Social-Behavioral Research

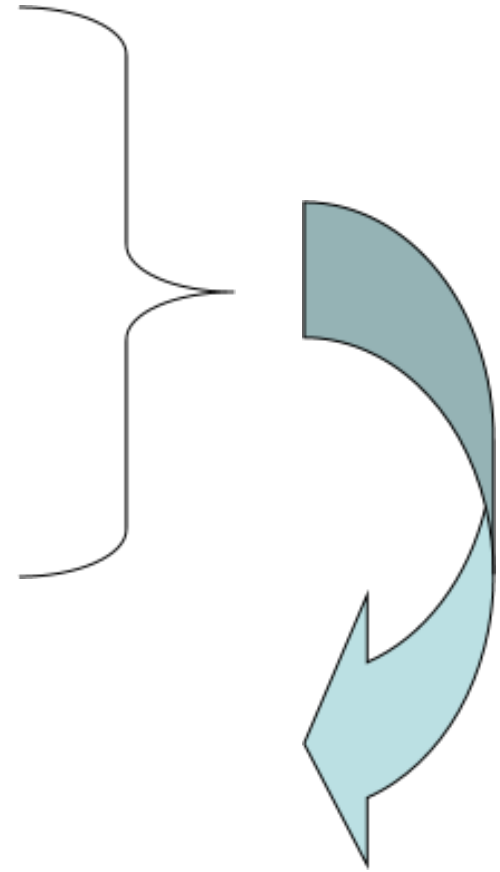
IRB Procedures and Operations

Kenyon College IRB

History of Research Transgressions

- Nazi medical war crimes

  Nuremberg Code 1947
- Tuskegee Syphilis Study
- Jewish Chronic Disease Hospital
- Willowbrook

