving risks to subjects or others.

21.2 REPORTING OF UNANTICIPATED PROBLEMS

An unanticipated problem is any problem, event, occurrence or new information related to the research project that is unanticipated and indicates subjects or others are at increased risk of Harm (including physical, psychological, economic or social harm) than was previously known or recognized.

An unanticipated problem is one that is unforeseen in terms of nature, severity or frequency of occurrence as documented in the research or other materials approved by the IRB.

PIs are required to promptly disclose a summary of each unanticipated problem, to the IRB using the IRB Unanticipated Problem form within 7 business days. Problems that are determined to be unanticipated require prompt reporting to the sponsor. The sponsor and/or investigator will then notify the proper regulatory authority OHRP (if DHHS funded), FDA, etc.). In many situations, an unanticipated problem will prompt a change in the consent form (e.g., listing an additional side-effect). In such cases, a revised consent form must be submitted by an amendment.
Additionally, when the researcher is the lead researcher of a multi-site study, information that is relevant to the protected population must be managed in accordance with GSU’s policies and procedures. Unanticipated problems that occur off-site must follow the reporting requirements as outlined in this section. Results of a multi-site study must be distributed appropriately and accordingly in the same manner as if researcher were conducted solely on GSU property. If modifications need to be made to the approved protocol; the same criteria will apply to multi-site studies as would apply to research studies conducted solely on GSU’s property.

21.3 EXAMPLES OF UNANTICIPATED PROBLEMS
An unanticipated event may be, but is not limited to, any of the following:

a. An actual unforeseen harmful or unfavorable occurrence to participants or others that relates to the research protocol (injuries, side effects, deaths);

b. An unforeseen development that potentially increases the likelihood of harm to participants or others in the future;

c. A problem involving data collection, data storage, privacy, or confidentiality;

d. A participant complaint about IRB approved research procedures;

e. New information about a research study (e.g., a publication in the literature, interim findings, safety information released by the sponsor or regulatory agency, or safety monitoring report) that indicates a possible increase in the risks of the research;

f. Changes in approved research initiated without IRB review and approval to eliminate apparent immediate hazards to the participant.

21.4 RESPONSIBILITIES OF PRINCIPAL INVESTIGATOR

a. Within 7 business days of knowledge of the unanticipated events, the PI is asked to submit the Unanticipated Event Form to the IRB Compliance Office.

b. Anticipated events (anticipated events described in the risks section of the consent form) are to be disclosed in the annual continuing review application.
21.5 **PROCEDURES IN RESPONSE TO A SUBMISSION OF AN UNANTICIPATED PROBLEM**

**Convened Full Board**

Minutes will document the IRB’s determination of whether the problem is unanticipated, related to the research, or involves new or increased risks to participants or other and any action that must be taken. All board members will have access to the Unanticipated Problem and the submission file.

**Expedited Board**

The reviewer will have access to the Unanticipated Problem submission and study file. The determination of whether or not the problem is unanticipated, related to the research or involves new or increased risks to participants or others is made on the reviewer checklist. If the determination indicates risks are more than minimal, it is referred to the Convened Full Board and any action that must be taken is documented in the Convened Full Board minutes. The Expedited Board is notified by monthly reports. Researchers are notified by letter.

The following includes, but is not limited to, example of possible actions that may be taken as a result of Unanticipated Problems:

i. No action necessary

ii. Notifying, and re-consenting, current participants when information about the unanticipated problem might affect their willingness to continue to take part in the research

iii. Alter the continuing review schedule

iv. Peer review monitoring

v. Approve with explicit changes:
   a. Notification of previous subjects
   b. Modification of consent and/or protocol;

vi. Suspension of some or all research activities;

vii. Approve the study for a shorter period of time (e.g. 6 months versus 12 months);

viii. Terminate the study for cause.
Following deliberation and determination of the IRB, unanticipated problems involving risks to participants are appropriately reported as outlined in the reporting policy described in Section 23.
Section 22: Suspensions and Terminations

22.0 Policy
22.1 Purpose
22.2 Reasons for Suspension or Termination
22.3 Authority to Suspend or Terminate Research Activities
   22.3.1 Principal Investigator
   22.3.2 IRB Chair
   22.3.3 IRB
   22.3.4 Institutional Officer
22.4 Notification of Suspension or Termination
22.5 Removing a Suspension or Termination

22.0 POLICY
An IRB or IRB designee may order a suspension or termination of approved research when in the judgment of the convened board or IRB designee research is not being conducted in accordance with IRB requirements, federal, state or local requirements or has been associated with unexpected serious harm to research participants.

22.1 PURPOSE
This purpose of this policy is to outline procedures for suspending or terminating research.

22.2 REASONS FOR SUSPENSION OR TERMINATION
A suspension is an action by a convened IRB, an IRB Chair/Vice Chair or the IO or his designee to stop, temporarily or permanently, some or all previously approved research activities short of permanently stopping all research activities. Suspended protocols are not closed and require continuing review.
A termination is an action by a convened IRB to stop permanently all activities of a previously approved research protocol. Terminated protocols are closed protocols, and they no longer require continuing review.
While continuing review is not required for studies that qualify for a limited review, the IRB retains the authority to suspend or terminate approval of research approved with a limited review.
Common reasons for suspending or terminating a research protocol or research activities include but are not limited to the following:
a. Research is not being conducted in accordance with IRB requirements (researcher non-compliance).

b. Research is associated with subject injuries.

c. Research is associated with or has led to an unexpected increase in harm to subjects.

The IRB may suspend or terminate research based on information received during its continuing review, findings from post-approval monitoring, or from complaints made to the IRB.

22.3 AUTHORITY TO SUSPEND OR TERMINATE RESEARCH ACTIVITIES

22.3.1 PRINCIPAL INVESTIGATOR

The PI is ultimately responsible for the conduct of the study, and as such, should always be aware of safety and welfare of subjects involved. The PI should not hesitate to suspend or terminate his/her own study in order to eliminate imminent hazards to subjects. If the hazard cannot be removed or corrected by modifying certain aspects of the study (e.g. inclusion, exclusion criteria, study design) then the study should be terminated. The PI should develop a plan for notifying and safely withdrawing subjects from the study, and any follow-up that may be needed to assure their ongoing safety. All unanticipated or adverse events and outcomes of such events must be reported to the IRB. The PI must notify the IRB if he/she voluntarily suspends or terminates a study. Any proposed modifications must be reviewed and approved by an IRB prior to restarting the study.

22.3.2 IRB CHAIR

Until a review can take place by a convened IRB, the Chair, in his/her authority, may independently suspend or terminate an approved research activity. The protection for rights and welfare of currently enrolled subjects must be considered. Therefore, if there is sufficient evidence of non-compliance by the research team that results in increased risk to the subjects, an IRB Chair can suspend or terminate the research activity. The PI will be notified of the decision immediately and be required to submit a response to the IRB Chair’s concerns. At the next convened meeting of the IRB, the Chair will report the suspension/termination, and discuss the rationale for the decision, review the PI’s response to the suspension/termination and lead the IRB discussion of events and actions items to take place. A Report of the suspension/termination will be submitted to the Institutional Official (See Section 23, Reporting Requirements).
22.3.3 IRB

An IRB, at a convened meeting, may suspend or terminate research activities as a result of the following:

   a. Reports of serious or continuing non-compliance by the PI and/or the research team.

   b. Reports of unanticipated problems or adverse events involving risks to subjects.

   c. Other reports that relate to the safety of subjects in a research activity.

