


IRB Protocol Guidance

This guide is meant to serve as a helpful tool when students are filling out their protocol and to offer a better understanding of 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, text will appear and offer more details about the question.

Question – Are the subjects *identifiable* either through direct interaction or through data collection AND does the collection of information include *sensitive* data?

Identifiable means the identity of the subject is known or may be readily ascertained by the investigator or associated with the information. In general, information is considered identifiable if it can be linked to specific individuals by the investigator either directly or indirectly through coding systems, or when characteristics of the information obtained are such by their nature a reasonably knowledgeable person could ascertain the identities of the individuals. If an investigator conducts interviews, then the participants are typically considered identifiable.

*Keep in mind, data can also be identifiable if it is combined with enough information to potentially identify a participant (otherwise known as indirect identifiers). While an investigator may not be collecting direct identifiers like a person's name, if they are collecting other indirect identifiers (e.g. age, gender, job function or employer, etc.), the combination of those identifiers may make a participant identifiable.

Data is considered *sensitive* if disclosure would pose increased social/reputational, legal, employability or insurability risk to subjects.

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?

Question - In lay language, describe how the research will be conducted. Step by step process of your research with the human subjects.

Writing only one sentence will typically not encompass a step by step process in research. This question requires a more detailed response.

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 interaction. Make sure to also include information as to how the data will be used.

Question – *Explain the use of any educational test or procedure, interview, or survey. Explain how information will be recorded.*

Be detailed with this question. Are you recording the information anonymously? Are you recording the interview and transcribing the answers later?

Question – *Describe the EXPECTED DURATION of the TOTAL STUDY (i.e. recruitment, data collection, data analysis, etc.), and the DURATION OF EACH SUBJECT'S participation. This should correspond to the dates you've listed on the cover page of this application.*

There are 2 parts to this question to answer – Expected duration of the total study AND the duration of each subject's participation.

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

Really consider what risks are possible, even if very remote, and what you've done to minimize those risks. For example, breach of confidentiality is a risk in most protocols.

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

Keep in mind that demographics are not limited to only age, gender, race and year in school. Occupation, income and education are other common demographics used to identify groups. Consider including multiple choice ranges to better protect anonymity. Consider if demographics are even relevant to the study.

Question – *Explain how subject recruitment is to be carried out. Provide copies of letters, media ads, posters, etc. or the Recruitment document in the Attachments section of the protocol with the attachment type 'Recruitment Materials'.*

Be detailed here and how you have access to the population. Consider that recruitment of employees or students as participants requires a heightened level of review to ensure participation is truly voluntary.

Question – *Does the investigator/researcher have a non-research relationship with the potential participant (e.g., teacher to student, employer/supervisor to employee)?*

If there is an existing non-research relationship, consider how an inherent power differential may affect voluntariness in participation and in subject responses. Does the recruitment and/or data collection method ensure participants do not feel unduly influenced or coerced? Depending on the details of the project, the IRB may request that a person who does not have a non-research relationship with the participants collect the data in order to minimize risk.

Question - *For each faculty advisor, investigator and co-investigator, including non-SIUE personnel, who are on this project:*

- 1) list their name and describe their experience/qualifications*
- 2) describe their role on the project*

The response here should include your information as well as your faculty advisor.

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.

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

Relevant Regulations and FAQs:

Family Educational Rights and Privacy Act (FERPA) is a federal law protecting the privacy of student education records. The Act gives parents and eligible students more control over their educational records and prohibits educational institutions from disclosing “personally identifiable information in education records” without written consent. However, FERPA does allow schools to disclose those records without consent under certain circumstances.

Q: Can I collect grades to use in my research study?

A: Under FERPA, yes you may collect grades, but you will need written consent from the minor student’s parent or the adult student (if 18 or older) before the records can be disclosed unless the researcher can meet one of the exceptions. A list of exceptions can be found [here](#).

Note: Collection of FERPA protected information may result in a more heightened level of protocol review.

Action Research involves systematic observations and data collection which can then be used to develop more effective instructional and classroom management techniques.

Q: If I'm conducting *action research* do I still need to submit to the IRB?

A: Yes. However, most action research protocols will qualify for *exempt* review under the federal regulations. The research must be conducted in established or commonly accepted educational settings and specifically involve normal educational practices. This includes most research on education instructional strategies, research on the effectiveness or comparison of instructional techniques, curricula or classroom management methods. If the activity would occur in the educational setting regardless of whether the research is conducted, it may qualify under this exemption.