Institutional Review Board

Human Subjects Committee (HSC) Review of Student Projects

Review of student projects involving human subjects:
Grambling State University policy requires that **all** research projects involving human subjects have Institutional Review Board (IRB) approval prior to the start of the study to ensure that the project meets University requirements and any applicable federal regulations.

What is research?
Systematic investigation designed to develop or contribute to generalizable knowledge. Simply put, research looks at one set of circumstances and tries to make conclusions that can be applied to, or is predictive of, other similar circumstances.

What is a human subject?
A human subject is a living person about whom an investigator gets identifiable private information through either a direct interaction with the person or through access to private data sources.

What is minimal risk?
Minimal risk is 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 healthy persons. This means that the risks of harm anticipated in the proposed research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Examples of student projects that require IRB review:

- Interviews and surveys, including on-line surveys that collect identifiable information, including instances when pseudonyms or codes are used and these pseudonyms/codes can be linked through a key to the identities of individuals.
- Observational studies where the individuals' identities are known or which take place in private locations or locations with a presumption of privacy (e.g., on-line chat rooms, dorm common rooms, private homes).
- Psychological studies.
- Focus groups
- Use of existing identified data sets, which are not publically available.

- Collection of biological specimens such as saliva, blood, or buccal swabs.
- Studies involving children, prisoners, mentally impaired or other vulnerable populations.
- Collection of physiological data such as skin conductance, pulse rate, etc.
- Any student project whereby the results of which may/might be disseminated off campus, at a professional conference, submitted for publication, or published on the World Wide Web.

Examples of student projects that may be EXEMPT from IRB review:

- Interviews or surveys, which do not collect information about a person.
- Interviews on government or corporate policies.
- Interviews regarding historical events which are intended to describe the event and not to be predictive of human behavior in other future events.
- Analysis of existing anonymous data.

When in doubt, the IRB can provide assistance in determining if a given project must be reviewed under GSU policy. Send an email providing a brief description of your project to irb@gram.edu.

What to do if your project requires review:

1. Complete Mandatory CITI Training - http://www.gram.edu/offices/sponsoredprog/docs/Procedurefor%20accessing%20CITI%20training.pdf

2. Go to the Sponsored Programs webpage and complete the **IRB Application for Human Subjects Review**: http://www.gram.edu/offices/sponsoredprog/

3. Email the application to the IRB (irb@gram.edu) along with all supplemental and/or required materials (i.e., survey instruments, Informed Consent, etc.)

Things to think about when designing a research study involving human subjects:

- Think about the **culture, political situation and experiences** of the subjects you want to study, and make sure your study is respectful to them and their values. Remember that what may be an acceptable question to one group can be upsetting or even inflammatory to another group.

- Think about **risks and benefits** the subjects will have during the study, or because of their participation in the study. Is there a way you can minimize the risks? Risks include potential psychological, social, financial, and judicial harms as well as physical harm to the participants. Consider whether there could be participants who are more likely to experience harm them others. Most risks in non-biomedical studies involve risk of harm from disclosure of information about the subject or disclosure of the subject's responses to the study questions. These harms can be minimized by adequately limiting the

possibility of a breach of confidentiality through data security and confidentiality protections as necessitated by the sensitivity of the data.

- Think about special, **vulnerable populations** such as children, economically or educationally disadvantaged, or those who may have a limited ability to make decisions for themselves. If it is necessary that the study include a vulnerable population, special precautions may be needed, such as getting a parent's or caregiver's permission to speak with the vulnerable person.

- Limit the **subject identifiers** that will be recorded. If possible, try to design the study so that subject names or other information that could specifically identify a person (such as date of birth) are not recorded. Studies that do not collect any information that could be used to identify the individual are considered **anonymous**. Note that even without names or other direct identifiers, data wouldn't be anonymous if the demographics recorded are sufficient to allow identification of the individual participants.

- If you need to collect names or other information that could identify an individual person, keep the information **confidential**. The HSC suggests creating a list that contains a link between the subject's name and a random code number or pseudonym, and then using only the code number/pseudonym to mark the data and responses from that subject. The list that contains the coded link should be kept secure, and separate from the data and responses. That way, the subject's data is kept confidential.

- In all cases, the investigator should **inform subjects** about:

    - The purpose of the study;
    - What is involved and duration of time required;
    - Potential risks and benefits associated with being in the study
    - Means for maintaining confidentiality - both the subject's identity and information provided;
    - Voluntary participation and withdrawal from study at anytime.