# Eureka College Ethical Treatment of Human Subjects Research Training

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# Part I. The Belmont Report Principles

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

# Brief History of The Belmont Report

Several unfortunate research efforts (Nazi physician research, the Thalidomide Tragedy, Milgram Obedience 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 Syphilis Study

- Began in Macon County, Alabama in 1932 to examine effects of untreated syphilis in African-American/Black men.
- 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 Syphilis 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 in the United States.

# The Belmont Report

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

# The Belmont Report

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

# The Belmont Report 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: https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html

# Common Rule

Common Rule is Federal Policy for the Protection of Human Subjects: 45 CFR Part 46

The Federal policy outlines acceptable practices for adherence to the following two (2) regulations of the Common Rule.

1. Research participants are selected equitably and give fully-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.
- Fully-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 or choosing radio button to participate for online studies
- 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 Eureka 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 Eureka 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 or a forced choice to consent (for online studies)

# 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.
  - Free health care for life or shortened parole would be inducements too difficult to turn down.

- Comprehension: Subjects must be told of all risks 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, or mentally or cognitively compromised adults.
  - Children must give assent in writing when possible.  Legal guardian must provide written informed consent.

# The Belmont Report Principle: Beneficience

- 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 includes:
  - 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.

# 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.
  - Women should not be the only gender studied

# Part 2. Eureka College Institutional Review Board (IRB)

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

# According to the 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 only. However, a course project or honors thesis may be considered research.
- Course or program assessments done to improve the course. However, if done to provide general information to other educators, then it may be considered 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, or 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-Eureka College investigator(s) interested in conducting research on campus

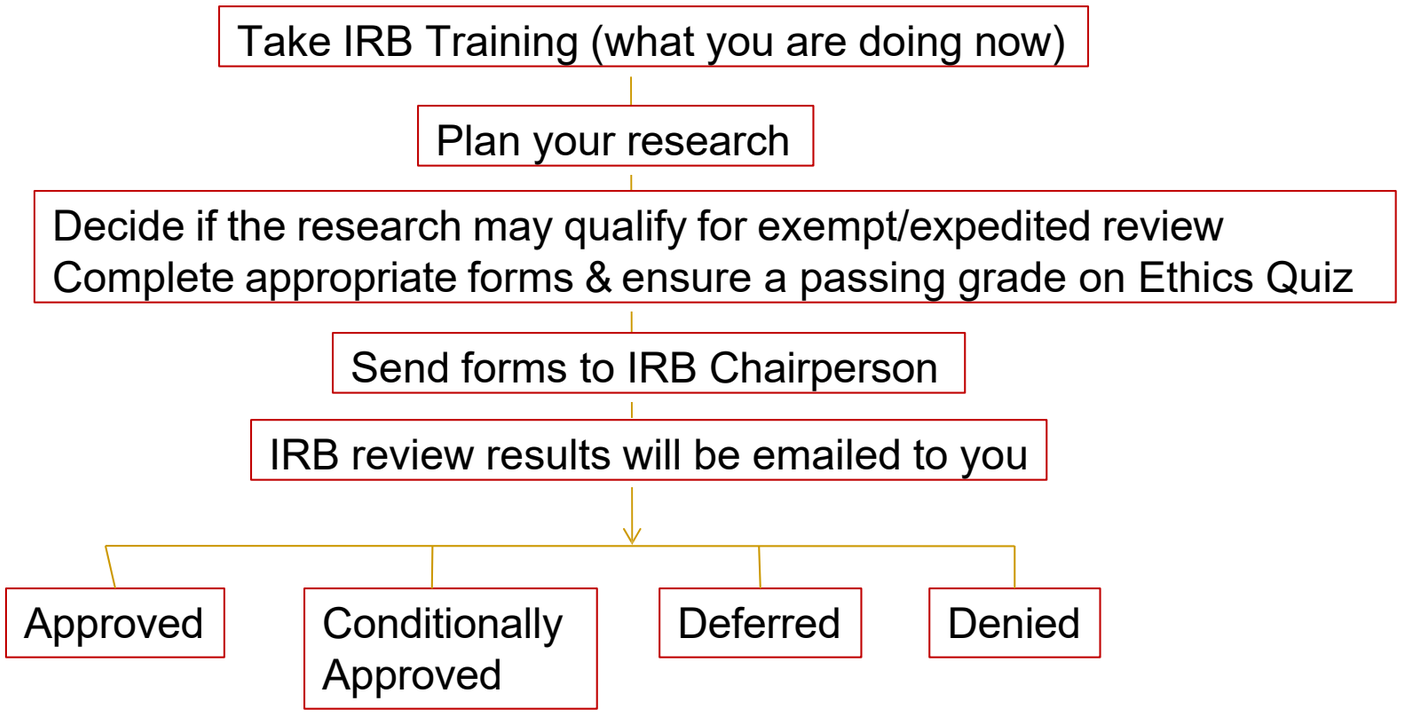
# Investigator Responsibilities

- 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 (e.g., 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 Eureka IRB approval as well as approval of any other organization involved in data collection from human subjects

# How do I begin?

- Take the IRB training and complete the Ethics Quiz on MS Forms (link on IRB webpage).
  - This should take about 30–45 min.
  - Must achieve 80% on Ethics Quiz to pass. May take as many times as needed.
- 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?

# Eureka College IRB Review process

1. Determine if research may be eligible for Exempt, Expedited, or Full IRB review.
    1. Exempt: IRB Chairperson reviews application only.
    2. Expedited: IRB Chairperson and one other IRB member reviews the research application.
    3. Full: All members of the IRB review the research application.
    4. Forms (Exempt, Expedited) are available to help with the determination of the review required. There is no form for Full Review, as failing to meet Expedited automatically invokes Full Review

# 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-Eureka College investigator(s) submits to the Provost, who will in turn submit it to the IRB Chairperson

# Include the following materials when submitting:

1. Complete Exempt or Expedited Application forms, and research/grant proposals that include relevant information may be attached.
2. Any recruitment materials, Informed Consent document, all materials (e.g., images or text) and measurements (e.g., scales or surveys), Debriefing, and protocol scripts.

# Review

- Please allow 10 business 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 cannot do the research. You may appeal.

# Are we done yet?

- NO!
- If any problems occur during subject recruitment or data collection, notify the IRB within five business (5) days.
- Give Informed Consent forms to IRB Chairperson for record keeping once data collection has ended.
- 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.
- Follow all policies and procedures when conducting research at Eureka College

# Part 3. Ethics Quiz

- Please click the following link: https://forms.office.com/r/kK4zixNu0Z

- You must sign in with your Eureka College email address/account.
  - Quiz is 10 MC questions
  - Must achieve 8/10 correct (80%)
  - If you receive 7 or fewer, you must take again until your name has an 8/10 in the responses. You can take as many times as needed!