Human Subjects Research & IRB

Office of Research Protections and Integrity
Division of Research

UNIVERSITY OF NORTH CAROLINA CHARLOTTE

Topics

Refresher: Core Ethical Principles

What is Human Subjects Research?
Defining research with human subjects.

The IRB Process
From submission to approval.

Tips for a Successful Submission
Practical advice for a smooth review.

Q&A and Resources
Your questions and where to find help.

Refresher: Core Ethical Principles (The Belmont Report)

Respect for Persons

Treating individuals as autonomous agents and protecting those with diminished autonomy. This is the basis for informed consent.

Beneficence

"Do no harm." We must maximize possible benefits while minimizing possible harms. This is the basis for the risk/benefit analysis.

Justice

Ensuring a fair and equitable distribution of the burdens and benefits of research. This guides the selection of subjects.

Is it “Research”?

Definition of Research

A **systematic investigation**, including research development, testing, and evaluation, designed to develop or contribute to **generalizable knowledge**. (45 CFR 46.102(l))

- Involves a plan, system, method. Searching for facts, detailed or careful examination. Test a hypothesis and draw conclusions.
- Add to scientific literature, expand knowledge in the field.
- Contribute to a theoretical framework or established body of knowledge.
- Information expressed in theories, principles, relationships.
- Benefit other researchers, scholars, and practitioners in the field of study. Results used to inform their daily practices, policies, their research design and methods, instruments, devices, and/or drugs.
- Inform a larger study or to aid in future planning of research activities (e.g., preliminary investigations, pilot studies).

Activities NOT Considered Research

Scholarly/Journalistic Activities: E.g., oral histories or biographies about a specific individual, not designed to draw general conclusions.

Public Health Surveillance Activities

Collection of Information for Criminal Justice or Criminal Investigative Policy

Operational Activities for National Security Purposes

Program Evaluation / QI: Internal activities to improve a program, not to create generalizable knowledge. (Unless dual purpose project.)

Class Projects: Research methods/experiential learning. Cannot be used outside of the class context. I.e., cannot be used for thesis, dissertation, research symposium, etc.

Will the research involve “Human Subjects”?

Definition of Human Subject

A living individual about whom an investigator conducting research:

Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or

Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.
(45 CFR 46.102(e))

Interaction or Intervention

Obtaining data through communication, interpersonal contact, or performing procedures. This includes surveys, interviews, focus groups, and experiments.

Private Information

Information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public.

Identifiable Private Information

Private information for which the identity of the individual is or may readily be ascertained or associated with the information.

Research with Interactions and Interventions

Common Examples:

Surveys and questionnaires

Interviews

Focus groups

Educational interventions

Behavioral experiments or interventions

Collection of biospecimens

Physical activity, collection of physiological and biometric data

Key Ethical Concerns:

Informed Consent: Is it clear, voluntary, and non-coercive?

Risk: Are questions sensitive? Is there a risk of distress?

Privacy & Confidentiality: How will you protect their identity and their responses?

Secondary Data Research

When is IRB Review Needed?

Review is required when the data is **Identifiable Private Information**.

Identifiable:

- Data includes direct identifiers
- Data is coded and there exists a code key that links data back to identifiers
- Data is indirectly identifiable through analysis, access, expertise, triangulation of data points or with other sources of data.

Private: The subject has a reasonable expectation of privacy (e.g., medical records, student transcripts, non-public social media posts).

When is it NOT HSR?

If the data is truly anonymous (no identifiers or codes).

If the data is publicly available (e.g., public census data, most public tweets).

Examples: Research using Secondary Data

- Using identifiable data/information from a previous study
- Using identifiable data/information from classroom activities or academic records from registration (data subject to FERPA)
- Using identifiable data/information that is now public but was once private or perceived as private
- Using identifiable assessment/evaluation information from a program or activity
- Using identifiable data/information from private or perceived as private social media sites
- Using identifiable blood samples from a biobank
- Using biospecimens collected elsewhere where the analysis includes re-identifying an individual from the samples/data

IRB Review Process

1. PI Submits

Researcher submits the complete application via Niner Research.

2. ORPI Pre-Review

IRB staff conduct an administrative review for completeness & review category determination/confirmation.

3. Exemption or IRB Review

Application reviewed for Exemption or routed to an IRB member or the Full Board for review.

4. Decision

A decision is issued: (1) Approved, (2) Changes Required (revisions), or (3) Disapproved.

5. Start Research

Once you have the official approval letter, you may begin research activities.

Reminder: submit an amendment for any changes before you implement the changes

What Level of Review is My Study?

Exempt

Less than minimal risk. Fits specific categories (e.g., anonymous surveys, analysis of de-identified data, benign behavioral interventions).

Expedited

Not greater than minimal risk. Fits specific categories (e.g., focus groups, identifiable surveys on sensitive topics, collection of blood samples by finger stick).

Full Board

Greater than minimal risk. Involves vulnerable populations (e.g., prisoners, children) or significant physical or psychological risks, invasive procedures.

Tips for Successful Submission

- **Be Consistent:** Your Protocol, Consent Form, and all survey/interview instruments must match perfectly. Discrepancies are the #1 reason for delay.
- **Write Clearly:** Avoid technical jargon. The IRB is a multidisciplinary committee (scientists, non-scientists, community members).
- **Complete Training:** Ensure all members of your research team have valid and up-to-date CITI (or equivalent) training certificates.
- **Plan Ahead:** It will take longer than you think it will. Allow weeks for Exempt/Expedited and possibly months for Full Board review.

More Tips

Data Use Agreements (DUA): Obtaining or receiving data? Start the DUA and Data Security Plan *first* with your College Data Security Officer and the DUA team (invent@charlotte.edu).

External Collaborations: Approval from a collaborator's institution? You still need to submit to UNCC. IRB reliance agreements may be possible for non-exempt studies. If the study qualifies for exemption, submit your own application.

Student Researchers: Remember that you are the responsible faculty and must mentor your student through the IRB process and oversee the student and how they implement the study.

Ask Questions: IRB office staff are glad to meet with you to brainstorm and provide guidance before you submit your application.

Resources & Contacts

Resources

Niner Research: infoed.charlotte.edu

Niner Research IRB: User Guides

Exemption Categories: Guidance Documents

Informed Consent: Template & Examples

Third Party Data/Data Security Plans: Research Data Registration

OneIT Data Security : Guidelines for Data Handling (refer to Level 2)

Artificial Intelligence: OneIT AI Software Guidance

Key Contacts

IRB Office Staff:
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Questions?

Thank you for your time.