

Module I: PAR in UCEDDs –

Community Research – We Begin with Strong Roots

Introduction

Icebreaker (Need chart paper/markers)

Introduce everyone

List questions/expectations on the chart

Handout list of ground rules – (discus and modify)

What Questions do you Have? 1. 2. 3.

What do you Expect to Learn? 1. 2. 3.
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Introduce Workshop

Activity – Discuss ideas and beliefs about research. Ask people to think about this sentence.

People should do research that benefits their communities. Do you:

Strongly agree
Agree

Disagree
Strongly disagree

This activity helps us think about research. Let's discuss how research helps or hurts people and communities. This is not a test. There is no "correct" answer. I would like you to talk honestly any ideas and opinions you may have. Think about what is right for our community and lives. All ideas are welcome. Sometimes we may disagree with what is said. Let's listen and work to understand different ideas. 1

¹ Family Health International, Research Ethics Training Curriculum for Community Representatives (Research Triangle Park, 2004) 2-3.

Tree Metaphor

The tree is a symbol of life. Trees give us shade, fruit, wood and fresh air. The roots and trunk of the tree support its leaves and branches. When the tree grows well, the creatures of the forest make their homes within the tree (community). Trees have meaning in different cultures. In some cultures the tree means strength, healing and new life. In other cultures trees stand for wisdom and support.



We try to use these same principals in research. The research process is like the roots and trunk of the tree. This process supports the branches, leaves and fruit. These are the outcomes of the research. (Discuss and expand on this idea. . .)

Participatory Action Research Modules

Module I – We Begin with Strong Roots

Health Research
Community Participation
The Importance of the History of Research

Module II – We Help the Tree Grow

Ethics Principles and Vulnerable Participants
Institutional Review Board/Ethics Committee

Module III – We Continue To the Branches

Research Process

1. Select a topic or issue

Design the study

3. Secure funding
4. Get approval from the IRB
5. Recruit Participants

Obtain Informed Consent

7. Plan data collection
8. Intervention or carry out the study
9. Collect and analyze the data
10. Share and publish the results

Form New Branches and Leaves

Good research grows new ideas and helps us reach our goals. Sometimes people with disabilities and their families want to be involved in research. This is called Participatory Action Research or PAR. We have created three new modules to help you learn more about PAR. The goal of PAR is:

The people in our community will become equal partners in making decisions.

Objectives – Through Participatory Action Research we will:

Add to your knowledge about different kinds of research.

Answer any question or concerns you may have.

Help others understand what you know about research.

Find and overcome roadblocks that might stop you from participating.

Make sure our research is respectful.

Module I: PAR in UCEDDs - We Begin with Strong Roots

Health Research

Community Participation

The Importance of the History of Research

1. Health Research

Objectives:

Define what the term health research means

Share examples of how health research can help people

Question – What is research? Who participates in research?



Good research helps to answer questions about everyday problems. Good research is organized. That means we use a well-planned way to collect the information we seek.

Information is also called data. Data is anything we observe, count or measure. Good researchers look for data that will help as many people as possible. They have a clear idea about what questions to ask. They know which methods will work best to get the information they need.

People become part of our research when we observe or gather information about them. Sometimes we review records. This data gives us information about real people. ² If you observe or test someone for a research project you must have that person's voluntary cooperation. Researchers must get that person's consent in writing.

Question – How does health research help people? What discoveries have saved lives, helped someone live longer, or improved their quality of life?

Researchers discover ways to reduce secondary conditions

Some disabilities may lead to other health problems. These problems are sometimes called secondary conditions. Examples include gaining weight, getting diabetes, or being tired, depressed or anxious.

Each state looks for new ways to help people with disabilities. These methods must work and be cost effective. Promoting good health can help people with disabilities. Lorig and others, in a Chronic Disease Study, were successful in reducing many health problems. They proved that you can improve the quality of someone's life and control costs at the same time.

Some people with disabilities report up to 14 extra symptoms. These secondary conditions decreased by 25% in the study by Lorig. The improvement continued for

² E. Eng, Protecting People Who Participate in Research_(University of North Carolina – Chapel Hill, 2004)

4 months. A larger study was also done. The improvement was still observed a year later. The healthcare costs were reduced by 37% ([Research Progress Report #7](#)).

Researchers create and test new vaccines



Vaccines show how research helps people. Vaccines provide safe and efficient ways to prevent illness and death from disease. Vaccines have nearly put an end to polio, smallpox and measles. 3 How was this done? It all started with research. First, the researchers developed and produced a vaccine. Next they did studies in the laboratory to decide if the vaccine would stop a disease. They tested each vaccine for side effects. Once the vaccines were ready, they were tested with humans to make sure they were safe.

Researchers help people realize that using tobacco is harmful

Using tobacco is harmful. Many studies look at how tobacco affects your body. Researchers have discovered that some cancers are caused by using tobacco. Smoking can harm your blood vessels. When people smoke they may develop lung disease. Anti-smoking campaigns help people stop using tobacco. They also lower exposure to second hand smoke. Today fewer adults smoke. Millions of smoking-related deaths have been prevented.⁴



Researchers help to reduce deaths from heart disease and stroke. Deaths from heart disease and stroke have declined because fewer adults smoke. High blood pressure has responded to early detection and better treatment. Death rates for coronary heart disease have decreased by 51% since 1972,. This is an improvement but more needs to be done. Over 250,000 women die each year from heart disease. Many of the therapies used to treat women are based on studies that involved mostly men. Women may not be diagnosed or treated as aggressively as men. Their symptoms may be very different from those of men having a heart attack. 5 Current research is now studying treatments to benefit women as well as men. We must educate the public about the risks of heart disease to improve the health of women. 6 Researchers share information with policymakers.