The IRB may request a review from an independent source with expertise in the type of research being conducted. A course of action and a timeline, which may include but is not limited to additional training, a plan for oversight, and internal audits will be developed and conveyed to the PI.

22.3.4 INSTITUTIONAL OFFICIAL

The Institutional Official may suspend a research activity or study.

22.4 NOTIFICATION OF SUSPENSION OR TERMINATION

If immediate action is required, the PI may be notified verbally, followed by written notification. Letters (written notification) to the PI will be sent within five business days of the effective date of suspension or termination. Contents of the letter include, but are not limited to the following:

   a. The reason for the suspension or termination.

   b. The effective date of the suspension or termination.

   c. If the notification was initially provided verbally, the letter will reference the date of the verbal notification.

   d. Aspects of the research activity that must cease (e.g. recruitment, enrollment, intervention, follow-up).

   e. Any corrective action or clarification that must take place.

   f. If applicable, instructions on how currently enrolled subjects should be managed.

   g. The date that a response is to be received from the PI, and to whom the response should be addressed.

When study approval is suspended or terminated, an IRB or an IRB Chair considers whether procedures for withdrawal of enrolled participants takes into account their rights and welfare (e.g., making arrangements for medical care outside of a research study, transfer to another researcher, and continuation in the research under independent monitoring), considers informing current participants of the termination or suspension, and has any adverse events or outcomes reported to the IRB.
22.5 REMOVING A SUSPENSION OR TERMINATION

To reinstate a project that has been suspended, the PI must satisfactorily resolve any pending issues required by the IRB. If the issues have not been resolved after one year, the study will be terminated. The IRB will send written notification to the PI when the suspension is lifted. The letter will be prepared by the IRB compliance staff, reviewed and signed by the Chair, and sent out by the staff. The IRB compliance staff will also send a copy of the letter lifting the suspension to all entities who received a copy of the notification of suspension.

To reinstate a project that has been terminated, the PI must submit the project to the IRB as a new IRB application and past issues must be resolved to the satisfaction of the IRB. The new IRB application is reviewed by the appropriate board (See Section 7.3).
Section 23: Reporting Requirements

23.0 Policy
23.1 Purpose
23.2 Notification to the Institutional Official
23.3 Notification to Regulatory and Sponsoring Agencies
23.4 Contents of the Report

23.0 POLICY
The GSU IRB Compliance Office will report IRB determinations of serious or continuing non-compliance, unanticipated problems involving risks to subjects or others and suspensions and terminations of the IRB approval to the Institutional Official, federal agencies, and sponsors.

23.1 PURPOSE
The purpose of this policy is to outline reporting requirements.

23.2 NOTIFICATION TO THE INSTITUTIONAL OFFICIAL
The Institutional Official should be notified within seven (7) business days after a determination by the IRB that an event posed an unanticipated event involving risks to subjects and/or others, an incident of serious and/or continuing non-compliance, or a suspension or termination of research activities has occurred.

23.3 NOTIFICATION TO REGULATORY AND SPONSORING AGENCIES
Upon determination of reports of unanticipated problems involving risks to subjects and/or others, incidents of serious and/or continuing non-compliance, or a suspension or termination of research activities has occurred, the Institutional Official will review the findings and forward (or return it to the Office of Research Integrity/IRB compliance staff for forwarding) it as appropriate to the regulatory agency or agencies. The maximum time between the determination of a reportable event and the time that a determination must be reported to fulfill the reporting requirements is 30 days.

Reports of this nature may be sent by email to the following:
   a. Office for Human Research Protections (OHRP)
   b. Food and Drug Administration (FDA)
   c. Principal Investigator (PI)
d. PI’s Chairperson and/or Dean

e. Faculty Advisors

f. GSU, Office of Sponsored Programs (OSP)

g. Sponsor/Funding Agency

h. Department of Defense (DOD)

i. Other organizational offices (e.g. Institutional Biosafety Committee, Radiation Protection Committee, Institutional Animal Care and Use Committee)

For DOD supported research, the following shall be promptly reported (within 30 days) to the DOD human research protection officer:

a. When significant changes to the research protocol are approved by the IRB.

b. The results of the IRB continuing review.

c. Change of reviewing IRB.

d. When GSU is notified by any federal department, agency or national organization that any part of the HRPP is under investigation for cause involving a DOD- supported research protocol.

23.4 CONTENTS OF THE REPORT

The report should contain the following information:

a. Name of the institution conducting the research

b. Name of the PI

c. Title of the research protocol and/or title of the grant proposal

d. Nature of the event (unanticipated problem or event involving risks to subjects and/or others, suspension or termination of research activities)

e. A detailed description of findings and rationale for the IRB’s determination

f. Action plan developed to address the problem (revised protocol, revised informed consent, increased monitoring, inform subjects, suspend enrollment, etc.)
Section 24: IRB Reliance Agreements

24.0 Policy

24.1 Purpose

24.2 Authorization Agreements

24.2.1 General Guidelines

24.2.2 IRB of Record, Georgia State University

24.2.2.1 Use of Commercial/External IRB

24.2.3 IRB of Record, Not Georgia State University

24.2.4 National Institutes of Health (NIH) Single IRB

24.2.5 Common Rule Single IRB Requirement

24.3 Individual Investigator Agreement

24.3.1 General Guidance

24.0 Policy

To comply with federal mandates for single IRB review and federal regulations for cooperative research at 45 CFR 46.114, decrease the number of IRB reviews of the same protocol, reduce duplication and variation across sites, and promote collaborative research efforts between institutions, when appropriate, GSU will enter into an Institutional Authorization Agreement. To cover the research activities of an individual investigator who is not acting as an employee or agent of an institution or an institution that does not have an FWA and does not regularly conduct human subjects research, GSU when appropriate, will extend an Individual Investigator Agreement.

24.1 Purpose

The components of a research project may be distributed across more than one institution. Frequently some or all of the research procedures may occur at more than one site. This section describes the procedures for implementing an IRB Authorization Agreement and the Individual Investigator Agreement.

24.2 Authorization Agreement

An IRB Authorization Agreement (IAA) is a formal agreement between two institutions that each have a Federalwide Assurance (FWA). This Agreement specifies that one institution agrees to rely upon the IRB
review used by the other institution for all components of the study and defines the responsibilities for each institution. Institutions may use different descriptive terms such as Reliance Agreement or Cooperative Agreement. Agreements may cover single studies, categories of studies, or all human subjects research under an organization’s Federalwide Assurance. These Agreements are most often negotiated by IRB offices. However, these Agreements are between two institutions rather than the IRBs. The IRB of record is a term sometimes used to refer to the IRB that assumes the IRB responsibilities of another institution for a specific study.

24.2.1 General Guidelines

All requests for a new IRB Authorization Agreement (or requests for GSU and another institution to share oversight of research based on an existing general reliance arrangement) are made via the iRIS portal. Use the External Reliance Agreement application where another institution’s IRB will provide review, and use the Expedited/Full Study application where GSU’s IRB is requested to provide IRB review.

