

**University of the Virgin Islands
Institutional Review Board (IRB)
IRB Basics for Social Science Senior Seminar
(STT/STX)**

**Ethics and Human
Subject Protections**

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IRB Function

The purpose of an IRB is to review research and to ensure that the rights and welfare of human subjects involved in research are adequately protected.

Why Do Human Research Subjects Need Protection?

Trigger Events

The Nazi Experiments

Tuskegee Syphilis Study

Ethical Milestones

Nuremberg Code 1947

National Commission for
the Protection of Human
Subjects of Biomedical &
Behavioral Research 1974

* Belmont Report 1978

* Common Rule 1991

The Belmont Report

The principles of the Belmont Report govern all research supported by the U.S. Government. The ethical principles outlined in the report are the basis for subsequent regulations designed to ensure protection of human subjects in research.

The Basic Principles of the Belmont Report

1. Respect for Persons
2. Beneficence
3. Justice

Respect for Persons

- o Treat individuals as **autonomous agents**
- o Do not use people as a **means to an end**
- o Allow people to **choose for themselves**
- o Provide extra protections to those with diminished autonomy (i.e., Prisoners, Children, Cognitively Impaired, etc.)

Beneficence

The two general rules formulated from the principle of beneficence are:

- **First, do no harm**
- **Second, maximize possible benefits and minimize risks**

Justice

- o Treat people **fairly**
- o **Fair sharing of burdens and benefits** of the research

An injustice occurs when:

1. benefits to which a person is entitled are denied without good reason, or
2. when burdens are imposed unduly.

The Common Rule

The “Common Rule” is the set of regulations which were developed to ensure compliance with the principles of the Belmont Report. The regulations fall under the Department of Health and Human Services. These regulations have been adopted by many other federal departments which regulate human research.

Protective mechanisms established by The Common Rule

- Institutional assurances of compliance
- Review of research by an IRB
- Informed consent of subjects

IRB Review of Research

All research projects are categorized into one of three categories for the IRB review process. Each category is different in the level of scrutiny and submission procedures. The IRB is responsible for making the final decision of which category a research project falls under.

- **Full**
- **Expedited**
- **Exempt**
- **Research Not Involving Human Subjects**

Full Review

- ▣ One or more persons(s) are assigned to review the complete protocol or amendment, consent form and any other documents pertaining to the protocol. Depending upon the contents, a decision may be made to convene a full IRB committee meeting.
- ▣ The full IRB committee evaluates the protocol's degree of compliance with the Belmont Principles and the Common Rule.

Expedited Review

- ▣ Protocols, amendments, or continuing reviews that meet specific federal criteria qualify for an expedited review.
- ▣ The complete protocol, consent form, and any other protocol materials receive review and approval by a Committee Chair.

Exempt from IRB Review

- ▣ Committee review is not required for certain categories of research activities that involve little or no risk to human subjects.
- ▣ **Only the IRB can make the determination of “Exempt” from formal committee review. This cannot be determined by researchers!**

The IRB has the authority to:

- **Approve**
- **Require modifications** prior to approval
- **Table**
- **Disapprove** all research activities including proposed changes in previously approved human subject research.

Criteria for IRB Approval

- **Risks are Minimized** (Consistent with a sound research design and does not unnecessarily expose subjects to risk)
- **Risks are Reasonable in Relation to Benefits**
- **Selection of Subjects is Equitable**
- **Informed Consent will be Sought for Each Prospective Subject**
- **Informed Consent will Be Documented**
- **Research Plan Adequately Provides for Monitoring the Data Collected to Ensure Safety of the Subjects**
- **Research Plan Adequately Protects the Privacy of Subjects and Maintains Confidentiality**
- **When some or all of the subjects are likely to be vulnerable to coercion or undue influence, additional safeguards need to be included in the protocol to protect the rights and welfare of these subjects.**

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Questions?

