

Module II:

PAR in UCEDDs – We Help the Tree Grow

1. Ethical Principles and Vulnerable Participants

2. Institutional Review Board/Ethics Committee

1. Ethical Principles and Vulnerable Participants:

Objectives:

- To learn the 3 most important principles of research ethics
- To identify which participants are vulnerable or easily harmed
- To learn how to include vulnerable participants with safety and dignity

Question – What is ethical research? What principles apply?

Three Basic Principles that Guide Research

Ethics is the study of how to make moral decisions. This study helps guide doctors and scientists when they do research. The study of ethics creates principles or rules that are followed when choices seem unclear. They make sure that harm is prevented.

The National Research Act became a law on July 12, 1974. This law created a National Commission. The commission was formed to protect humans who are studied by health care providers and scientists. The job of the National Commission is to identify ethical principles to guide research. The term “human subjects” means the people who take part in experiments or who answer questions. In 1978, the Commission published the Belmont *Report*.

The Belmont Report sets out three basic principles. These rules must be followed when conducting research that involves people. The three rules are:

- **Respect people**
- **Benefit people**
- **Act with justice**¹

These principles are universal. They apply everywhere in the world, to all people. They do not have national boundaries. They apply to rich and poor people alike. Everyone involved in human research studies should understand and follow them.

¹ Human Subject Protection Power Pt.

These principles guide the thinking and behavior of everyone involved in planning, conducting, and sponsoring research that involves people. Sometimes there is little money to fund an ethics committee to review proposals. This cannot be used as an excuse to avoid following these rules.

1. Respect for Persons

Question – How do we define respect?

The word respect means to honor another person as sacred. We treat that person well even when we disagree with their choices or lifestyle. Every human being deserves our respect. This is a vital principle in research. Respect means that we view each person's perspective as unique and important. We want their cooperation in the research to be voluntary. This means that every person must be free to make up his or her own mind. If we respect each person, then we treat that person with dignity. We use a respectful way of doing research. We give each person enough information and opportunity to make informed decisions. We avoid techniques that may cause harm whenever possible.

We do not want to violate anyone's basic human rights. To avoid that we must make sure that people in our research make informed decisions. Community members can tell us how people make and express decisions. They can suggest the best ways to help participants to make decisions that are their own.

Vulnerable Persons

We need to get each person's informed consent before we begin. The word *informed consent* means that you agree to take part in the study after you fully understand what is going to happen. Some people who are asked to participate are vulnerable. The word vulnerable means that you have a reduced ability to make decisions. Someone who is vulnerable may need accommodations or special considerations to become informed or make choices. Good researchers are careful when they study vulnerable people.

Some groups of people have always been viewed as vulnerable. They include:

- Minors (children)
- Pregnant women (risk to unborn child & additional concerns women face when pregnant)
- Prisoners (in jail with limited freedom)
- Persons with mental health conditions (may lose ability to decide what is best for their health)
- People who have intellectual disabilities, brain injury or other cognitive limitations

In recent years, other types of participants have been considered vulnerable:

- Persons with limited education that may have trouble reading or understanding written information.

- Persons with little money who may not have good health care and who may think that taking part in research is the only opportunity to get the care they need.
- Women in some settings (some women must ask their husbands before consenting to participate in a study).
- Drug users or others who take part in illegal activities.

Vulnerable people can still be part of a research study. However, they may need special protections. Their perspectives are valuable. No one else has their unique viewpoint. Yet, it is still important not to exploit their willingness to take part.

We don't want to take advantage of a vulnerable person. Suppose we decide to pay participants for taking part in a study. We hope that they will still give us objective answers to our questions. We know that even small gifts or payments could shape someone's decisions. Yet advocates often argue that we should pay both professionals and participant. They believe this is the only way to be fair. Sometimes making the right decision is not easy.