GSU is a Smart IRB participating institution and uses Smart IRB tools/templates to facilitate reliance arrangements. The Smart IRB tools/templates (and equivalents) noted below are used to define the responsibilities of a relying organization and a reviewing IRB, and to establish and communicate procedures that ensure the rights and welfare of research participants are protected when GSU shares oversight of research with a cooperating institution.

24.2.2 IRB of Record, Georgia State University:

IRB compliance staff work with the IRB Office at a cooperating institution to establish a reliance arrangement as follows:

a. Confirm that investigators at cooperating institution are engaged in the research (see definition of Engaged in Human Subjects Research);

b. Confirm the institution’s willingness to establish an IRB Authorization Agreement;

c. Verify the other institution has a current FWA;

d. Determine whether the other institution should be listed (designated) on GSU’s FWA;

e. Complete the GSU approved Authorization Agreement or GSU’s Smart IRB Acknowledgement of Site Agreement to Cede IRB Review and Reviewing IRB to Provide Oversight (available when collaborating institution participates in Smart IRB). From time to time, the other institution may wish to use their own Agreement template. A Smart IRB Agreement Implementation Checklist and Documentation Tool (see Appendix H), or
equivalent, will be completed and made an attachment to the Authorization Agreement or Smart IRB Acknowledgment of Site Agreement to Cede IRB Review and Reviewing IRB to Provide Oversight to delineate responsibilities of GSU’s IRB and the cooperating institution;
f. A Communication Plan for Smart IRB (see Appendix G), or equivalent, will be completed to detail responsibilities for communicating key information and requirements among GSU’s IRB, the cooperating institution, and investigators. A copy of the completed plan will be distributed to:
  − Each IRB office
  − GSU PI and study contact(s)
  − Cooperating institution’s lead investigator and study contact(s) (this will occur once the cooperating institution and its investigators have been approved by GSU IRB and entered into iRIS as Study Contacts)
g. A Smart IRB Point of Contact Survey (see Appendix I), or equivalent, will be solicited from cooperating institution’s IRB office to collect local context and site policies.
h. Determine any conditions the other institution may have with respect to the order of signatures, requirement for original copies, IRB approval letters, etc.;
i. If different from the standard Agreement, negotiate the terms of the Agreement. All non-standard conditions and terms of the Agreement must also be reviewed by the GSU Office of Legal Affairs.
j. Complete the Execution of the Agreement by ensuring both institutions have signed the Agreement and all relevant parties have copies.

Once a reliance arrangement is in place, the GSU PI will use the iRIS study application to seek IRB approval for the investigator(s) at the cooperating institution(s). The local context and site policies solicited during the reliance arrangements will be made available to the GSU PI, who will incorporate relevant information into the iRIS study application. GSU IRB office staff will verify that local context and site policies have been incorporated into the IRB submission. If reliance is reached prior to initial IRB approval of the study, the cooperating investigator(s) may be eligible for approval at initial review. More often, GSU IRB reviews requests to add cooperating investigators and institutions as amendments to approved studies. These amendments are typically eligible for expedited review if the cooperating investigators will be following protocol procedures already described in the IRB-approved application.

Relevant IRB records, including but not limited to minutes, approved protocols, consent documents, and other records that document GSU IRB’s determinations will be made available to
cooperating institutions to the extent not restricted under applicable law. GSU IRB’s policies are publicly available via its website and IRB compliance staff contact information is posted so cooperating investigators can contact the IRB to discuss questions, concerns or suggestions.

The lead investigator from each cooperating institution will be designated as a Study Contact in iRIS to receive study-related notifications of the IRB’s decisions, as well as broadcast notifications of major IRB policy updates communicated to all active iRIS users. Relying study teams may request that additional persons be designated as Study Contacts to receive these notifications. Cooperating institutions are also encouraged, during reliance negotiations, to designate a representative of their IRB office to be designated as a Study Contact in iRIS to facilitate these notifications at an organizational level.

24.2.2.1 Use of Commercial/External IRB:

For certain funded studies where GSU has been designated as the reviewing IRB, GSU IRB may at its discretion, defer its review to a Commercial IRB. The designated Commercial IRB chosen by Georgia State University is Advarra. If this procedure is chosen for a study, the IRB compliance staff will notify the lead investigator.

Responsibilities of the Commercial IRB:

a. Advarra IRB will designate one point of contact between GSU IRB and Advarra IRB;
b. Advarra IRB will provide protocol submission requirements including specific software programs that must be used for submissions;
c. Advarra IRB must provide a mechanism by which the investigator and the GSU IRB Office will receive a copy or electronic access to all related approvals and other regulatory documents.

Responsibilities of the Investigator:

a. Communicate directly with Advarra IRB to obtain approval for GSU and all study sites involved in the research;
b. Obtain all applicable GSU ancillary approvals for the study including, but not limited to IBC, Protection Committee, IACUC, COI;
c. Once IRB approval is obtained, complete the Tracking Information for Commercial IRB Review for in iRIS;
d. Continue to work with Advarra IRB for the duration of the study to provide information; obtain approval for any amendments, continuing reviews, and reportable events;
e. Follow all procedures, regulations, and guidelines as outlined by the IRB;
f. Once the research is finished, submit a study closure report to Advarra IRB and also notify the GSU IRB.

24.2.3 **IRB of Record, Not Georgia State University:**

IRB compliance staff work with the IRB Office at the reviewing institution to accomplish the following:


b. Verify the other institution has a current FWA and a registered IRB;

c. Request that the designated institution use their specific template;

   – A Smart IRB Agreement Implementation Checklist and Documentation Tool (see Appendix H), or equivalent, will be completed and made an appendix to the agreement if similar content is not addressed in the template

d. Determine any conditions the other institution has with respect to the order of signatures, requirement for original copies, IRB approval letters, etc.;

e. If different from the standard Agreement, negotiate the terms of the Agreement. All non-standard conditions and terms of the Agreement must also be reviewed by the GSU Office of Legal Affairs; and

f. Complete the Execution of the Agreement by ensuring both institutions have signed the Agreement and all relevant parties have copies.

When relying on an IRB that is not AAHRPP-accredited for research that is greater than minimal risk, GSU IRB compliance staff will consider additional protective measures to include, when appropriate:

a. Evaluating relevant policies and procedures of the reviewing IRB;

b. Having a representative of GSU serve as a consultant to the non-accredited IRB for review of a particular study;

c. Reviewing relevant portions of the minutes of the IRB meeting where the particular study is reviewed, or IRB records of the study reviewed; and/or

d. Conducting not-for-cause monitoring of the IRB.

24.2.4 **National Institutes of Health (NIH) Single IRB Review**

For NIH grant applications with due dates on or after January 25, 2018, NIH expects all domestic sites of NIH-funded multi-site studies, where each site conducts the same protocol involving non-exempt human subjects research, use a single IRB (sIRB). This may be either an independent IRB, or the institutional IRB of one of the participating sites. The plan for use of a sIRB is expected to be included
in grant applications and contract proposals submitted to NIH on or after January 25, 2018.

NIH considers exceptions to the sIRB requirement where the proposed sIRB would be prohibited by a federal, state, or tribal law, regulation or policy (policy-based exceptions). The NIH sIRB policy allows the consideration of requests for exceptions not based on policy if there is a compelling justification for the exception; these must be approved by NIH and documented in grant applications (or awards) in conjunction with GSU’s Office of Sponsored Proposals & Awards. Refer to NIH’s Guidance on Exceptions to the NIH Single IRB Policy.