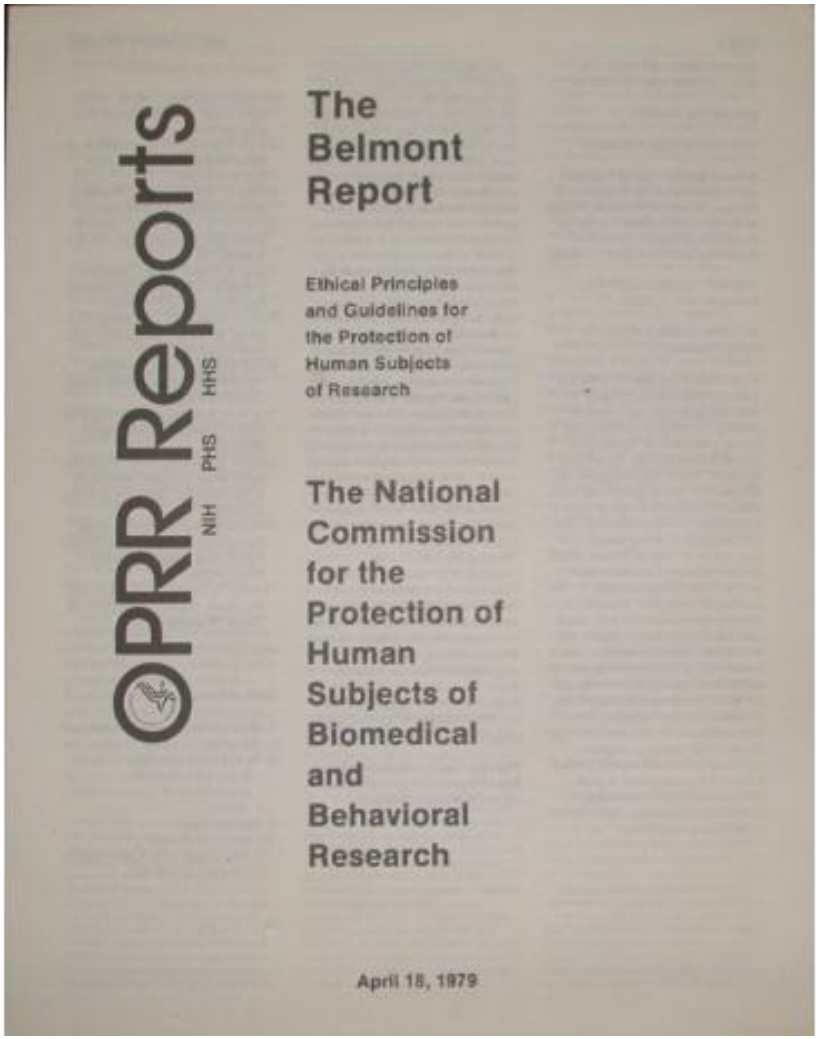


Leads to research oversight

by the federal government

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

. The Belmont Report 1978



Respect for Persons

Beneficence

Justice

Belmont Principles

are the ethical foundation of federal regulations for research

Respect for persons →	informed consent privacy & confidentiality
Beneficence →	benefit/risk or burden assessment
Justice →	distribution of risk and benefit inclusion/exclusion

Federal Regulations and Policy stemming from Belmont Principles

45 CFR 46 – DHHS Policy for Protection of Human Research Subjects- Subpart A

Originally adopted January 13, 1981; Revised June 18, 1991

"The Common Rule" – adopted by 17 federal agencies, including FDA-regulated research in 1991

Protective Mechanisms Established by the Common Rule

- Institutional Assurances of compliance
- Review of research by an Institutional Review Board (IRB) or Ethics Committee
- Informed consent of subjects

Federal-wide Assurance (FWA)

FWA – Kenyon's promise to the federal government that research will be compliant with regulations

From OHRP webpage http://www.hhs.gov/ohrp/assurances/assurances_index.html

If your institution is engaged in human subjects research (not otherwise exempt) that is conducted or supported by any agency of the U.S. Department of Health and Human Services (HHS), then your institution must have an OHRP-approved assurance of compliance with the HHS regulations (45 CFR 46.103) for the protection of human subjects.

Institutional Review Board (IRB)

- Established to provide ethical review of research
- Assures that federal regulations are followed
- Members include researchers, non-researchers and a member of the local community

Activities needing IRB approval

- RESEARCH –

  A systematic investigation designed to develop or contribute to generalizable knowledge. 45 CFR 46.102(d)

- HUMAN SUBJECT -

  A living individual about whom an investigator…conducting research obtains

  1. data through intervention or interaction with the individual, or
  2. identifiable private information45 CFR 46.102(f)

Generally NOT ‘generalizable’, i.e.

Not HR research (but ask!)

- Quality improvement/ assessment/ assurance projects – *designed with goal of improving institutional/organizational practice*
- Case reports, case series, anecdotal narratives – *if no systematic investigation, i.e. no statistical or data analysis; no outcome measures; no predictive claims*
- Class projects involving research methods where the findings stay in the classroom.

Start with ‘research’

- ‘Systematic’: use of statistical analyses, scientific methods – can include ‘non-research’

AND

- What about ‘generalizable’?

  Is the intent of this project to contribute to knowledge in the field or discipline?

  Are there hypotheses or research questions?

  Will analysis of data lead to generalizable claims?

  Is there an intent to publish or present the project as research? If ‘yes’ >>> the project is research

What about ‘human subjects’?

- More straightforward
  - Interventions or interactions with persons
  - Access to **identifiable** personal data
- Secondary data sets without ANY identifiers or **codes** generally do not involve human subjects
- Human subjects comprise living individuals and/or their private information – what about companies?
- *Suggestion*: Refrain from the word ‘research’ if project not to be considered human subjects research under IRB purview

Is an Activity "Research Involving Human Subjects" Covered by 45CFR part 46?

