Ethics

Ethics the Belmont Principles

You are conducting research and are responsible for the ethical treatment of any and all subjects. It is mandated by law that you adhere to strict rules.

THE REASON THESE RULES WERE DEVELOPED IS BECAUSE OF THE UNETHICAL TREATMENT OF RESEARCH SUBJECTS

These rules are known as **THE BELMONT PRINCIPLES.**

Respect

This principle focuses on respect for individuals. Part of respecting an individual has to do with respecting their autonomy or right to self-determination and to make their own decisions and choices. The rules for informed consent in medicine derive from the principle of autonomy. In medicine, there is also a special emphasis on respecting individuals from vulnerable populations.

Permission forms or consent forms explain to participants or guardians the information about the procedure or event, what to expect, and any and all possible consequences, good or bad, which may result. It allows the participant the ability to (self-determine) and make their own decisions as whether they participate or not.

Beneficence (Do Good/ Do no harm)

Do Good (beneficence) stresses directly helping others, acting in their best interest, and being a benefit to them. It requires positive action.

Do No Harm (no maleficence) relates to one of the most traditional medical guidelines, the Hippocratic Oath (first of all, do no harm). It requires individuals to not intentionally or directly inflict harm upon others.

Justice (Be fair)

This principle relates to “Giving to each that which is his due” (Aristotle.) It dictates that persons who are equals should qualify for equal treatment and that resources, risks and costs should be distributed equitably.

Some ethicists also add:

Care

Focus on the maintenance of healthy, caring relationships between individuals and with a community. The principle of care adds context to the traditional principles and can be used in a complementary way alongside them. (Northwest Association for Biomedical Research, 2009)

The Belmont Principles Diagram

Ethics – Procedures for recruiting subjects

Respect: When recruiting subjects to participate in a survey, you first explain to them what the survey is about, (subject), why you are conducting it, (for a research project for HSTA to learn about_____), how you are going to protect their autonomy, (they can chose to not participate or may cease to participate if they become uncomfortable), and how you will protect their anonymity, (no names or identifiers will be used). Then, depending upon the level of research you have a permission slip signed and returned or, if an IRB project, you obtain consent, (and assent if the subject is under 18), on the IRB permission forms.

Beneficence: Explain to the subjects how your research may benefit them or others by increasing or improving the knowledge about what you are testing. For instance, explain how 10 minutes of morning exercise might improve math scores.

Justice: Make sure that you treat everyone equally. This means being fair. You need to offer participants the same opportunity (to use equipment, earn a prize, learn material).

Care: Be sure that what you are doing does not pit one faction against another.

Ethics Checklist

Before you begin your research, make sure you have covered these points in your recruiting speech to participants.

Did you:

- Explain what the research or project is about (Your question)
- Explain why it is being conducted
- Explain why you want them to participate
- Explain what they will be asked to do
- Explain when and how they will be asked to do it
- Explain how you will measure it
- Explain how you will protect their privacy and information
- Explain how they don't have to participate or may opt out at any time
- **GET permission (Depends on Project)**
- Explain how what is learned may benefit them or others
- Explain how safeguards are in place to prevent harm
- Choose your participants fairly (not pick one group over another because you like them better)
- Provide all subjects the same opportunity

Ethics Research Terms

Assent: If participants are under the age of 18 they cannot grant consent. Their parent or guardian must do this. Assent is an explanation of the research written on the level of the participant and is signed by them in conjunction with the

Consent: Signed by the adult. It literally means to acknowledge or agree. Not all studies involving minors require signed assent in addition to consent.

Belmont Report: Report by the U.S. National Commission for the Protection of Human Subjects in Biomedical and Behavioral Research in 1979, which has had a significant influence over human subjects research ethics, regulation, and policy.

Beneficence: The ethical obligation to do good and avoid causing harm.

Care: Be sure that what you are doing does not pit one faction against another.

CITI training: Collaborative Institutional Training Initiative or CITI. It is a college level ethics training that all researchers affiliated with a University or Institution must complete before beginning any research.

Coercion: Using force, threats, or intimidation to make a person comply with a demand.

Compliance: In research, complying with laws, institutional policies and ethical guidelines related to research.

Conduct: Action or behavior. For example, conducting research involves performing actions related to research, such as designing experiments, collecting data, analyzing data, etc.

Confidentiality: The obligation to keep some types of information confidential or secret.

Consent: A process where the researcher gives the participant a written explanation of the procedures that covers any risks involved and probable consequences and the alternatives. It is important that the researcher explains these to the participant. The participant is allowed to ask and have answered any questions.

Discrimination: Treating people differently based on irrelevant characteristics, such as skin color, ethnicity, or gender.