If funding is secured at GSU, GSU’s IRB will typically opt to serve as the IRB of record. GSU’s IRB intends to serve as the sIRB for non-exempt, federally-funded multi-site projects where a GSU PI is the primary awardee and GSU’s IRB resources are adequate to support the project. PIs are advised to anticipate project needs and are directed to contact GSU’s IRB early in the grant writing process to assess GSU’s capacity to serve as the sIRB.

The process detailed in Section 24.2.2 IRB of Record, Georgia State University will be followed to ensure reliance agreements document respective authorities, roles, responsibilities, and communication between the participating organizations. Where cooperating institutions are located outside of the United States and not subject to the sIRB mandate, see Section 13 International Research for requirements to ensure appropriate ethical oversight in local jurisdiction.

GSU’s own documentation for authorization agreements entered in support of NIH’s sIRB mandate will be maintained as described in Section 24.2.1 IRB Reliance Agreements, General Guidelines. The Director, Human Research Protection Program is responsible for managing authorization agreements at GSU. Awardee institutions are responsible for entering reliance agreements and independently maintaining documentation thereof.

If GSU is designated as the single IRB on a NIH grant, the IRB review may be managed by an independent/commercial IRB as contracted by GSU with associated charges. The NIH has confirmed this option is acceptable. Commercial IRB review costs should be included in the proposed budget. The fee schedule for the independent/commercial IRB contracted to perform the sIRB review for GSU will be maintained by the IRB Compliance Office.

See Section 6.13 Certificates of Confidentiality for a discussion of Certificates of Confidentiality for NIH-funded projects.

While the primary awardee institution in a multi-site NIH-funded study is often responsible for meeting
additional certification requirements including those relevant to the NIH Genomic Data Sharing Policy, this is variable. Investigators should verify with their NIH project officer to determine which participating institution will certify.

24.2.5 **Common Rule Single IRB Requirement**

Cooperative research projects are those projects covered by the Common Rule that involve more than one institution (see [45 CFR 46.114](#)). In the conduct of cooperative research projects, each institution is responsible for safeguarding the rights and welfare of human subjects and for complying with the Common Rule. Any institution located in the United States that is engaged in cooperative research must rely upon approval by a single IRB for that portion of the research that is conducted in the United States. The reviewing IRB will be identified by the funding agency or proposed by the lead institution subject to the acceptance of the funding agency. The following research is not subject to this provision:

a. Cooperative research for which more than single IRB review is required by law (including tribal law passed by the official governing body of an American Indian or Alaska Native tribe); or

b. Research for which any funding agency determines and documents that the use of a single IRB is not appropriate for the particular context.

If funding is secured at GSU, GSU’s IRB will typically opt to serve as the IRB of record. GSU’s IRB intends to serve as the sIRB for non-exempt, federally-funded multi-site projects where a GSU PI is the primary awardee and GSU’s IRB resources are adequate to support the project. PIs are advised to anticipate project needs and to assess GSU’s IRB capacity early in the grant writing process.

24.3 **Individual Investigator Agreement**

This Agreement is used when researchers at GSU engage in research with a collaborating investigator who is affiliated with another institution that does not have its own IRB or Ethics Committee to review a study or an institution that does not have a Federalwide Assurance and does not regularly conduct human subjects research.

The Individual Investigator Agreement is a commitment statement that the unaffiliated investigator will comply with the human research subject protection policies and IRB oversight of GSU. The Agreement describes the expectations and responsibilities for the individual.
24.3.1 General Guidance

a. A request for the Individual Investigator Agreement is made to the IRB compliance staff who confirms that this type Agreement is appropriate.

b. The form is provided to the GSU researcher who completes the study information aspects of the form. The form is then provided to the Individual Investigator who completes the section of the form that provides the signature, date, contact information, and verification of appropriate human subjects training. The form is returned to the GSU researcher who provides the form to the IRB compliance staff.

c. The IRB compliance staff reviews the form for completeness and forwards the form to the IO for signature.
It is the policy of GSU that investigational devices will be used in compliance with federal regulations (21 CFR 812 and 21 CFR 814). When the primary intent of an investigational use of a device is to develop information about the product’s safety or efficacy, an Investigational Device Exemption (IDE) may be required. If an IDE is required, the Investigator proposing to conduct the study must first obtain FDA approval of an IDE application either directly or indirectly via a device sponsor.

The purpose of this policy is to provide guidance to researchers who wish to employ the use of medical devices as part of their research.

A medical device is defined within the Food Drug and Cosmetic Act as being an instrument, apparatus, implement, machine, contrivance, implant in vitro reagent or other similar or related article, including any component, part or accessory, which is recognized in the official National Formulary or the United States Pharmacopeica, or any supplement to them, intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment or prevention of disease, in man or other animals or intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its primary intended purposed through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes.

Devices may have a potential for significant risk. The determination of whether a device has a
significant or non-significant risk is a key decision for the IRB when reviewing applications for use of devices.

If a research activity appears to use a device for an indication for which it has not been cleared, it is the PI's responsibility to contact the FDA regarding whether an IDE is required. The researcher must provide this documentation to the IRB. The IRB staff will review the FDA regulations to verify that the research meets the definition of a device investigation. Device studies must satisfy one of the following:

1. Have an investigational Device Exemption (IDE) approved by the FDA under 21 CFR 812.30;
2. Categorized as fitting abbreviated requirements under 21 CFR 812.2 (b); or
3. Deemed by the FDA as being exempt from the requirement to have an IDE under 21 CFR 812.2(c).

25.3 SIGNIFICANT RISK AND NON-SIGNIFICANT RISK DETERMINATIONS

The Sponsor is responsible for making the initial risk determination and presenting it to the IRB. If the Sponsor claims a device is not a significant risk, then the IRB will review the research involving the investigational device at the convened meeting. The IRB will determine whether the study using the device is a significant risk, within the context of the overall study by reviewing the criteria set forth in 21 CFR 812.3(m).

25.3.1 Significant Risk Device (SR) means a device that presents the following:

1. Is intended as an implant and presents a potential for serious risk to the health, safety, or welfare of a participant;
2. Is purported or represented to be for use supporting or sustaining human life and presents a potential for serious risk to the health, safety, or welfare of a participant;
3. Is for a use of substantial importance in diagnosing, curing, mitigating or treating disease or otherwise preventing impairment of human health and presents a potential for serious risk to the health, safety or welfare of the participant; or
4. Otherwise presents a potential for serious risk to the health, safety, or welfare of a participant.

Significant risk device studies are governed and must follow all of the Investigational Device Exemption (IDE) regulations (21 CFR 812). IRB submissions for research on the use of a significant risk device must be accompanied by an approved IDE from the FDA that includes a valid IDE number before proceeding.