Go to Kenyon IRB page of FAQs

Is it Human Subjects Research?

http://documents.kenyon.edu/provost/irb_is_it_research.doc

OHRP Decision Charts

http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html

Examples of social science projects that will likely require IRB submission

- Interviews – quantitative or qualitative approaches
- Focus groups
- Pretest – intervention – posttest (eg., analysis of writing samples)
- Surveys, including Internet-based surveys
- Randomized intervention and control group
- Data analysis of primary or secondary data that contain identifiers or codes
- School-based research

The IRB determines if a project is research and if it is “exempt”

Call the Administrator and

ASK!!!

pbx 5748

IRB Review Continuum

Level of potential risk determines
route of review for biomedical and social-behavioral research

Exempt Expedited Full

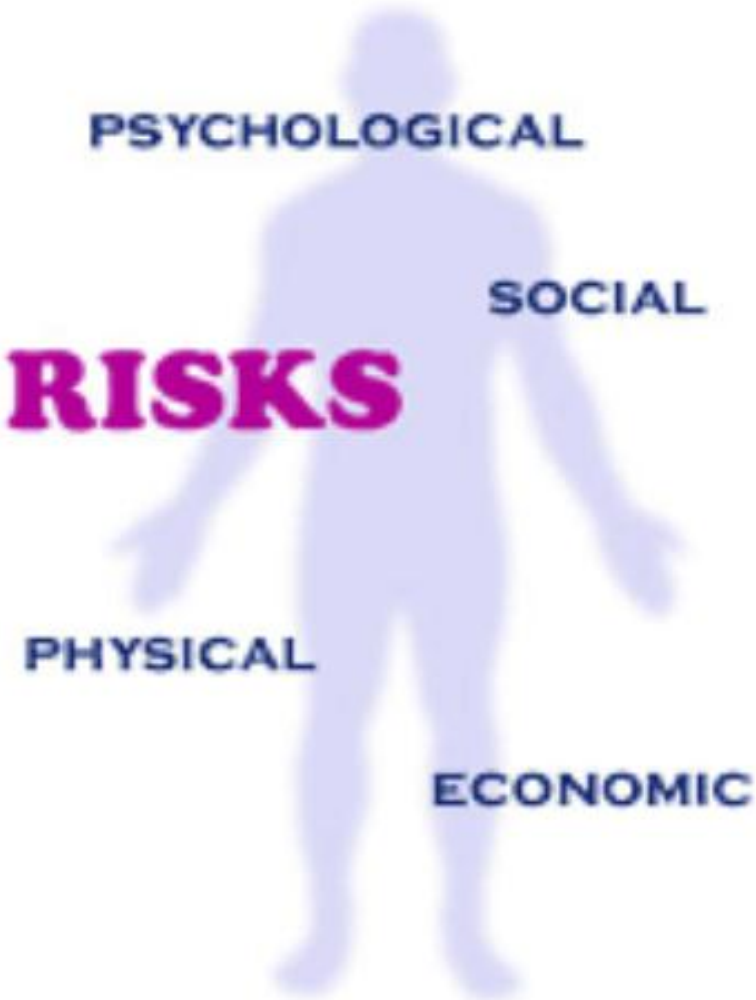
Low ← *Risk* → High

Definition of Minimal Risk 45 CFR 46.102(i)

"Minimal Risk" means that the **probability and magnitude** of harm or discomfort anticipated in the research **are not greater** in and of themselves than those ordinarily encountered in **daily life** or during the performance of routine physical or psychological examination or tests.

“Risk/Benefit Assessment”

IRB considers the risk of criminal/civil liability, financial risk, employment risk, stigmatization, insurability, and embarrassment in deciding if risk is truly minimal.



Privacy and Confidentiality

- *"When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data"* 45CFR46111(a)
- Breaches of privacy and/or confidentiality are the main risk in social-behavioral research or research that is no greater than minimal risk

Populations specifically protected in federal regulations 45CFR46

- **Pregnant women - Subpart B**

- **Prisoners – Subpart C**

- **Children – Subpart D**

Other considerations may also count as “Vulnerable”:

- Language
- Culture
- Current Events or Incidents
- Age (elderly)
- Age (adolescents)
- Educationally, economically disadvantaged
- Transient Cognitive Impairment
- Substance Use
- Health Status
- Students
- Employees

Exempt <<< Review >>> Expedited

- Minimal risk
- Does not include identifiers
- Topic generally not sensitive
- Non-vulnerable populations

May be Reviewed by one IRB Admin, Chair, or Board member.

