Introduction

The purpose of this document is to provide a brief summary of the information in the USU Institutional Review Board Handbook for Human Studies (Investigator’s Handbook). It is not intended to replace the information in the Handbook. The full Investigator Handbook may be found on the IRB website.

The IRB uses an on-line program called Protis for IRB applications, reviews, and protocol management. As the initial step in preparing an application to the IRB, it is suggested that you review the Protis Help website before you begin. Archived forms are available on the IRB website if you wish to review the types of questions that will be asked in your Protis application.

Research and Human Subjects

If you are doing research with human beings (or their previously-collected data), then you must submit an application to the IRB for review.

How do you know if you are doing research?

The federal regulations define research as a “systematic investigation, including research development, testing, and evaluation designed to develop or contribute to generalizable knowledge.” However, this definition may not be enough for you to determine if the work you are doing is research. Sometimes the issue of whether or not the study will “contribute to generalizable knowledge” is unclear. For example, some qualitative studies, which may not directly “contribute to generalizable knowledge,” are still research. In addition, course research assignments conducted by students may be research even if they are limited in scope.

How do I know if my study will “contribute to generalizable knowledge?”

Generalizable knowledge: is knowledge that is “expressed in theories, principles, and statements of relationships” that can be widely applied to our experiences. Generalizable knowledge is usually created to share with other people, such as through presentations and publications. Masters’ theses and Ph.D. dissertations are considered to present generalizable knowledge.

“Generalizable knowledge” would include one or more of the following concepts:

- The knowledge contributes to a theoretical framework of an established body of knowledge
- The primary beneficiaries of research are other researchers, scholars and practitioners in the field of study
- Publication, presentation or other distribution of the results is intended to inform the field of study
- The results are intended to be replicated in other settings
- Web based publication for professional purposes”

(Used with permission from Michigan State University’s IRB)
If you are uncertain about whether or not your work is research that needs IRB review, it is suggested that you first complete and submit a Request for Determination through Protis.

**How do you know if you are doing human subjects research?**

Human subjects are defined as: living individual(s) about whom an investigator conducting research obtains (1) data through intervention or interaction with the individual; or (2) identifiable private information. *If you are not using human subjects in research, you do not need to submit to the IRB.*

**What if I'm using existing data that were previously collected for a different purpose?**

Research using existing data that were collected under an IRB-approved protocol or that are available in the public domain may be exempt from federal regulations. If you are conducting research using existing data, refer to the federal guidelines for Exempt Category #4 to see whether your research is eligible for this exemption.

**Exemption #4 (45 CFR 46.101(b)(4))**

Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

**What does the IRB look for in a human subject research project?**

Before approval, the IRB must determine that the following requirements are satisfied.

1. The proposed research design is scientifically sound so as to not unnecessarily expose participants to risk.
2. Risks to participants are minimized.
3. Risks to participants are reasonable in relation to anticipated benefits.
4. Participant selection is equitable.
5. Safeguards are included for participants likely to be vulnerable to undue influence or coercion.
6. Informed consent is sought from each participant or the participant’s legally authorized representative
7. Participants’ safety, privacy, and confidentiality are maximized.

An archived version of the Reviewer’s Checklist used by the USU IRB for reviewing applications can be found on the [IRB website](#).

**Submitting to the IRB**

**Who does the submitting?**

It is the responsibility of the principal investigator (PI) to submit an application for approval before the research begins by submitting one of three types of applications: General, Exempt, or Course Research Assignment. Your answers to the decision tree questions in Protis will direct you to the application you need.

**What are the deadlines for submitting IRB applications?**

You may submit an IRB application at any time. Applications are entered in the queue for review in the order they are received.
Most human subject research does not need the full board’s review. As soon as a protocol application is received by the IRB office, we will determine if the application can be reviewed under the regulations for Expedited Review and, if so, the review process will begin without waiting for a convened board meeting.

Submission deadlines only apply to applications that require Full Board Review and they must be received 4 weeks before a scheduled meeting. The IRB meets on the first Tuesday of each month. For IRB meeting dates and submission deadlines click here. Protocols that require full IRB review but are not received by the deadline will be held over for consideration until the next meeting.

Research that requires Full Board Review includes any protocol in which the risk to participants is more than minimal. Minimal risk is where, “the probability and magnitude of harm or discomfort are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.” In addition, the Full Board must review any research that does not fit any of the Expedited Review categories of the federal regulations.

**What do I need to submit and how should it be submitted?**

Protis is the method for submission of all IRB applications, forms and supporting documents. Unless otherwise instructed by an IRB administrator, paper or emailed forms are no longer accepted.

The following items must be included in the Protis submission, as applicable:

1. Answers to all questions in the Protis application.
2. A draft of the Informed Consent, Letter of Information or Parental Permission/Assent formatted to the template on the IRB website.
3. A description of the proposed research (either a research proposal or a summary) which includes a description of the research methodology. If the research is for a student’s thesis (including honors thesis), dissertation, or Plan B, the entire proposal should be submitted.
4. Copies of any questionnaires or survey instruments which participants will complete.
5. Any advertising used to recruit participants for the research.

**What happens after that?**

You will be notified by e-mail if there are any questions or changes required by the IRB. These questions and your responses will be exchanged through the Protis application. Once the IRB receives your responses and they are found to be acceptable, your study will receive approval.

You will be asked to print and return a signed copy of the approved Informed Consent, Parental Permission/Assent or Letter of Information to the IRB office. Once the signed document is received, you will be notified that the research may begin and the official IRB approval letter will follow by email.

Until the research project is completed, you will be asked for an annual status report about the project in order to receive approval for continuation. You will be sent a Protocol Status Report form which you must complete and return one month prior to the approval expiration date. This gives the IRB time to review your report and issue the continuation before a lapse in approval.

*Updated 4/18/2012*
What else should I know?

If you make any changes to the methodology, study population, or study personnel, you must submit an Amendment/Modification request to the IRB before implementing the changes. If your application was submitted through Protis, refer to the Protis Help site for instructions on amending protocols.

If you experience an unanticipated problem related to your research you must notify the IRB by submitting the Unanticipated Problems Reporting Form. Unanticipated problems include events that are unexpected and place participants at greater risk of harm than was previously known.

What about IRB Certification?

USU and federal regulations require that Principal Investigators, Co-Investigators and any research personnel who will be in contact with participants or performing data analyses must receive training in the ethical protection of human participants. USU uses CITI online training to fulfill this requirement.

CITI training is not required for personnel who are strictly involved in clerical work such as data entry, filing, etc. unless the training is required by the PI. In all cases, the PI is responsible for the confidentiality of data and protection of participant privacy through appropriate training of staff and/or use of employee confidentiality agreements.