

Introduction

Human subjects research must meet the definition of both Human Subject and Research.

Human subject

A human individual about whom an investigator/researcher applying research obtains data through intervention or interaction, or the investigator will have access to identifiable private information.

Research

A systematic investigation, which may include research development, testing and evaluation, and designed to develop or contribute to generalizable knowledge.

Some activities may involve human subjects but are not research, such as projects for quality improvement or quality assurance only. Most classroom assignments are not considered research. Some activities may be research but do not involve human subjects, such as research on budget forecasts or systematic literature reviews. If in doubt, ask the IRB at IRB@Westcliff.edu

Part 1: Human Subjects Research

Research involves human subjects if any of the following criteria are met:

Direct Interaction with Participants

- Collecting data through interviews, surveys, questionnaires, focus groups, or experiments involving people (even if it is anonymous).
- Testing interventions or treatments directly on individuals (e.g., clinical trials, behavioral studies).

Human Subject Observation

- Observing or recording identifiable behavior in a non-public setting (e.g., classrooms, workplaces)
- Observing or recording identifiable behavior in a public setting (e.g., parks, concerts, stores, workplaces).

Use of Identifiable Private Information

- Accessing private, identifiable information about individuals (e.g., medical records, educational data, employment history).
- Using online or archived data that contains identifiable personal information (e.g., email addresses, IP addresses, social security numbers).

Informed Consent

Participants are required to provide a signed informed consent before participating in the research (or the IRB grants a signed informed consent waiver).

- Data collection involves vulnerable populations (e.g., minors, prisoners, patients, employees under a researcher's authority).

Examples of Human Subjects Research

- Psychological or sociological studies involving surveys or interviews.
 - Behavioral observation studies in private settings.
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Part 2: Non-Human Subjects Research

Research qualifies as non-human subjects research if all of the following criteria in bold font are met:

No Direct Interaction with Humans (one must be checked)

- Data is obtained from publicly accessible sources (and no special permissions are needed to obtain the data).
- Data is secondary, meaning it was originally collected by another party and the principal investigator and study team has no direct interaction with those participants or access to identifiable data.

De-Identified Data (both must be checked)

- Existing data is anonymized or de-identified, with no way to trace back to individuals. The PI and the study team do not have any access to the identifiers and are not the ones de-identifying the data.
- Data use complies with terms and conditions of the dataset's source or permissions.



No Private or Confidential Information (both must be checked)

- Data does not include any sensitive or identifying personal information (e.g., financial records, health information, academic performance).
- Data involves aggregated or statistical summaries not tied to individual identities.

Examples of Non-Human Subjects Research

- Analyzing publicly available financial reports or stock market data.
 - Using de-identified data from research repositories or archival sources.
 - Studies using computer simulations, models, or datasets unrelated to humans.
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Part 3: Additional Considerations

Special Cases

- Are you using datasets that include sensitive information (e.g., HIPAA-protected health data, educational records under FERPA)?

If yes, you must verify that the data is de-identified or exempt from human subjects criteria.

- Are you conducting research involving environmental data or machine learning models?

If yes, human subjects criteria likely do not apply.

Institutional Requirements

- Have you checked with your Institutional Review Board (IRB) or equivalent body to confirm your research status? Email IRB@westcliff.edu to confirm.
 - Have you reviewed the permissions or licenses required for using datasets?
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Results

- If any criterion in Part 1 is checked, the research likely involves human subjects and will require IRB approval with appropriate informed consent protocols.
- If all criteria in bold font in Part 2 are checked, your research may qualify as non-human subjects but still requires an IRB determination for compliance.