



# Sam Houston State University

*A Member of The Texas State University System*

## INSTITUTIONAL REVIEW BOARD

### **Institutional Review Board Guidance: Human Subjects Protections: Does my Research Need IRB Review?**

Before submitting an Institutional Review Board (IRB) application, first determine if IRB review is actually required for your project. Review the guidance below to assist in this determination.

#### **Why this Matters**

- If your activity does not fit one of the definitions of research (below), you do not need to obtain IRB approval or a determination of exempt status.
- The specific definition (if any) that applies to your activity determines which regulations and requirements govern your research.

#### **The Regulations**

Federal regulations require that research projects involving human subjects be reviewed by an IRB. The IRB must approve or determine the project to be exempt prior to the start of any research activities. The IRB cannot provide approval or determinations for research that has already been concluded.

Institutional Review Board review and approval is required for projects that:

- Meet the definition of research
- Involve human subjects and
- Include any interaction or intervention with human subjects or involving access to identifiable private information, unless it is part of a program, product, or service evaluation

#### **What is Research?**

Research is defined as a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

A **Systematic Investigation** follows a predetermined plan for looking at a particular issue, testing a hypothesis or research question, or developing a new theory that may include:

- Collection of quantitative or qualitative data
- Collection of data using surveys, testing or evaluation procedures, interviews, or focus groups
- Collection of data using experimental designs such as clinical trials
- Observation of individual or group behavior

Contribute to **Generalizable Knowledge** means that the purpose or intent of the project is to test or to develop scientific theories or hypotheses, or to draw conclusions that are intended to be applicable and/or shared beyond the populations or situations being studied. This may include one or more of the following:

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Presentation of the data at meetings, conferences, seminars, poster presentations, etc. outside of Sam Houston State University

The knowledge contributes to an already established body of knowledge

Other investigators, scholars, and practitioners may benefit from this knowledge

Publications including journals, papers, dissertations, and master's theses

If the project does not meet the definition of research (i.e., is not a systematic investigation or does not contribute to generalizable knowledge), as described above, then the project does not require IRB review and an IRB application is not required.

### **My Project is Considered Research, Now What?**

If the project meets the definitions of research (i.e., is a systematic investigation or does contribute to generalizable knowledge), as described above, the next set of questions apply.

### **Are Human Subjects Involved?**

A Human Subject is a living individual about whom an investigator conducting research obtains (1) data through intervention or interaction or (2) identifiable private information.

If the project does not meet the definition of research or the project does not include human subjects, as described above, then the project does not require IRB review.

### **My Project Includes Human Subjects, Now What?**

If the project does include a human subject aspect, you need to determine if there is any interaction or intervention with subjects or if there is any access to identifiable information.

- **Interaction**—Any communication or interpersonal contact between the investigator(s) and subject(s). This includes in-person, mail, telephone, etc. Online surveys (even if anonymous) involve interaction.
- **Intervention**—Physical procedures or manipulations of the subject or his/her environment (e.g., taking blood samples, exercise studies, use of devices, cognitive tasks, etc.)

### **Access to Identifiable Private Information**

**Private Information**—Information about behavior that occurs in a context in which the individual can reasonably expect that no observation or recording is taking place (e.g., person's home, exam room, public restroom, etc.) OR has been provided for specific purposes with a reasonable expectation that it will not be made public (e.g., medical records, student records, employee file, etc.)

**Identifiable Information**—Information that permits the identity of an individual to be directly or indirectly inferred, including any information that is linked or linkable to that individual, regardless of whether the individual is a U.S. citizen, lawful permanent resident, visitor to the U.S., or employee or contractor to the Department.

If the project does not include any interaction or intervention with human subjects or include any access to identifiable private information, then the project does not require IRB review. If even one of the above categories are met (intervention, intervention, access to identifiable private information), an IRB application is required.

### **Example of Studies that Generally Require IRB Review**

- Pilot studies that involve human subjects (if generalizable and will be published externally from SHSU)
- Master's theses
- Dissertations

- Use of identifiable information from medical records, private student records, employment records, or other private sources, research studies that collect data about human subjects through interaction or intervention with subjects (e.g., interviews and focus groups that explore thoughts, perceptions, feelings about themselves or others), surveys (paper, online, telephone, etc.), cognitive testing (unless it is part of regular diagnostic testing), etc.
- Research studies that include subjects to examine food, drugs, supplements, etc.

**Examples of Studies that Generally Do Not Require IRB Review**

- Data collected for internal departmental or administrative purposes, such as teaching evaluations, student performance data, etc.
- Internal presentation of the data at meetings, conferences, seminars, poster presentations, etc. (e.g., SHSU capstone, internal conferences, class presentations, etc.)
- Activities designed solely for quality improvement or evaluation of a program, course, process, method, software, etc.
- Oral histories or biographies (unless data will also be used to contribute to generalizable knowledge)
- Training activities unless the training activity is conducted for research purposes
- Single case studies
- Research studies that include subjects to examine devices or products
- Instrument validation

Still have questions?

Complete and submit the [IRB Determination Request Form](#) to the IRB Office for a formal determination.