



Lincoln College

Ethical Treatment of Human Subjects Research Training

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*Special thank you to Eureka College for
adoption of their training materials.*

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Part I. The Belmont Principles

- Objective: To be able to apply the Belmont Report principles to specific research studies.

Brief History of The Belmont Report

- A number of unfortunate research efforts (Nazi physician research, The Thalidomide Tragedy, Milgram Study) resulted in:
 - Nuremberg Code 1947
 - Amendments to the Food, Drug, and Cosmetics Act 1962
 - Declaration of Helsinki, 1964
- The Belmont Report was created as a result of the Tuskegee Syphilis study

THE TUSKEGEE STUDY

- Began in Macon County, Alabama in 1932 to examine effects of untreated syphilis in African-American males.
- Subjects believed they were being treated.
- In 1943, penicillin was accepted as the standard of care treatment for syphilis. It was widely available for treatment by 1952, but was withheld from study subjects.
- The study was exposed in 1972, subjects were given treatment in 1973 and families of participants were offered treatment in 1974.

THE TUSKEGEE STUDY

- Led to the National Research Act of 1974, requiring regulatory protection for human subjects.
- This act also created the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.
- This Commission wrote the **Belmont Report** in 1979, which is the cornerstone statement of ethical principles for treatment of research subjects.

The Belmont Report

- The Belmont Report contains the ethical principles upon which the federal regulations for protection of human subjects (Common Rule) are based.
- Basic Principles of the Belmont Report:
 - Respect for Persons
 - Beneficence
 - Justice

The Belmont Principles

- Respect for Persons

- Respect for persons incorporates at least two ethical convictions: first, that individuals should be treated as autonomous agents, and second, that persons with diminished autonomy are entitled to protection.
- In most cases of research involving human subjects, respect for persons demands that subjects enter into the research voluntarily and with adequate information.

- Beneficence

- Two general rules have been formulated as complementary expressions of beneficent actions: **(1) do not harm and (2) maximize possible benefits and minimize possible harms.**

- Justice

- Who ought to receive the benefits of research and bear its burdens? This is a question of justice, in the sense of "fairness in distribution" or "what is deserved."
- An injustice occurs when some benefit to which a person is entitled is denied without good reason or when some burden is imposed unduly.
- Link to the Belmont report principles
<http://ohsr.od.nih.gov/guidelines/belmont.html#gob>

The Belmont Report

- In 1981, the Department of Health and Human Services (DHHS) and the Food and Drug Administration (FDA) published convergent regulations that were based on the Belmont Principles.
- In 1991, after 10 years of negotiation, 17 federal department and agencies agreed to adopt the basic human subjects protections –the Common Rule.

Common Rule

- Common Rule is Federal Policy for the Protection of Human Subjects 45 CFR46
- The Federal policy outlines acceptable practices for adherence to the following 2 regulations of the Common Rule.
 - 1. Research participants are selected equitably and give full informed, voluntary written consent.
 - 2. Research is reviewed by an independent oversight group referred to as an Institutional Review Board (IRB)

Principle: Respect for Persons

Informed Consent

- The principle of respect for persons is demonstrated in the consent process.
- Full informed, voluntary written consent is required
 - Informed consent contains 3 elements; information, comprehension and voluntariness
- Informed consent remains in place throughout the life of the research project.
 - Informed consent is in place in recruitment materials
 - At the beginning of study with signing of informed consent document
 - During study, participants have the right to stop participating at any time without penalty to them
 - During debrief of the participant after the study

Informed Consent Components

- Participants should be informed of the following in the Lincoln College Informed Consent document:
 - Statement that this is a research project and the anticipated number of subjects participating
 - Purpose of the research. If the purpose can not be fully disclosed, then the statement “We cannot explain all of the details of the experiment to you at this time, but they will be explained fully at the conclusion of the experiment” should be included
 - Expected duration of the subject’s participation
 - A description of the research procedures that allows subjects to understand what they are volunteering to perform
 - A description of the risks or discomforts to the subject