25.3.2 Non-Significant Risk Device (NSR) means a device that does not meet the
definition for a significant risk study. NSR device studies have fewer regulatory controls than 
SR device studies and are governed and must follow the abbreviated requirements [21 CFR 
821.2(b)]. A device fulfills the abbreviated requirements when the following are met:

i. The device is not a banned device;

ii. The sponsor labels the device in accordance with 21 CFR 812.5;

iii. The sponsor obtains IRB approval of the investigation after presenting the reviewing IRB 
with a brief explanation of why the device was not a significant risk device, and maintains 
approval;

iv. The sponsor ensures that each investigator participating in an investigation of the device 
obeys the IRB’s requirement and documents it unless documentation was waived;

v. The sponsor complies with the requirement of 21 CFR 812.46 with respect to 
monitoring investigations;

vi. The sponsor maintains the records required under 21 CFR 812.140(b) (4) and (5) and 
makes the reports required under 21 CFR 812.150(b) (1) through (3) and (5) through (10);

vii. The sponsor ensures that participating investigators maintain the records required by 
21 CFR 812.150(b) (1) through (3) and (5) through (10);

viii. The sponsor ensures that participating investigators maintain the records required by 21 
CFR 812.140(a)(3)(i) and make the reports required under 812.150(a) (1), (2), (5), and (7); 
and

ix. The sponsor complies with the prohibitions in 21 CFR 812.7 against promotion and other 
practices.

The FDA is usually not apprised of the existences of NSR studies because sponsors and IRBs are not 
required to report NSR device study approvals to the FDA. Non-significant risk device studies to not 
have to have an IDE application approved by the FDA.

If the IRB determines that the study using the device is not significant risk, it will document that 
determination in the primary and secondary reviewer checklist and the minutes, along with the IRB’s 
rationale for that decision. The IRB will notify the PI of its determination, and the study may begin 
without submission of an IDE application to the FDA.

If the IRB disagrees with the sponsor’s or PI’s assessment that a device study is non-significant risk and 
determines that the study using the device is a significant risk, it will notify the PI, and where applicable, 
the sponsor (21 CFR 812.66) and document its determination in the IRB minutes. The study will be
tabled, the sponsor or PI must provide the IRB with the FDA’s approval letter or conditional approval letter as part of the re-submission.

25.4 **Exempt Device Research**

Those investigations that are deemed exempt from IDE regulations also require IRB review and approval. An investigation of a medical device in human subjects research that is exempt from the IDE regulations must fall into one of the following categories based on criteria under 21 CFR 812.2 (c).

1. A device legally marketed in the U.S. that is used or investigated in accordance with the indication in the FDA-approved labeling.

2. A diagnostic device (i.e. an in-vitro diagnostic device) if the testing:
   a. Is non-invasive.
   b. Does not require an invasive sampling procedure that presents significant risk.
   c. Does not by design or intention introduce energy into a participant.
   d. Is not used as a diagnostic procedure without confirmation of the diagnosis by another, medically established diagnostic product or procedure.

3. A device undergoing consumer preference testing, testing of a modification, or testing of a combination of two or more devices in commercial distribution, if the testing is not for the purpose of determining safety or effectiveness and does not put all subjects at risk.

4. A custom device as defined in 21 CFR 812.3(B), unless the device is being used to determine safety or effectiveness for commercial distribution.

5. A device, other than a transitional device, in commercial distribution immediately before May 28, 1976, when used or investigated in accordance with the indications in labeling in effect at that time.

6. A device other than a transitional device, introduced into commercial distribution on or after May 28, 1976, that the FDA determined to be substantially equivalent to a device in commercial distribution immediately before May 28, 1976, and that is used or investigated in accordance with the indications in the labeling the FDA reviewed under subpart # of part 807 in determining substantial equivalence.

25.5 **RESPONSIBILITIES OF THE PRINCIPAL INVESTIGATOR (PI)**

The PI must:

1. Not begin the study or obtain informed consent of any participant prior to IRB and
(where applicable) FDA approval.

2. Ensure the clinical investigation is conducted according to the signed PI agreement for the investigation, the investigational plan, applicable regulations (21 CFR 812; 21 CFR 814), any conditions of approval imposed by the reviewing IRB or FDA.

3. Supervise all testing of the device involving human subjects in accordance with 21 CFR 821.43 (c)(4)(ii) and 21 CFR 812.110 (b).

4. Permit use of the investigational device only with participants under the supervision of the PI and to supply the investigational device only to those individuals authorized to receive it.

5. Provide for control or take adequate precautions, including storage of the device in a securely locked area to which access is limited to prevent inappropriate use of the device in accordance with 21 CFR 812.100.

6. Permit inspection and copy of records pertaining to the investigation by the FDA.

25.5.1 The IRB submission and associated documents should include:

1. description of the device
2. reports of prior investigations conducted with the device
3. the proposed investigational plan
4. participant recruitment criteria
5. a risk assessment and the rationale used in making its Significant Risk or Non-Significant Risk determination
6. communication from the sponsor or a letter from the FDA to the sponsor
7. documentation from the FDA regarding whether an IDE is required.

Providing all required documents enables the primary reviewer to determine whether the study has a valid FDA-approved, issued IDE. If not, the primary reviewer will determine whether or not the study meets the requirement for an abbreviated IDE or exemption from the requirement for the IDE. A study requiring an IDE will not be approved until the IRB verifies a valid IDE is in place. Note: GSU’s IRB will not provide oversight for significant risk device studies but may enter into a reliance agreement with a cooperating institution (or commercial IRB partner) to provide such oversight.

25.6 GUIDANCE

The IRB Chairperson and Associate Vice President for University Research Services and Administration (URSA) are responsible for meeting with an Investigator who plans to hold an IDE to assure that the Investigator understands and puts into writing the plan that he/she is to act as the
“sponsor” and will adhere to the sponsor responsibilities outlined in 21 CFR 812 and 21 CFR 814.

25.6.1 REGULATORY REQUIREMENTS FOR INVESTIGATORS WHO HOLD IDEs

It is the policy of GSU that investigators who hold investigational device exemptions (IDE) follow the Food and Drug Administration’s (FDA) requirements for sponsors, sponsor/investigators, and investigators. Below is a list of regulatory guidance.

**For devices only:**

- 21 CFR §812 (Establishment Registration and Device Listing for Manufacturers and Initial Importers of Devices)
- 21 CFR §812 (Investigational Device Exemptions)
- 21 CFR §814 (Premarket Approval of Medical Devices)
- 21 CFR §820 (Quality System Regulation)
Section 26: Additional Requirements for Federally Funded Agencies

26.0 Policy

26.1 Purpose

26.2 National Institutes of Health

26.3 Department of Defense

26.4 Department of Navy

26.5 Department of Justice

26.6 Department of Education

26.7 Environmental Protection Agency

26.0 POLICY

All human subjects’ research that has sponsorship from federal agencies shall comply with all additional federal regulations, directives and instructions as appropriate.

26.1 PURPOSE

The purpose of this policy is to highlight additional requirements as they apply to human subject research that is supported by various federal agencies.

26.2 National Institutes of Health (NIH)-Clinical Trials

All NIH funded studies that qualify as clinical trials must be registered at clinicaltrials.gov within 21 days of enrolling the first participation. It is the responsibility of the PI to register the study and PIs may contact the IRB office at irb@gsu.edu to request a user account in the federal system. NIH requires training on Good Clinical Practice (GCP). This can be completed through the CITI program at www.citiprogram.org.

NIH requires a Data Safety Monitoring Plan (DSMP) to describe how subject safety will be tracked and assessed, the frequency of such monitoring, how unanticipated problems will be characterized and reported, and the rules for stopping the study, if warranted. Depending on the level of potential risk to subjects and the complexity and size of the study, the Data Safety Monitoring Plan may require the establishment of a Data Safety Monitoring Board. See Informed Consent of Research Participants for additional required elements for NIH trials.
26.3 DEPARTMENT OF DEFENSE (DOD) RESEARCH

As a practice, GSU does not conduct nor does the GSU IRB review non-exempt, classified human subjects research projects.