Some people have guardians appointed by the courts. The guardians make legal decisions. They give consent for that person to be part of a research study. The guardian tries to act in the best interest of the vulnerable person. But the guardian and the person may not see the situation in the same way. It is also important to ask that person if he or she wants to participate. This is called "assent." It is also important to notice if people act like they are uncomfortable or don't really want to be part of the study, even though they may have agreed. Participants may need to be reassured and not just told that they can drop out whenever they want. Some vulnerable people may believe that you will get angry with them if they don't cooperate. Others may have been conditioned to go along with authority figures and may not really understand that they can refuse.

Some people believe that we must involve people with learning problems in every part of the decision making process to be fair. They believe that unless this is done we are imposing our will on these people.

Vulnerable people have been treated unfairly in the past. It may be hard to get approval for projects which involve people with cognitive disabilities. In PAR projects the participants help design the research. They decide what questions that will be asked. Many IRBs want to see all the questions *before* they will approve that project. It usually works best to explain the steps that you will take to treat participants with respect as you design the project together.

2. Beneficence

The word beneficence was first used by Immanuel Kant. It means to take responsibility for another person's well being. The Belmont Report also uses the word beneficence to speak of protecting people from harm. The Belmont Report gives two general rules for researchers: 1) do no harm and 2) get as much good as possible from the research.

All research studies have some degree of risk for anyone who participates. Some risks are very low. Other risks may be high. Often, risks may be hidden. What kinds of risks are acceptable or unacceptable in a study?

The principle of beneficence makes the researcher responsible for the physical, mental, and social well-being of people who take part. We must make sure that the benefits to the research participant are as great as possible while the risks are kept as small as possible.

It is important to be aware of emotional as well as physical risk to people with cognitive disabilities. A cognitive disability is a condition that makes it difficult for people to remember, use good judgment, organize their thoughts or control emotions.

Many people feel shame when stared at or treated unfairly because of a disability. Others feel shame when they are unable to do what others do easily. Some research questions or experiences can bring up strong, negative emotions or memories of painful experiences. It is important to monitor whether the research experience elicits possible negative emotions. If a person talks about difficult personal experiences, it is important that researchers take the time afterwards to talk with the person and let him or her fully express whatever feelings may have been called up by the research.

The risks to a person taking part in a research study must be balanced against potential benefits and knowledge to be gained.

3. Justice

The word justice means to treat people fairly. Research procedures should be carefully chosen. The costs and benefits should be shared fairly. Study teams cannot select participants based on what is convenient. People who bear the risks of research should benefit from it.² Recruiting and selecting participants must be done in a fair and equal manner. Justice forbids exposing one group of people to a risk only to benefit another group.

For example, in the Willowbrook Studies, 800 children were infected with hepatitis virus. This was done so that doctors could study how the disease progressed from the earliest stages. Parents were told that they had to agree to this, or their children wouldn't be admitted to the school. While the doctors could argue that the study gave them a way to help other patients with hepatitis, it was clearly at the expense of the health of the Willowbrook students.

IRBs must ensure that community participation in a research study is justified. This means the benefits to the people participating must outweigh the risks. It also means that one group cannot be exploited to benefit another group. Fair treatment means we use appropriate protections for vulnerable people. We must pay special attention to the benefits that participants will receive. We avoid using money or gifts in a negative way. We don't make one group take all the risks unless they also can benefit.

² Human Subject Protection Power Pt.

Summary: Principles of Research Ethics

Health research is conducted according to three universal principles:

- Respect for persons
- Beneficence
- Justice

Researchers must work for the well-being of people who participate in their studies. These principles were developed to make sure that the well-being of each participant is always considered. Community representatives should understand these research ethics principles and how to apply them in their communities.³

Comments & Questions

³ FHI, 40-41.

2. Institutional Review Board/Ethics Committee:

Objectives:

- To define the role(s) of the IRB
- To link the community and the IRB board for the well-being of the participant
- To explain difference between medical & behavioral research & IRB committees

Institutional Review Board (IRB)/Ethics Committee

Universities and state agencies review research proposals. They have committees to do this important work. These are called Institutional Review Boards (IRB) or Ethics committees. Each committee brings together people from different backgrounds. They conduct an independent review of any proposed study. The main purpose is to protect people from harm. This is more important than the interests of the researcher or the institution.

