How will the new IRB regulations affect me?

On January 19, 2017, new regulations for the protection of human research subjects are expected to go into place. The regulations will replace some of the regulations currently in 45 CFR 46. This document will detail how Georgia State University is implementing the changes and how it will affect researchers on campus. All the applications mentioned in this document can be found in iRIS, the IRB’s electronic submission program.

New Definitions
Several definitions have been added or changed such as the definitions of clinical trials, human subjects, research, and legally authorized representative. For those exact definitions see the Definition Handout at http://ursa.research.gsu.edu/files/2017/12/Definitions.docx

Secondary Research
Research that involves data or biospecimens that have already been collected or are collected solely for non-research purposes are considered secondary research. The new Secondary Data or Biospecimens Application can be used if you are conducting secondary research. If the data or biospecimens have not yet been collected, the researcher cannot be involved with the design (i.e. what instruments are used) or the implementation (researchers can have nothing to do with the collection of the data) and must justify why informed consent cannot be obtained. This application cannot be used if the researchers are hiring a company to collect data for a study. If researchers are requesting to use data they collected for research purposes previously, IRB approval must have been obtained for the original data collection.

Educational Research
Research involving normal education practices in a normal educational setting will be reviewed with the new Educational Research Exempt Application. This application can be completed for research on regular and special education students and research comparing or testing effectiveness of instructional techniques, curricula, or classroom management. It cannot be used for research involving prisoners, it adversely affects students’ opportunity to learn, or if it is not a normal educational practice in a normal educational setting.

Exempt Categories
Studies that qualify for one of the exempt categories should be submitted using the new Exempt Application. The exemption based on educational tests, surveys, interviews, or observation now includes collection of identifiable data including audio recording. An additional category includes benign behavioral interventions. Benign behavioral interventions cannot involve children and must be brief in duration, harmless, painless, not physically invasive, not have a lasting impact on participants, and not offensive or embarrassing. For more information on benign behavioral interventions and these terms, please see the guidance: https://www.hhs.gov/ohrp/sachrp-committee/recommendations/attachment-b-august-2-2017.html. Benign behavioral interventions cannot involve any physical sensors like blood pressure or eye tracking. They can include deception or concealment as long as participants are told about the deception or concealment in the informed consent form. Examples of benign behavioral interventions include playing on online game, solving puzzles under various noise conditions, and deciding how to allocate a nominal amount of cash between themselves and others. If the exempt application is completed, but the IRB determines that the study does not qualify as exempt, the expedited/full application must be completed.

Exempt Consent
A new consent template has been developed with fewer requirements than the expedited/full consent form. Please see the new template and guidelines on the IRB webpage at http://ursa.research.gsu.edu/files/2017/11/Consent-Template-Exempt-00211_29_17.docx

Expedited/Full Consent Template
An updated consent template for full board and expedited studies has been provided. The changes include additional requirements for informing participants about their rights for future research and contact information.

**Continuing Review or Status Check**

Studies that are reviewed as exempt and many expedited studies will no longer require yearly continuing review. In order to keep the system up-to-date a status check is required every 3 years and entails submission of a very brief Status Check Application to the IRB to let us know the study is continuing. Check the approval letter for expedited studies to see if a continuing review for the study is required. Continuing review for expedited studies may be required at the discretion of the IRB reviewer for reasons such as risk or a history of non-compliance. Full board studies will still require yearly continuing reviews.

**Transition Period for Existing Expedited Studies**

Expedited studies that are currently approved or approved before January 19th will have a two year transition period before review under the new regulations is necessary. Studies will be allowed one continuing review. After the continuing review, when the study is expiring another continuing review cannot be submitted. If data collection or analysis of identifiable data is ongoing, a new application must be submitted. Exempt and Full board studies will not require any additional action.

**Studies Currently in iRIS**

Studies in iRIS that have not yet been approved will continue to be reviewed. Studies that are approved after January 19th will be required to conform to the new rules, regardless of when submitted to the IRB. If a study is submitted using the expedited/full application, but can be reviewed under the exempt categories, the application will be reviewed as exempt. If an exempt application is submitted that does not meet the requirements for an exempt study, the researcher must submit a new expedited/full application.

**NIH Studies**

If your study is funded by the NIH (National Institutes of Health) and is completed at multiple sites, you will be required to only use one IRB for the entire study. Please contact the IRB for assistance. If your study meets the definition of a clinical trial, you will also be required to complete Good Clinical Practice training through citiprogram.org and register your study on clinicaltrials.gov. You can see the NIH website for more information and an updated definition of clinical trials: https://grants.nih.gov/policy/clinical-trials.htm