Ethics (or morals): 1. Standards of conduct (or behavior) that distinguish between right/wrong, good/bad, etc. 2. The study of standards of conduct.

Exemption: A level of award given by the IRB which states that the proposed research is of minimal risk to subjects. An example of an Exempt project is:

Will students' reaction time differ when testing dominant and non-dominant hands? Often a letter of consent is required from participants that explains what is to occur and when it is going to happen. (A permission slip)

Expedited: An award given by the IRB states that the proposed research is of minimal or slight risk to subjects and will require: Consent if subject is 18 years of age or Parental consent (if subject is under 18, and in addition sometimes, student Assent) An example of an expedited proposal was *the My First Patient* project. Participants had a finger stick blood draw, their cholesterol checked, and height and weight measured.

Full Review: A project that requires a full review will be presented to the whole IRB panel and carefully examined for safeguards and protections for participants. Informed Consent and Assent, (if under 18) will be required. An example of a project that requires full review would be the testing of a new cancer drug on patients to measure its effectiveness

Honesty: The ethical obligation to tell the truth and avoid deceiving others. In science, some types of dishonesty include data fabrication or falsification, and plagiarism.

Human Subject: A living individual involved in research where data is collected from them.

Human Subjects Research: Research involving the collection, storage, or use of private data or biological samples from living individuals by means of interactions, interventions, surveys, or other research methods or procedures.

IRB Document: Document that is also the detailed research plan. It is submitted to the IRB Panel for approval. It includes any and all procedures, background research, timelines, questions, etc. that the researchers intend to use or perform. This is a legal and binding document and once approved by the IRB, becomes the legal research protocol. If a researcher deviates from the approved plan he/she is in violation of law and can be fined $250,000.00 and get up to 25 years in jail per count.

IRB- Internal Review Board: Every institution that conducts research has an IRB panel. These men and women must review all research submissions to make sure that all research is legal, ethical and moral. The panel is composed of members

who understand the law and guidelines as well as the subject matter of what is being researched.

IACUC- International Animal Care and Use Committee: To work with any vertebrate you must complete extensive CITI ethics training and develop and research plan that suits the IACUC laws and guidelines. This is a long and arduous process that is difficult for undergrads to obtain unless they are working in a certified research lab. It must have all details included such as feeding, cleaning, exercise schedules, just for example. Housing requirements, temperature control, contact time, and a care and living plan for the animal after the experiment are a few of the other plans that have to be considered.

Invertebrate: Organisms that neither possess nor develop a vertebral column.

Justice: Make sure that you treat everyone equally, be fair.

Minimal Risk: The level of harm or discomfort the research subject may face will not be greater than experiences in their normal daily life.

Plagiarism: Misrepresenting someone else's work (e.g. words, methods, pictures, ideas, or data) as one's own without giving them credit.

Protected Health Information (PHI): Any information in the medical record or designated record set that can be used to identify an individual.

Respect: The concept that all people deserve the right to fully exercise their autonomy. Showing **respect** for persons is a system for interaction in which one entity ensures that another has agency to be able to make a choice.

Sensitive Topics: Any interview, survey or questionnaire that proposes to investigate opinions and/or experiences regarding personal topics like sexual information, drug use, mental health, traumatic experiences, etc. (Speak with a CRA if you have questions.)

Vertebrate: Animal with a spinal cord surrounded by cartilage or bone.

Vulnerable Populations: Certain human subjects are grouped as vulnerable populations and require special treatment with respect to safeguards of their well-being. Examples: pregnant women, human fetuses and neonates, children,

cognitively impaired persons, prisoners, students and employees, and educationally disadvantaged individuals.

Ethics Contract

- I understand and will put into practice always the Belmont Principles.
- As a Researcher or Investigator, I will conduct my research with integrity and safeguard my research participants/subjects and any data I may gather.
- I will protect all participants/subjects and adhere to the research standards set forth in federal and state code.
- I will design my research to be fair and provide the same opportunity to all subjects. I will adhere to my approved research protocol.
- When recruiting subjects/participants I will explain:
    - what the research is about
    - why it is being conducted
    - why I want them to participate
    - what they will be asked to do
    - how and when they will be asked to do it

- I will explain how the research data will be measured and collected and the plan to protect their privacy and information.
- Furthermore, I will explain to the subject/participant how the knowledge learned from the research may be of benefit to them or others.
- I will explain any possible harm that may occur during the research, and the safeguards in place to prevent such harm.
- I will assure them that they may chose not to participate or may opt out of participation at any time with no repercussions.
- I understand the importance of research and will conduct my research with honor and integrity.