Informed Consent Components

- The Lincoln College Informed Consent form also includes standard wording. This wording includes:
 - A statement of anonymity and confidentiality
 - Whom to contact for information
 - A statement that participation is voluntary
 - A statement guaranteeing the legal age of subjects
 - Signature lines

Informed Consent

- **Voluntariness:** Subjects must understand what they are volunteering to do and the risks they are undertaking.
 - Consent must be voluntary. Subjects should not feel pressure to participate with an inducement that is too difficult to turn down.
 - For example, Free health care for life, shortened parole would be inducements too difficult to turn down.
- **Comprehension:** Subjects must be told of all risks to participation in language they understand.
 - Their native language
 - Appropriate vocabulary, minimize scientific jargon

Informed Consent vs. Assent

- Individuals with diminished autonomy include:
 - fetuses, pregnant women, children, prisoners, seriously ill, mentally or cognitively compromised adults.
- Children must give assent in writing when possible. Legal guardian must provide written informed consent.

THE BELMONT REPORT

Principle: Beneficence

- The obligation to protect persons from harm by maximizing anticipated benefits and minimizing possible risks. Possible risks to human subjects should be weighed against possible benefits of the research, as well as against the possible improvement of knowledge.
- Benefits of the research must outweigh the risks to the participants.
- Deception is sometimes necessary in research. Is the risk of deception worth the benefit of the research?

Deception

- The deception must be necessary for the manipulation of the construct being studied.
- Deception
 - Failure to provide complete information (the whole story)
 - Lie for the purpose of the study
 - Hoax to create a test situation for the study
- Subjects **MUST** be told of the deception during the debrief after participation in the study.

Debrief

- Debrief should take place as early as possible after the subject has participated in the study.
- Debrief should reveal any deception.
- Debrief should reduce any stress or anxiety the study may have induced.

Risks to Subjects

- Mitigate the following risks to subjects
 - Subject's reputation by asking about sensitive behaviors (drug use, illegal conduct, sexual behavior)
 - Subject's financial support by asking information or failing to keep information confidential
 - Subject's physical well-being
 - Subject's mental health

THE BELMONT REPORT

Principle: Justice

- Fairness in the distribution of research benefits and burdens. In selecting human subjects for research, investigators should ensure that no group of subjects is either consistently selected to participate or, consistently deprived of the opportunity to do so.
- Examples:
 - General Psychology students should not be the only participants in every study.
 - Females should not be the only gender studied



Part 2. Lincoln College Institutional Review Board Process

- Objective: To be able to follow Lincoln College's IRB process.

According to Common Rule Research Is...

- "Research" means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Or any experiment that involves a test article and one or more human participants, and that either involves the use of drugs or medical devices, or the results of the research are intended to be later submitted to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit. [45 CFR §46.102(d); 21 CFR §50.3(k); 21 CFR §50.3(c); 21 CFR §56.102(c)]

What is not Research?

- Classroom laboratory exercises meant for instruction
- Course or program assessments done to improve the course. If done to provide general information to other educators, then it may be research.

Who is a human subject or participant?

- “A Participant” is a living individual about whom a research investigator (whether a professional or a student) obtains data through intervention or interaction with the individual or from individually identifiable information or an individual who is or becomes a participant in research, either as a recipient of a test article or as a control who may be either a healthy human or a patient. [45 CFR §46.102(f)] [21 CFR §50.3(g) 21 CFR 56.102(e)]

Who is a human subject? Know the culture

- Some cultures do not speak of the dead or allow bones to be touched. In these cultures, the nonliving are considered human subjects. Be respectful.
- Otherwise, research Albert Einstein, Abraham Lincoln, Ted Kennedy. They would not be considered human subjects or participants.

Who is an investigator?

