IRB Protocol Guidance

This guide is meant to serve as a helpful tool when faculty, students or other research personnel are filling out an IRB protocol to help clarify what information is being requested. The following questions have been pulled directly from the Kuali protocol. It is important to read each question thoroughly and not rush through your answers.

Note: Help bubbles appear throughout the protocol in the form of a ? icon. If you hover over the icon, the text will appear and offer more details about the question.

SIUE Personnel Section

- The response here should include information for the PI as well as any co-investigators or faculty advisors. Typically, in a student-led project, the PI would be a student and the faculty member would be a co-investigator or faculty advisor depending on the faculty member's role in the project. All student-led protocols must include the faculty advisor in this section.
- **ALL** fields in this Personnel Section should be filled out before submitting. Don't forget to fill in the Researcher Experience and Researcher Involvement fields for all personnel!
    - The Home Unit selection should generally be the same as the Lead Unit in the "General Information" section.
    - If your CITI Certificate does not auto populate, please attach a copy in this section.

Question – *Is this a student-led project?*

If the principal investigator is faculty or staff, then the project is not student-led. If the project falls within the Classroom Protocol determination, please select "no" to this question as the faculty member is the leader of the project.

Question – *Indicate which type of review you are requesting from the IRB*

The response here will vary depending on the protocol being submitted. A protocol can fall into three different review categories: Not Human Subjects Research, Exempt, and Expedited/Full Board.
Guidance on these review categories can be found here and within the regulations.

Question – *Please select the appropriate category…*

The response here will vary depending on the type of review selected in the previous question (see guidance on the Exempt categories and Expedited categories). Please note, it is possible that more than one category may apply.

Question – *Are you collecting data anonymously?*

If you are interviewing participants or will be collecting data with direct identifiers (i.e., subject names, email addresses, etc.) or indirect identifiers (i.e. uncommon race, ethnicity, extreme age, unusual occupation) the data is not considered anonymous.

Question – *Anticipated Project Ending Date*

When submitting a protocol, please submit early and allow plenty of time for the review process. The review period timeline can vary depending on the review category.

Question – *Indicate which of the following are expected sites of investigation (check all that apply):*

If any of the work for the study will be conducted on campus, please select SIUE here.

Question – *Provide a brief statement regarding the purpose of the research. (Why are you doing this research?)*

Are you trying to increase current understandings in a specific area? Is there a gap in the literature? This question is more about why you've chosen this topic. It is not asking "why" in a broad sense (i.e., for a class).

Question – *Please state the anticipated amount of time subjects will be required to participate?*

Please state the TOTAL amount of anticipated participation time. If you have multiple elements (e.g., survey and interview), also include the estimated amount of time to complete each element. This time should be consistent throughout the protocol and also be included in the recruitment material and consent document.

Question – *Are subject incentives or payment to subjects offered?*

If you select "yes," then you must also describe and justify the incentive being offered. The description should include details like the amount offered and how the compensation is being delivered. For example, if cash is being offered, will it be transferred via Venmo, PayPal, check?

Question – *Are you using existing data?*

Please note, if the existing data you will be using was collected for **non-research** purposes, then the answer here should be "yes." For example, data from a medical record is typically not collected for research purposes and is considered existing data. A data collection sheet reflecting what existing information is being collected for this project must be included in the Attachments section.

Question – *Will demographic information be collected?*

If demographic questions are being asked then those questions should be part of the survey or interview questions attachment. If the questions are not included in those attachments, then a

separate document with the demographic questions should be included in the Attachments section.

Question – *List all demographic information that will be collected (e.g. age, sex, income, etc.)*

The demographics listed here need to align with the demographic questions asked in the survey or interview. Keep in mind that demographics are not limited only to age, gender, race, or year in school. Occupation, income, and education are also common demographics. It is best to consider if demographics are even relevant to the study.
Using multiple choice ranges should be considered to help better protect anonymity. For example, instead of asking for a participant's specific age, list a range of ages a participant can choose from.

Question – *Electronic Data Security: Mark at least two that apply*

Two responses must be selected for this answer.

Question – *Explain how subject recruitment is to be carried out.*

The explanation here should fully describe the process of how you intend to conduct recruitment. Are you emailing a specific group of potential participants? Will you post on social media, and if so, which sites are you using and do you have permission? Please be as detailed as possible.

If "other method not listed above," is selected in the follow up question, please clarify what the other method is within the protocol.

Question – *Informed Consent. Please select all that apply*

Projects being reviewed as Expedited or Full Board traditionally require written informed consent with the participant's signature. If you would like deviate from that type of informed consent, select the appropriate reason from the list provided. You will need to then justify why traditional informed consent is not appropriate for your project.

*Please note, if your project is being reviewed under an Exempt category of review, signatures should not be collected in order to protect participant anonymity.

Question – *In lay language, describe how the research will be conducted.*

The response here should describe a step by step process of your research with the human subjects so the reviewers have a clear understanding of your study and how it will be conducted. It should include information such as the recruitment process, how you'll obtain consent, how and where surveys or interviews will take place, is there any debriefing after the research activity, etc. The answer here can even be numbered, for clarity. This question requires a detailed response, and a one sentence response is generally not sufficient.