Educational Requirements

All individuals involved in the design, conduct, or approval of human subjects research must complete the human subjects training. Georgia State’s requirements for required training and refresher courses meet this requirement. The Department of Defense component may evaluate the education policies to ensure the personnel are qualified to perform the research, based on the complexity and risk of the research.

Scientific Review

Scientific review of the submission prior to IRB review is required for all new DOD supported human research projects. The department heads or their designees are responsible to review and attest to a protocol’s scientific validity before it is submitted to the IRB. Therefore, this requirement is fulfilled. The IRB will also conduct a scientific review. All amendments to approved human subject projects must also undergo a scientific review. The scientific review of amendments to approved studies will be conducted by the IRB.

DOD Review Requirements

After the IRB completes its review and issues the letter of approval, documentation of approval, risk level, and the expiration date of the research approval must be submitted to the DOD component funding the project by the PI. The DOD may also request additional documentation to verify compliance with federal mandates.

- Surveys performed on DOD personnel must be submitted to, reviewed and approved by the DOD after the research protocol is reviewed and approved by the IRB. Investigators may not initiate the study until the human research protection officer within the sponsoring DOD component reviews and approves the study.
- Studies that involve human testing of chemical or biological agents is typically not allowed.
Researchers should be aware that when following DOD regulations, the definition of minimal risk based on the phrase, "ordinarily encountered in daily life during the performance of routine physical or physiological examination or tests" shall not be interpreted to include the inherent risks certain categories of human subjects face in their everyday life. For example, the risks imposed in research involving human subjects focused on a special population should not be evaluated against their inherent risks encountered in their work environment (e.g. emergency responder, pilot, soldier in a combat zone) or having a medical condition (e.g. frequent medical test or constant pain).

Research Monitor Required: More than Minimal Risk Studies

A research monitor is required for those studies funded by DOD and deemed greater than minimal risk. The following are additional IRB considerations:

− An independent medical monitor has been appointed by name.
− The IRB approves a written summary of the monitors’ duties, authorities, and responsibilities.
− The duties of the research monitor are determined on the basis of specific risks or concerns about the research.
− The medical monitor is a physician, dentist, psychologist, nurse, or other healthcare providers capable of overseeing the progress of the research protocol, especially issues of individual subject/patient management and safety.
− The medical monitor is independent of the investigative team.
− The medical monitor possessed sufficient educational and professional experience to serve as the subject advocate.
− The medical monitor possessed sufficient educational and professional experience to serve as the subject advocate.
− The IRB or HRPP official shall communicate with research monitors to confirm their duties, authorities, and responsibilities.
− The medical monitor has the authority to stop a research study in progress, remove individual subjects from a study, and take whatever steps are necessary to protect the safety and well-being of research subjects until the IRB can assess the medical monitor’s report.

For those studies that are more than minimal risk and also involve military personnel, the following criteria must be met:

− Unit officers and non-commissioned officers will not influence the decision of their subordinates
to participate or not to participate as research subjects;

- Officers and non-commissioned officers may not present at the time of recruitment;

- When applicable, officers and non-commissioned officers have a separate opportunity to participate;

- During the recruitment briefings to a unit where a percentage of the unit is being recruited to participate as a group, an ombudsman not connected in any way with the proposed research or the unit will be present to monitor that the voluntary nature of individual subjects is adequately stressed and that the information provided about the research is adequate and accurate;

- Federal employees while on duty and non-federal persons may be compensated for blood draws for research up to $50 for each blood collection.

Requirements for Pregnant Women
The DOD requires additional protections when the research involves pregnant women, fetuses, and neonates, including the application of 45 CFR 46, Part B. These requirements include:

- For the purposes of applying Subpart B, the phrase “biomedical knowledge” shall be replaced with “generalizable knowledge”.

- The applicability of Subpart B is limited to research involving pregnant women as participants in research that is more than minimal risk and includes interventions or invasive procedures to the woman or the fetus or involving fetuses or neonates as participants.

- Fetal research must comply with the US Code Title 42, Chapter 6A, Subchapter III, Part H. 289g.

Requirements for Prisoners as Subjects
The DOD requires additional protections when the research involves prisoners as subjects, including the application of 45 CFR 46, Subpart C. (See Section 12.4).

- Research involving any person captured, detained, held or otherwise under the control of DOD personnel (military and civilian, or contractor employee is prohibited

- Research involving prisoners of war is prohibited.

Requirements for International Populations
For research conducted internationally, refer to Section 13: International Research. This section
must meet the DOD requirements which includes consideration of subject populations, the
cultural context, the languages understood by the human subject, identifying and considering
laws, regulations, customs and practices. In addition, determinations are made as to whether the
sponsoring DOD component requires an additional ethics review by the host country and/or a
local DOD IRB with host country representation.

Multi-site or Collaborative Research Requirements
When developing proposals for DOD funding that involve collaborating institutions, the PI must
consult with the sponsoring DOD component to identify additional requirements for the multi-
site research. A formal agreement is required to specify the roles and responsibilities of each
party including a Statement of Work (SOW) and specific assignment of responsibilities.

a. When appropriate, research protocols must be reviewed and approved by the IRB prior
to Department of Defense approval. Consult with the Department of Defense funding
component to see whether this is a requirement.
b. The IRB may rely on outside experts to provide an evaluation of the scientific merit.
c. Department of Defense employees (including temporary, part-time, and intermittent
appointments) may not be able to legally accept payments to participate in research and
should check with their supervisor before accepting such payments. Employees of the
Department of Defense cannot be paid for conducting research while on active duty.
d. Department of Defense components might have stricter requirements for research
related injury than the DHHS regulations.
e. If appropriate, the CITI Department of Defense education modules will be completed by
IRB staff, chair, members, and researchers, and research staff.
f. When appropriate, the IRB Office will ensure that IRB staff, chair, and members, and
researchers and research staff become aware of the specific requirements contained in the
Department of Defense regulations and education about these requirements.
g. There may be specific Department of Defense educational requirements or
certification required.
h. If the research is conducted in an International setting, the IRB reviewers are required
to complete the checklist related to International research.
i. Other specific requirements of Department of Defense (DOD) research can be found in
the “Additional Criterion for Department of Defense (DOD) Research” section in the
IRB’s reviewer check sheet.
Provisions for Research Related Injury

The PI is responsible for informing the IRB if there are any additional requirements from the DOD component regarding the provision of care in the case of a research-related injury. If the DOD component has stricter requirements than the Common Rule or GSU's policies, the specified language will need to be discussed with the Office of Legal Affairs. These requirements must also be disclosed in the informed consent document.

26.4 DEPARTMENT OF NAVY (DON) RESEARCH

The Department of Navy (DON) supports research with human subjects conducted by DON commands, extramural performers through contracts, grants, cooperative agreements or other arrangements; by collaborators with the DON. Human research protection requirements are implemented through the Common Rule (32 CFR 219), Department of Defense (DOD) policies (DoDI 3216.02), and DON policies (SECNAVINST 3900.39D). This instruction applies to all biomedical and social-behavioral research involving human subjects conducted by Navy and Marine Corps activities or personnel, involving naval military personnel and DON employees as research subjects, or supported by naval activities through any agreement (e.g., contract, grant, cooperative agreement, or other arrangement), regardless of the source of funding, funding appropriation, nature of support, performance site, or security classification. It also applies to human subject research using DON property, facilities, or assets.

