Common Stipulations and IRB Tips for iRIS Applications

This guidance highlights some of the IRB application responses that most frequently require corrected (or supplemented) responses.

Additional Personnel Information

Human Subjects Training is a requirement for approval. Have you and your research team members completed Human Subjects Training?

IRB tip: All researchers must have up-to-date CITI training before an application is accepted by the IRB.

Is the PI listed a faculty member at Georgia State University?

IRB Tip: The PI must be a GSU faculty member. If needed, return to the Personnel section of the application to make the PI a GSU faculty member.

General Research Information

Describe in lay terms the purpose of the research including the research question and what you hope to gain.

IRB Tip: This item is intended to be a brief summary. Providing information that is duplicated elsewhere in the application can lead to inconsistencies in this document, and as changes are made later via study amendments. Here (and in other parts of the application), the IRB recommends limiting answers to the information requested.

Is this study or any part of this study contributing to a dissertation or thesis?

IRB Tip: The research protocol is a separate word document that should include: the study title; a summary; a description that includes a rationale, objectives, methodology, and data management and analysis; ethical consideration; and references.

IRB Tip: The WHO provides a helpful guide for writing a research protocol available at https://icahn.mssm.edu/files/ISMMS/Assets/Research/IHCDS/Guidelines%20for%20Writing%20the%20research%20protocol%20by%20WHO.pdf

Location

IRB Tip: For international research, all research staff will complete the CITI International Research module. Please visit http://ursa.research.gsu.edu/ursa/compliance/human-subjects/citi- course-registration/ for instructions on accessing the International Research module.

Recruitment

Describe in detail the recruitment plan.

IRB Tip: This section should describe how you will go about recruiting participants for your study. Will you be making an in-class announcement? Will you be recruiting via email? Who will be recruiting? You as the teacher, or a TA? Please be as specific as possible. You will also need to include any recruitment materials (flyer, email, verbal script) for review.

IRB Tip: Recruitment materials should include the following information:

a) a contact person's name and identify the institution b) specify the project is research c) where the research will be conducted d) purpose of research e) a summary of the criteria that will be used to determine eligibility f) a brief list of participation benefits g) the number of participants to be enrolled h) time or other commitment required i) compensation, if any

IRB Tip: For “word of mouth” recruitment methods, it would be a violation of privacy for participants to share a name and contact information with the researcher. Instead, the participants can provide the researcher's name and contact information to others who would be interested in joining the study.

Will participants be compensated or incur any costs for their participation?

IRB Tip: The State of Georgia closely regulates the operation of lotteries/raffles. For more information on lotteries for research, review section 6.10 of the IRB Manual. If you would like to utilize a raffle as a means for participant compensation, provide the information as stated in the manual, Section 6.10 a-h, in this section.

Participant Data

Will information that personally links the participants to the research be collected?

If **Yes**, state what identifying information will be collected. Identifying information includes (but is not limited to) name, social security or student ID number, date of birth, contact information including email address or phone number, photographs, and audio or video recordings.

IRB Tip: If you will be collecting participant names, address, social security numbers, phone numbers, or any other identifying information, that must be described here. If you will be using a key code or link to connect participants identifying information and the data, that must be described. Identifying information should be kept separate from the data. You may want to remove and destroy any identifying information after the data collection is complete.

Will photographs, audio recordings, or video recordings be used?

If **Yes**, describe and provide information how any special precautions used to protect photographs, audio or video recordings.

IRB Tip: If participants will be audio or video recorded, describe that here. Recordings should be kept separate from the data, and researchers should describe how recordings will be stored and kept confidential. Describe whether recordings will be destroyed after transcription. Audio and video recordings are always considered identifiable, but will the recordings contain additional identifying information?

State where and how any data will be collected, stored, and transported; who will have access to the data and what will be done with it after the study is over, sharing hard-copy and electronic data (flash drive, cloud storage, Drop Box, etc.).

IRB Tip: Provide information on how data will be protected. State how the hard copy data will be stored (e.g., in a locked cabinet). Consent forms should be stored separately from the data. Describe how electronic data will be kept safe (i.e. password protected, firewalled computer). If data are stored on a lap top or flash drive, describe how it will be kept safe (e.g., encryption). State who will have access to the data. State how long the data or link to identifying information will be kept. (The IRB does not require or recommend that researchers destroy their human subject's data at the completion of the research. Indeed, researchers are encouraged, when appropriate, to make provisions in their research protocol and consent forms for future use of their de-identified data. It is suggested that data be made available to other researchers in accordance with what is stated in the consent form and in the application.) If you would like to use participants' identities in a publication or presentation, describe how the participants will be made aware.

IRB Tip: Please mention how identifiable data will be managed if it is inadvertently collected (e.g. the participant gives someone's name during the interview). For example, you can say "If any identifying information about the participant or others is inadvertently collected during interviews, that data will not be transcribed or analyzed."

Informed Consent

Provide a description of the informed consent procedures.

IRB Tip: Remove reference to "understand" from the Informed Consent process. The consent process should not ask people if they "understand", although you can ask if they have questions.

What is the estimated lowest reading level of each population?

IRB Tip: Half of all adult Americans read at or below the 8th grade level. If the reading level is above the 8th grade level, it must be justified or the consent will need to be revised to be consistent for a lower reading level. To do this, review the readability guidelines found on the model consent form located at the bottom of this page IRB Expedited and Full Consent Form Template.

Does the population include participants that are non-English speaking?

IRB Tip: When a translated consent document is submitted, one of the following must apply:

The translation is provided by a certified translator not involved in the study, and a certificate of translation is provided along with the English version and the translated version of the consent.

- or -

Translated consent documents must be translated and back-translated by two different individuals who are not involved in the study. The names of these individuals must be provided and the translation and back-translation uploaded for review (in addition to the original English version).

Explain and justify the waiver of documentation of consent. Describe how your study meets each of the requirements for a waiver of documentation of consent listed in the table above. A waiver of documentation of consent can be used, for example, in the case of a web-based consent form in which a participant clicks 'agree' to participate or oral consent. With the waiver of documentation of consent, a document containing all the required elements of consent must still be uploaded for review.

IRB Tip: If all procedures for a study will be conducted online, it is advisable for the researcher to obtain a waiver of documentation of consent, eliminating the need to obtain a physical signature on the consent document.

Uncheck 'Signed Consent Required' and check 'Waiver of Documentation of Consent'. Then, continue through the application to provide justification for the waiver. Part of the justification should be that the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.