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## Guidelines for Research Activities Protecting Human Subjects in Research

Southeast New Mexico College (SEPMC) is committed to protecting individuals who participate in research activities. This responsibility applies to a wide range of research endeavors. The following guidelines provide clarity on when Institutional Review Board (IRB) review and approval are required.

### A. How Does the IRB Determine Whether Federal Definitions of “Human Research” Are Met?

1. The IRB begins by evaluating whether the activity meets the U.S. Department of Health and Human Services (HHS) definition of “research”:
  - **Is the study a systematic investigation** that uses one or more predefined scientific methods to explore a specific topic, answer a question, test a hypothesis, or develop theory?  
—AND—
  - **Is the study designed to contribute to generalizable knowledge?**  
Generalizable knowledge refers to information or data collected from a population sample, with the results intended to describe, explain, interpret, or predict outcomes applicable to that and potentially other populations. This may apply to many people or only a few. However, if the data are gathered for purposes *other than* generalization—such as diagnosing illness or tracking the source of a disease outbreak—the activity is **not** considered research, even if a systematic approach is used.
  - If **both** of these questions are answered “yes,” the IRB then evaluates whether the activity qualifies as human subjects research under HHS guidelines.

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### B. What Types of Activities Do Meet the Federal Definitions of Human Research and Require IRB Review?

Any directed or independent research projects conducted by SEPMC students, faculty, or staff—or by external researchers on the SEPMC campus—that involve systematic data collection with the intent of contributing to generalizable knowledge are subject to IRB review. If the activity also involves human participants as defined by HHS, **IRB review and approval must occur before any data collection begins.**

Only the IRB has the authority to determine whether a project qualifies as human subjects research.

**Exception:** Course assignments that involve interaction, intervention, or observation of living individuals—intended solely to teach research methods—may be excluded (see Section C3 below).

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### **C. What Types of Activities May Not Meet Federal Definitions of Human Research and May Not Require IRB Review?**

Some activities may resemble research but do not meet the federal definitions and therefore may be exempt from IRB review. Examples include:

#### **1. Internal Data Collection for Institutional Use**

Activities such as course evaluations or employee satisfaction surveys, when conducted by SENMC personnel **solely** to improve institutional services or develop new programs, do not qualify as human research.

However, care must still be taken to ensure:

- The privacy of individuals is protected
- Individual responses remain confidential
- Participation is voluntary

**Note:** If such data is later intended for use outside SENMC (e.g., presentations, publications) or applied to a new study to generate generalizable knowledge, **IRB consultation is required before reuse.**

#### **2. Fact-Finding Interviews Not Focused on Individuals**

Examples include:

- Asking librarians about inter-library loan procedures
- Surveying employees on organizational policies or costs  
These do not involve collecting personal information about individuals and are not considered human research.

3. **Educational Activities Conducted Solely for Teaching Purposes**

When information is collected from human participants as part of a class exercise and is **not intended for use outside the classroom**, IRB review is not required.

**However**, if students intend to present or publish their findings publicly, **IRB consultation is necessary**. Instructors and students in research methods courses are encouraged to contact the IRB Chair before disseminating any results.

4. **Research About a Single Individual (e.g., a Biography)**

If findings are not generalizable beyond that individual, IRB review is typically not required.

5. **Independent Evaluations for External Organizations**

Activities such as quality assurance evaluations, program assessments, and ergonomics studies conducted under contract, where the results are not intended to be generalized beyond the specific organization, may be exempt.

6. **Research Involving Deceased Individuals**

Projects that focus solely on deceased persons do not require IRB review.


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**Need Assistance?**

For help determining whether your project requires IRB review, contact:

**Dr. Narmin Ghalichi**

Institutional Research (IRB committee member)

 505-566-3373