The DOD and DON mandate additional requirements for research with human subjects. Key additional requirements and the corresponding information should be reviewed at: [DoDI 3216.02; SECNAVINST 3900.39D para 4a(1) and 6g].

1. Initial and continuing research ethics training for all personnel who conduct, review, approve, oversee, support, or manage human subject research [DoDI 3216.02; SECNAVINST 3900.39D, para. 6a(2)]
2. Written determination by a designated official (other than investigators) whether research meets criteria for exemption [SECNAVINST 3900.39D, para. 6c]
3. New research protocols must undergo scientific approval prior to ethics (IRB) review [DoDI 3216.02]
4. Conflicts of interest [SECNAVINST 3900.39D, para. 6b]
5. Appointment of Research Monitor for greater than minimal risk research [DoDI 3216.02]  
6. Provisions for research-related injury [DoDI 3216.02; SECNAVINST 3900.39D, para 6a(5)]
7. Additional protections for military research subjects to minimize undue influence
8. Additional protections for pregnant women, prisoners, and children (Subparts B, C, and D of 45 CFR 46) [DoDI 3216.02; SECNAVINST 3900.39D, para. 6a(6)]

9. Additional safeguards for research conducted with international populations [DoDI 3216.02; SECNAVINST 3900.39D, para. 6i]

10. Consent by legally authorized representatives [DoDI 3216.02; SECNAVINST 3900.39D, para. 6a(3); 10 USC 980]

11. Limitation on exceptions from informed consent in emergency medicine research [DoDI 3216.02; SECNAVINST 3900.39D, para. 6a(3)and 7a(1); 10 USC 980]

12. Limitations on compensation for U. S. military personnel [Dual Compensation Act and 24 USC 30]

13. U. S. Navy-wide survey research may require additional review [SECNAVINST 3900.39D, para. 6e; OPNAVINST 5300.8B]

14. Reporting suspensions, allegations of non-compliance, unanticipated problems, etc.

15. Oversight by the DON HRPP through headquarters-level review of research protocols after local institutional approval [DoDI 3216.02; SECNAVINST 3900.39D, para. 8b, and 8d]

16. Addressing and reporting allegations of research misconduct [DoDI 3216.02]

17. Research with human subjects using investigational test articles (drugs, device, and biologics) [DoDI 3216.02; DoDI 6200.02; SECNAVINST 3900.39D, para. 6h]

(Please Note: GSU does not review investigational drugs research)

18. Prohibition of research with prisoners of war (POW) and detainees [DoDI 3216.02; SECNAVINST 3900.39D, para. 6a(8)]

19. Classified Research [SECNAVINST 3900.39D, para 6i]

(Please Note: GSU does not review classified research)

Researchers should review the Research Protocol Documentation Table and also determine if an Assurance is needed:


26.5 DEPARTMENT OF JUSTICE

PIs who are the recipient of funds from the Department of Justice (NIJ) are required to comply with all DOJ regulations at 28 CFR 46 (Protection of Human Subjects) and also 28 CFR 22, which include the following additional requirements.
a. IRB approval must be submitted to the Bureau Research Review Board for final approval.

b. The research must have a Privacy Certificate approved by the National Institute of Justice Human Subjects Protection Officer. Information about Privacy Certificates may be found at the NJI website. A model form for the Privacy Certificate can be found at: https://www.nij.gov/funding/humansubjects/pages/model-privacy-certificate.aspx

c. Sign and maintain an Employee Confidentiality Statement for the research team. A model employee confidentiality statement can be found at: https://nij.ojp.gov/funding/model-employee-confidentiality-statement

d. Informed Consent
   The consent document must contain a statement that confidentiality may only be broken if the participant reports immediate harm to participants or others.

e. Confidentiality Protections
   All researchers and research staff are required to acknowledge in writing the confidentiality protections of the study, and copies of that acknowledgement must be maintained by the responsible researcher.

f. Data Retention Requirements
   Identifiable portions of the data must be destroyed after the three year data retention period has expired and a copy of all de-identified data must be sent to the National Archive of Criminal Justice Data including de-identified informed consent documents, data collection instruments, surveys or other relevant research materials.

Research Involving the Bureau of Prisons

Research within the federal Bureau of Prisons is subject to additional requirements of 28 CFR 512. The regulations apply to any research involving inmates in the custody of the Attorney General, and assigned to the Bureau of Prisons, regardless of the institution in which the inmate is incarcerated.

- Research protocols within the Bureau of Prisons must be approved in advance by the federal Bureau Research Review Board (“BRRB”), and by the warden of the individual facility in which the research is to be conducted.
- No medical experimentation, cosmetic research or pharmaceutical testing is permitted. Only research studies that advance knowledge about corrections will be considered.
- Research protocols may not offer incentives to inmate subjects, except for soft drinks and snacks to be consumed at the test site. Non-confined research subjects may be offered nominal monetary recompense for time and effort provided that such subjects
are
i. no longer in Bureau of Prisons custody, and
ii. participating in approved research being conducted by Bureau of Prisons employees or contractors.
iii. Risk to participants are minimized and reasonable in relation to anticipated benefits.
iv. Selection of participants is equitable within any one organization.

− The researcher must assume responsibility for actions of any research staff engaged to participate in the project.
− The researcher must provide a project design that contributes to the advancement of knowledge about corrections.
− Researchers must agree to abide by the rules of the institution where the research will be conducted.
− The researcher must provide documentation of experience in the area of study of the proposed research and documentation of the review of related literature.
− The researcher must provide documentation that research records will be destroyed or individual identifiers will be removed from the records after the research is complete.
− The researcher provides documentation for maintaining confidentiality of data preliminary to the research, during and after the conclusion of the research.
− The researcher agrees not to maintain records electronically that contain non-disclosable information directly traceable to a specific person at the institution (NOTE: computerized data records may only be maintained at an official DOJ site).
− The researcher must submit planned methodological changes in the research to the IRB for review and approval prior to the initiation and revise study procedures in accordance with the methodology, as appropriate.
− Researchers must sign an acknowledgement to adhere to the regulations of the Bureau of Prisons at 28 CFR Part 512.
− The investigator must agree not to provide research information that identifies a subject to any person without the subject’s prior written consent to release the information.
− Projects conducted within the Bureau of Prisons must have an adequate research design and contribute to the advancement of knowledge about corrections.
− The Informed Consent Document for a study to be conducted in the Bureau for Prisons must include the following elements, in addition to the elements required under the
Common Rule.

i. Identification of the investigators;

ii. Objectives of the research project;

iii. Procedures to be followed in the conduct of the research;

iv. Purpose of each procedure;

v. Anticipated uses of the results of the research;

vi. A statement of benefits reasonably to be expected;

vii. A statement of concerning discomfort and risk, including a description of anticipated discomfort and risk;

viii. A statement that participation is completely voluntary and that the subject may withdraw consent and end participation in the project at any time without penalty or prejudice (e.g. the inmate will be returned to regular assignment or activity by staff as soon as possible);

ix. A statement regarding the confidentiality of the research information and exceptions to any guarantees of confidentiality required by federal or state law (i.e. an investigator may not guarantee confidentiality when the subject indicates intent to commit future criminal conduct or harm himself/herself or someone else, or if the subject is an inmate, indicates intent to leave the facility without authorization);

x. A statement that participation in the research project will have no effect on the inmate subject’s release date or parole eligibility.

xi. An offer to answer questions about the research project

xii. Additional information, as appropriate, to adequately describe the nature of risks related to the research.