An IRB must have at least five members of different backgrounds. They must include a community representative. There are two main types of IRB Committees: biomedical and behavioral.

Biomedical This committee looks at the medical results of using different drugs. This kind of research also looks at treatments that may help diagnose or prevent disease. The idea is to measure how effective they are in improving health. An example of this is trying a special diet to help control seizures.

Behavioral This committee looks at studies of human behavior. The research looks at how people interact, behave or react. Researchers use open-ended questions, interviews, or surveys. They ask about individual or group knowledge, attitudes, or experiences. These studies test how effective different kinds of interventions may be.⁴ An example would be looking at wheelchair pushups will decrease pressure sores in children.

Membership

Both committees review studies to decide if they are ethical. They decide if studies follow the principles of respect, beneficence & justice. The members need to be diverse to do this fairly. The guidelines state:

- Some members should have a background in science or research. These members should be qualified to review specific research activities. They should review the acceptability of the proposed research, using rules of their institutions, laws that may apply, and standards of professional conduct.

⁴ Institutional Review Board Committees, (University of Arkansas Medical Sciences)
<http://www.uams.edu/irb?IRB_Comm.asp> (14 March 2006)

- Some members should have a non-scientific background. This will help the review be balanced. They may include religious or other community leaders. They may also include former study participants. These members help the ethics committee consider how the research might affect the community. These members must receive the same voice and power of the vote as the scientific members. These people represent the community perspective. Members should reflect:
- Different genders, ages, race and ethnic/cultural backgrounds.
- Outside consultants with knowledge of research & ethics if necessary.

Review of Research

IRB or ethics committee look at six basic issues to decide if proposed studies are ethical.

- ***Scientific design and conduct of the study.*** A study's design outlines what methods will be used. It shows how you think it will work. The committee should consider the impact of the design on the safety of the participants.
- ***Recruitment of research participants.*** This is the process of enrolling people in research projects. People may be different ages, cultures, or gender. The committee will look at how fairly participants are treated.
- ***Community considerations.*** The study should address a local need or problem. The committee will check to see if the community is treated respectfully. Community representatives can help the committee to do this.
- ***Care and protection of research participants.*** The study must protect people who are vulnerable. The committee will look at how the study helps or hurts participants. It will also look at their communities. PAR will ask participants about their concerns instead of having researchers decide ahead of time if the research is appropriate and safe.
- ***Informed consent.*** The committee must decide if the consent forms and process are adequate. It is important to translate the jargon of academic research into terms that can be understood by the potential participants. Community representatives can provide an important perspective on the informed consent process.
- ***Confidentiality issues.*** The ethics committee must review the steps taken by the study team to protect the confidentiality and privacy of participants. This may be the greatest risk for some kinds of research. **Special attention is necessary to secure computer or internet data files.**

When these concerns have been addressed the committee can grant approval for the study to begin. Some committees also make other decisions such as who owns the data or budgets.⁵ After the research is done, it is important to share the results with the participants.

⁵ FHI, 25-28

Policy on Misconduct

The Institutional Review Board (IRB) can withdraw approval of a project if it is not following all IRB or federal rules. It can also shut down a project if there has been unexpected harm to subjects. This is called ending the project for cause. Researchers are notified of any IRB action in writing.

The IRB and Investigator will work together to notify participants that a study cannot continue. They must keep their rights and welfare in mind. They will tell participants when follow-up is permitted. Researchers must report any adverse events or unanticipated problems involving risks to the IRB.

Summary:

The primary role of an IRB or Ethics committee is to protect participants. These committees meet at least once a year to approve or disapprove new research projects. They also review the progress of ongoing studies. They have a minimum of five members. Some members have a background in research or science, while others represent community interests.

IRBs or Ethics committees look at many parts of a study before giving approval. They consider the scientific design and methods. They look at participant recruitment and community considerations. They weigh the care and protection of participants. They evaluate the informed consent process and confidentiality issues. Sometimes it works best if a formal working group contacts the committee and express readiness to help.⁶

Comments & Questions

⁶ FHI, 29