- Anyone can be an investigator
 - Students
 - Faculty
 - Staff and Administration
 - Non-Lincoln College investigator interested in conducting research on campus

There are two types of Investigators:
Principal Investigators and Co-Principle Investigators

Who is an investigator?

- Principal Investigator and Co-Principal Investigator
 - **Principal Investigators** may be: Faculty members, Staff members, Administrators, and Non-Lincoln College investigators interested in conducting research on campus.
 - Principal Investigators are required to sign a Principal Investigator Assurance statement indicating they take responsibility for the conduct of the study and ensuring that IRB policies and requirements are met.
 - **Co-Principal Investigators** are secondary investigators who work with the Principal Investigator to conduct the research. Co-PIs also have a responsibility to ensure compliance with IRB policies and requirement.
 - NOTE: Students may not serve as a Principal Investigator. All students must have a supervising faculty member who acts as the Principal Investigator. The IRB will not approve research protocols in which a student is listed as the Principal Investigator.

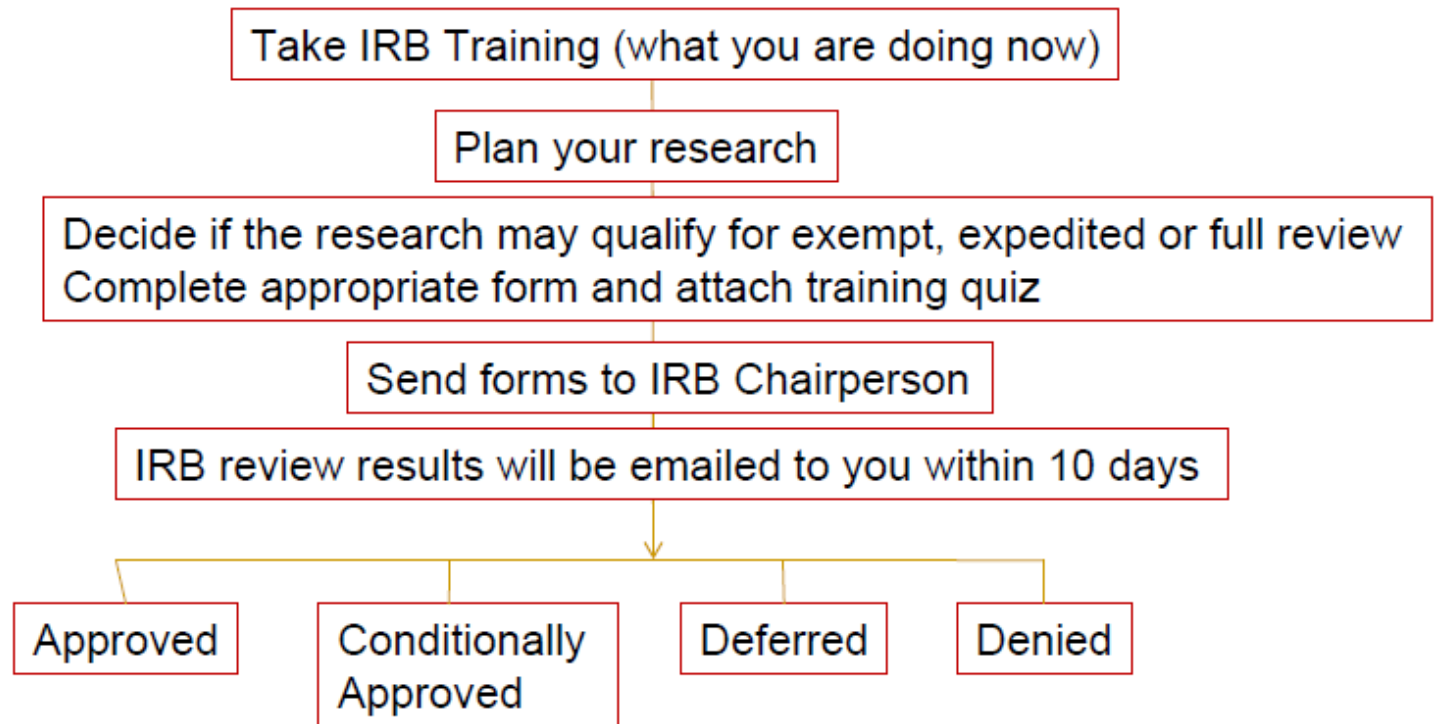
Investigator Responsibilities

- The study must be designed to ensure minimal risk to participants
- Investigators must identify potential risks that may result from participation in the experiment and must work to minimize these risks
- Investigators evaluate alternatives to the experimental design that could minimize risk
- Investigators keep their data secure and private, when necessary, to monitor participant safety
- Investigators contact the IRB with any questions or concerns about minimizing risk or when their research activities are subject to human protection standards

Investigator Responsibilities

- The researcher is responsible for ensuring that:
 - The study is properly designed and is scientifically sound (exception, student research may have flaws for learning purposes. Sometimes you learn more from a mistake.)
 - The investigator and research staff have necessary backgrounds to comply with human subjects and research regulations, such as those concerning IRB review, informed consent requirements, reporting requirements, maintenance of records, retention of records, and supervision of research conduct
 - The investigator has the resources (personnel, space, equipment and time) to conduct research that protects the rights and welfare of participants

The IRB Process



When do I need approval?

- Before the research begins, you will need IRB approval.
- For research spanning years, annual IRB review of the research is required.

Does research location matter?

- Does the location of data collection matter? YES!