Research Proposals

When submitting a research protocol to the Bureau, the following information must be present:

- Name(s) and current affiliation(s) of the researcher(s);
- Title of the study;
- Purpose of the project;
- Location of the project;
- Methods to be employed;
- Anticipated results;
- Duration of the study;
- Number of Subjects (staff/inmates) required and amount of time required from each;
− Indication of risk or discomfort involved as a result of participation.

**A comprehensive statement that includes:**
− The review of the literature;
− Detailed description of the research method;
− Significance of anticipated results and their contribution to the advancement of knowledge;
− Specific resources required from the Bureau;
− Description of all possible risks, discomforts, and benefits to individual subjects or a class of subjects, and a discussion of the likelihood that the risks and discomforts will actually occur;
− Description of steps taken to minimize any risk;
− Description of physical and/or administrative procedures to be followed to
  i. Ensure the security of any individually identifiable data that are being collected for the project, and
  ii. Destroy research records or remove individual identifiers from those records when the research has been completed;
− Description of any anticipated effects of the research project on institutional programs and operations; and
− Relevant research materials such as vitae, endorsements, sample informed consent statements, questionnaires, and interview schedules.
− If applicable, a statement regarding assurances and certification required by 28 CFR part 46.

**Post Study Obligations**
Research Conducted in the Bureau of Prisons must acknowledge the Bureau of Prisons participation in any publication of the results and include a disclaimer in the results for publication that the approval or endorsement of the published material is an expression of policies or view of the Bureau of Prisons.

Researchers must provide, at least 12 working days before any report of findings to be released, one (1) copy of the report, which includes an abstract of the findings, to each of the following:

− The Chairperson of the BRRB;
− The Regional Bureau of Prisons Director; and
− The Warden of each institution which provided data or assistance.
At least annually, the researcher must report on the progress of the research and provide at least one report of findings to the ORE Chief.

Researchers must submit two (2) copies of the results of the research project for informational purposes only to the Chief, Office of Research and Evaluation, Central Office, Bureau of Prisons prior to submission for publication.

26.6 **DEPARTMENT OF EDUCATION (ED) RESEARCH**

The Family Educational Rights and Privacy Act ("FERPA") is a federal law that gives parents certain rights with respect to their children’s education records. These rights transfer to the student when he or she reaches the age of 18 or attends a school beyond the high school level ("Eligible Students")

FERPA requires that written permission from parents or Eligible Students be obtained before releasing any information from student Education Records, except in the case of specific exceptions set forth in 34 CFR § 99. (See Section 1.6)

The IRB must verify compliance of the researcher with the US Department of Education regulations that schools are required to develop and adopt policies in conjunction with parents regarding the following:

a. Each school at which the research is conducted must provide an assurance that they comply with the Family Educational Rights and Privacy Act (FERPA) and the Protection of Pupil Rights Amendment (PPRA).

b. The school in which the research is being conducted must have policies regarding the administration of physical examinations or screenings that the school may administer to students.

c. Applicable procedures must be in place for granting request from parents or guardians reasonable access for inspection of all instructional material to include teacher’s manuals, films, tapes, or other supplementary instructional material which will be used in connection with any research or experimentation program or project of children engaged in such research. (Research or experimentation program or project means any program or project in any research that is designed to explore or develop new or unproven teaching methods or techniques).

d. Applicable policies are in place related to the collection, disclosure, or use of personal information collected from students for the purpose of marketing or for selling that information (or otherwise providing that information to others for that purpose), including arrangements to
protect student privacy that are provided by the agency in the event of such collection, disclosure or use.

e. Children are persons enrolled in research who are not above the elementary or secondary education level, and who have not reached the age of majority as determined under state law.

Research funded by the Department of Education must comply with additional protections under PPRA, 34 Part 98. No student shall be required, as any part of any research project, to submit without prior consent to survey, psychiatric examinations, testing or treatment, in which the primary purpose is to reveal information concerning one or more of the following:

a. Political affiliations or beliefs of the student or student’s parent(s).
b. Mental or psychological problems of the student or the student’s family.
c. Sex behavioral or attitudes.
d. Illegal, anti-social, self-incriminating or demeaning behavior.
e. Critical appraisals of other individuals with whom respondents have close family relationships.
f. Legally recognized privileged or analogous relationships, such as those of lawyers, physicians, and ministers.
g. Religious practices, affiliations, or belief of the student or the student’s parent(s)
h. Income (other than that required by the law to determine eligibility for participation in a program or for receiving financial assistance under such program).

Compliance with the US Department of Education regulations that schools are required to develop and adopt policies in conjunction with parents must be adhered:

a. The right of a parent of a student to inspect upon request of the parent, any instrument used in the collection of personal information before the instrument is administered or distributed to a student.
b. The right of a parent of a student to inspect upon request of the parent, a survey created by a third party before the survey is administered or distributed by the school to a student.
c. Applicable procedures for granting a request by a parent for reasonable access to surveys or instruments within a reasonable period of time after the request is received.

Applicable consent procedures must be implemented for research funded by ED. In addition, if the study is funded by the National Institute on Disability Rehabilitation Research, the study must verify whether or not the intent is to purposefully include children with disabilities or individuals with mental disabilities as research participants.
26.7 ENVIRONMENTAL PROTECTION AGENCY (EPA)

Intentional Exposure
The EPA does not support or conduct research that involves the intentional exposure of any substance to human subjects who are pregnant women (and therefore their fetuses), nursing women, or children. Other individuals who choose to participate are protected under the EPA’s rule, “Protection for Subjects in Human Research”, which requires the proposed research protocols describing intentional exposures be reviewed by the EPA and its IRB.

Observational Research

Pregnant Women and Fetuses
The EPA requires compliance of 40 CFR 26 Subpart D to provide additional protections to pregnant women as subjects in observational research, (i.e., research that does not involve intentional exposure to any substance).

Children, Not Greater than Minimal Risk
The EPA requires compliance of 40 CFR 26 Subpart D to provide additional protections to children as subjects in observational research, (i.e., research that does not involve intentional exposure to any substance).

Children, Greater than Minimal Risk
Observational research involving greater than minimal risk but presenting the prospect of direct benefit to children is allowable only if the IRB finds that (See Section 12.5):

1. The intervention or procedure holds out the prospect of direct benefit to the individual subject or is likely to contribute to the subjects’ well-being;
2. The risk is justified by the anticipated benefit to the subjects;
3. The relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by alternative approaches; and
4. Adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians.
Section 27: Appendices

Appendix A: 45 CFR 46
Appendix B: 21 CFR 56
Appendix C: Belmont Report
Appendix D: iMedRIS
  Application
  Application for Continuing Review
  Unanticipated Problem Form
Appendix E: Informed Consent Template
Appendix F: iRIS Application Guide
Appendix G: Communication Plan for Smart IRB
Appendix H: Smart IRB Agreement Implementation Checklist and Documentation Tool
Appendix I: Smart IRB Point of Contact Survey