- Minimal risk research
- May include identifiers (direct or indirect)
- Topics not sensitive OR may include some sensitive topics, but confidentiality securely protected
- Populations may include regulated vulnerable & others with adequate protections

May be reviewed by IRB Admin and one Chair or Board member outside of convened meeting.

Exempt <<< Review >>> Expedited

- Exempt from formal informed consent requirement, but subjects deserve to know about the research and the IRB may require information sheet for subjects.
- Exempt from continuing IRB review
- Fits one of 6 categories of research

- Requires a formal informed consent process OR justification for a waiver of consent
- Requires IRB continuing review at least annually
- Fits one of 9 expedited categories

Exempt Categories: 45 CFR 46 101 (b)

1. Typical educational practices
2. *Educational tests, surveys, interviews, or observation of public behavior (non-sensitive, no identifiers)
3. Research with elected public officials, appointed public officials, candidate for public office)
4. *Existing data, documents, pathological specimens, if publicly available or unidentifiable
5. Evaluation of public benefit service programs
6. Taste and food quality evaluation and consumer acceptance studies

Categories for Expedited Review

- Materials (data, documents, specimens etc.) have been collected or will be collected for non-research purposes
- Collection of voice, video or digital data for research purposes
- Individual or group behavior, surveys, interviews, oral histories

Full Board Review

- If the research does not meet criteria for exempt or expedited it is classified as a Full Board study (it is likely greater than minimal risk or includes protected subject groups)
- Discussed at convened meeting of the IRB and motions for changes or approval are by majority vote. Application must be received at least one week before the next scheduled IRB meeting
- Requires ‘continuing review’ at least annually

Required elements of informed consent –

BASIC ELEMENTS 45 CFR 46.116(a)

- *Statement that the study involves research*
- *Reasonably foreseeable risks/discomforts*
- *Reasonably expected benefits*
- *Disclosure of appropriate alternative procedures*
- *Confidentiality of identifiable records*
- *For high risk, what happens if injured in research*
- *Whom to contact about research, problems, or concerns (PI, FA, & IRB admin)*
- *Participation is voluntary*, refuse to *participate without penalty,* and *discontinue participation at any time*

Waiver of some or all elements of informed consent 45CFR46.116(d)

IRB may approve a waiver if:

(1) The research involves no more than minimal risk to the subjects;

(2) The waiver or alteration will not adversely affect the rights and welfare of the subjects;

(3) The research could not practicably be carried out without the waiver or alteration; and

(4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

Waiver of documentation:45CFR46.117(c)

An IRB may waive or alter documentation if it finds either:

(1) That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or

(2) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

Kenyon IRB process

- PI completes application (from website) and submits to IRB administrator as email and the PI gets appropriate signatures on the assurance page and delivers hard copy of assurance page to the IRB administrator, Bailey House. PI must have Training Certificate.
- Protocol is reviewed by the administrator to assign level of review, work with PI on revisions, and complete initial review.
- Initial review goes to a secondary reviewer and in the case of a Full review is presented during a convened board meeting.
- IRB approval to begin research = formal written approval letter via email (pdf). The original is sent in campus or U.S. mail.
- Implementation of research must reflect the protocol approved by the IRB. Any changes to the protocol must be reviewed and approved by the IRB. (use “Protocol Amendment” form.)

Criteria For IRB Approval

45 CFR 46.111

- Minimized risks
- Reasonable risk/benefit relationship
- Equitable subject selection
- Informed consent process
- Informed consent documentation
- Data monitored for safety, if appropriate
- Confidentiality/privacy maintained
- Vulnerable populations protected

Questions?

Contact

Jami Peelle peelle@kenyon.edu

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Bailey House

You may contact the IRB Administrator any time that you have questions about completing an application.