Question – *In lay language, describe the role of subjects' interaction with the individual or the use of their data/specimens.*

Consider if you are employing a survey with no direct interaction vs. an in-person interview with direct action.

Question – *Specify the risks to the subject(s) and the steps you will take to minimize each risk.*

This is a two-part question requiring answers to both risk and how you'll minimize risk. Consider what risks are possible, even if very remote, and what you will do to minimize those risks.

Question – *Specify the benefits to the subjects*

This question is in reference to what intrinsic benefit the participant might receive. A gift card, extra credit or some other form of compensation is not considered a benefit to the participant, but more of a thank you for participating and to compensate them for their time. If there is no benefit to the participant, you may state that in this section.

Attachments Section:

Read the instructions below the attachments. They are customized to the answers on this protocol form and will give you guidance on which attachments to upload.
To add an attachment, please click the +Add Line button on the right.

Please note the highlighted description in this section. It is meant to direct the submitter to the forms that are likely needed based on how the questions have been answered (e.g., The Researcher Participant Form w/AV language should be used if recording interviews.) Please note, the survey or interview questions are always required attachments.

All template forms can be found on our website.

Expected Timelines

Once you complete your protocol, submit as early as possible. IRB determination and review may take multiple weeks.

The following approximation timelines are provided, but note, that it is impossible to determine exactly how long a review will take:

- Exempt review 1-3 weeks
- Expedited review 3-6 weeks
- Full Board review 4-8 weeks or longer.

Please note that if the protocol is not filled out completely and fields are left blank, the review process will take longer. If there are questions about the protocol, and to facilitate a more efficient review, please reach out to researchcompliance@siue.edu BEFORE submission.

Reference Links

Human Subjects Research FAQs - https://www.siue.edu/graduate/faqs/index.shtml?tag=human-subject-research

SIUE Compliance Human Subjects Research - https://www.siue.edu/compliance/human-subjects/index.shtml

Human Subjects training through CITI - https://www.siue.edu/compliance/training/index.shtml

U.S. Department of Health and Human Services Office for Human Research Protections Decision Charts - https://www.hhs.gov/ohrp/regulations-and-policy/decision-charts-2018/index.html

NIH Human Subjects Research Definition - https://grants.nih.gov/policy/humansubjects/research.htm

IRB Expedited Review Category Fact Sheet

This guide is meant to serve as a helpful tool for faculty, students or other researchers when determining which review category their project falls into and covers the most commonly-seen categories of review at SIUE.

Expedited Category 4 v. Exempt Category 3

Expedited Category 4	Exempt Category 3	Expedited Category 4 Example	Exempt Category 3 Example
Collection of data through noninvasive procedures routinely employed in clinical practice, excluding procedures involving x-rays or microwaves.	Research involving benign behavioral interventions thorough verbal, written responses, when: • Recorded information cannot readily identify the subject **OR** • No sensitive information is being collected (illegal behaviors, medical records, etc.)	• Physical sensors applied to the surface of the body or at a distance. • MRI • Moderate exercise, muscular strength testing, body composition assessment	• An intervention where participants are being exposed to stimuli such as color, light, or sound at a safe level. • Performing cognitive tasks • Solving puzzles under various noise conditions.

Expedited Category 5 v. Exempt Category 4

Expedited Category 5	Exempt Category 4	Expedited Category 5 Example	Exempt Category 4 Example
Research involving materials (data, documents, records, or specimen) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis).	Secondary research with identifiable information/specimens collected for some other initial activity, when: • Identifiable private information or biospecimens is publicly available, OR • The recorded identifiable private information has been de-identified.	• Chart reviews, studies using student records, or collection/use of discarded tissues that contain identifiable information.	• Analysis of public officials' leaked emails available on X. • Chart review of de-identified patients so they cannot be readily identified.

Expedited Category 6 v. Exempt Category 2

Expedited Category 6	Exempt Category 2	Expedited Category 6 Example	Exempt Category 2 Example
Collection of data from voice, digital, or image records made for research purposes.	Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview, or observation of public behavior, when: • Recorded information cannot readily identify the subject OR • No sensitive information is being collected (illegal behaviors, medical records, etc.)	• Audio/video recordings of interviews or focus groups involving sensitive information, • Video recordings of participants completing an intervention or task.	Conducting an interview, not asking sensitive information, and the information cannot readily identify the subject.

Expedited Category 7 v. Exempt Category 2

Expedited Category 7	Exempt Category 2	Expedited Category 7 Example	Exempt Category 2 Example
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.	Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview, or observation of public behavior, when: • Recorded information cannot readily identify the subject OR • No sensitive information is being collected (illegal behaviors, medical records, etc.)	• Interviewing or surveying a vulnerable population such as children or pregnant persons. • Focus groups or interviews of a sensitive topic (i.e., related to illegal behavior, sexual activities/practices, traumatic experiences).	Conducting an interview, not asking sensitive information and the information cannot readily identify the subject.

Please note, a project can fall into more than one Expedited review category. If you believe your project should be reviewed under multiple categories, please select all that apply when submitting your protocol in Kuali Research.

If you believe your project falls within Expedited Categories 1-3 or you have any questions, please email researchcompliance@siue.edu.