- Any student, faculty or staff conducting research elsewhere will need Lincoln College IRB approval, as well as approval of the other organization.

How do I begin?

- Take the IRB training and turn in the quiz to indicate training is complete.
 - I. Requires about an hour
- Design your research study.
 - How will recruitment and the protocol adhere to informed consent.
 - Complete informed consent form
 - How will risks to participants be mitigated?
 - Is deception necessary?
 - What methods will be used to protect confidentiality of participants and the data?

Lincoln College IRB Review Process

- Determine if research may be eligible for Exempt, Expedited or Full IRB review.
 - Exempt – IRB chairperson reviews research
 - Expedited – IRB chairperson and one other IRB member reviews the research
 - Full – All members of the IRB review the research
- Forms (exempt, expedited) are available to help with the determination of the review required.

Submit materials for review

- Faculty and Staff submit materials to IRB chairperson
 - Students submit materials to faculty advisor or sponsor, who will then submit to the IRB chairperson
 - Non-Lincoln College investigator submits to the Vice President for Academic Affairs who will in turn submit it to the IRB chairperson

Include the following materials when submitting

- Date of completion of training certification (indicated in PART I. General Information of the IRB submission form)
- Complete exempt, expedited, or full review forms as applicable. (Research/grant proposals that include relevant information may be attached).
- Any recruitment materials, informed consent document, paper and pencil/online measurements (e.g. surveys), debriefing and protocol scripts.

Review

- Please allow 10 days for the IRB to review.
- Investigators will be notified of review outcome via email.
- Outcomes
 - Approved – go ahead recruit and collect data
 - Conditionally approved – Make suggested changes, notify IRB and go ahead recruit and collect data
 - Deferred – Revise the proposal and resubmit
 - Denied – You can not do the research. You may appeal.

Are we done yet?

- NO!
- If any problems occur during the study, notify the IRB within 5 days.
- Give informed consent forms (if the research is conducted in a research setting) to IRB chairperson for record keeping
- When study is complete, notify IRB via email so that file can be closed and records managed.
- When study is complete, dispose or store data properly

Summary

- Investigators bear the ultimate ethical responsibility for their work with human subjects.
- Society entrusts them with the privilege of using other humans to advance scientific knowledge.
- Society expects investigators to show respect for research subjects.

Part 3. Quiz

- Please contact the Chair of the IRB to request access to the online quiz:

Chair: Mr. Jeff Kratz at

jkratz@lincolncollege.edu (309) 268-4301