Example: Rural Health Research Centers (RHRC)

These centers help others understand rural communities. Each year new topics are studied. Recent topics include public health, access to health care and chronic illnesses.

³ National Institute of Health, Vaccine Research Center, Strategic Plan: Research Toward Development of an Effective AIDS Vaccine, 2001, <<http://www.vrc.nih.gov/vrc/pdf/vrcsp.pdf>> (29 March 2006).

⁴ Center for Disease Control, Ten Great Public Health Achievements-United States, 1900-1999, <<http://www.cdc.gov/mmwr/preview/mmwrhtml/00056796.htm>> (8 February 2006).

⁵ Agency for Healthcare & Quality Research, Research on Cardiovascular Disease in Women, <<http://www.ahrq.gov/research/womheart.htm>> (28 March 2006).

⁶ Nanette K. Wenger, Leon Speroff, and Barbara Packard, Cardiovascular Health and Disease in Women (The New England Journal of Medicine, 1993), 329 (4), 247-256.

Research centers help policymakers understand how rural health care systems work. They show how to put new programs into action. The results are shared at the local, state, and federal level. This information helps communities develop laws. It also helps communities start programs and decide which services should be funded.

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Example: One example is the Unequal Treatment Study done by the Institute of Medicine. This important study showed the need to improve health care for people of different ethnic backgrounds.

Comments & Questions

⁷ Rural Health Research Centers, Program Overview, <<http://ruralhealth.hrsa.gov/policy/rhrccoop.htm>> (27 December 2006).

2. Community Participation

Objectives:

Define the term community

Show why community participation is important in the research process

Identify differences between traditional and participatory research

Questions – What is a community? What are some communities to which you belong? What makes you a member of a community? Why is it important for you to belong? How are some communities unique?

Characteristics of a community



In 2001, researchers studied 118 persons with different social and ethnic backgrounds. From this study they defined community as:

“a group of people with diverse characteristics who are linked by social ties, share common perspectives (ideas), and engage in joint action in geographical locations or settings.”

Community is a “sense of place, something that could be located and described, giving people a sense of locale or boundaries.” A community may be a city, village, neighborhood, or even a workplace.

People belong to a community when they share common interests and perspectives. We often share the values, interests, and suffering of other people who live in the same area. These shared experiences continue for many generations. Community also includes the events that bring people together. These can be celebrations or social ties with family and friends.

Research Communities

Some research may target people who all belong to a specific community. Examples include people with/from:

The same health condition or disability. Example: breast cancer or cerebral palsy.

The same type of job. Example : health care providers or teachers

The same population. Examples: teenagers, seniors, prisoners or drug users.

One geographic area. Example: cities, small towns, health clinics, or truck stops.

Value: People who live in research communities should participate in the design, review, and conduct of any research that may impact them.

We can make sure that the views and needs of a community are considered. We do this when we involve people from that community in research. The benefits and risks of our research affect not only the individual participants, but also the entire community.

Question – Why should you participate before, during and after a research study? What are some barriers that make it difficult for people to participate? We can build a bridge between the community and the research staff. This kind of involvement:

- Helps to make sure that important research is done
- Helps to protect research participants
- Enhances understanding of shared research goals
- Improves the way research is designed
- Provides clear direction on research procedures
- Increases the chances that the research effort will continue
- Allows for a shared evaluation of the meaningfulness of the results
- Creates supporters for sharing the results of the study

Barriers to community participation in the research process happen when:

Researchers are arrogant and do not want to share power
Clear roles and expectations are not laid out for community participants
Ways to reimburse people for their time and expenses are not considered
Ways to support participation by addressing the need for accommodations (e.g., day care, accessible transportation) are not considered.



Take a few minutes to think of any others barriers?

Communities can get involved in many ways. Sometimes people form a group to start a research project. This group voices local questions and concerns. Sometimes a university or hospital may ask a person with a disability to help review research. He or she can represent all participants. These groups are called community advisory boards or working groups.

Researchers use guidelines to conduct good studies. These guidelines do not always tell the best way to get people involved. Researchers may choose people from the local community. They may even ask someone with a state wide or national perspective.

Roles and Responsibilities of Community Representatives

- Make sure that research is done to answer local questions and not only to satisfy scientific curiosity.

- Make sure that the research design is sensitive to the needs and expectations of people with disabilities or health conditions.
- That does not mean researchers have to meet all expectations. In fact, that may be impossible. Good research is sensitive to what the community expects.
- To advocate for the well-being of participants.
- Many review committees find that people with disabilities are very helpful. They can help to design the informed consent process. They make sure the process is easy to understand. They also make sure that the process is voluntary. They use methods that are culturally appropriate.
- To help identify the benefits that participants may receive once the study is completed.
- To help identify respectful treatment for study participants.

Important sample questions for a community representative to ask:

- Is this important to the community?
- Will it make a significant difference?
- Will it be available to the participants someday?
- Who will make it available? Under what conditions? For how long?
- Will the quality of health care improve?
- Will the research result in the looked-for changes in behavior?
- Can the data be used to leverage change?
- What other benefits will the community receive?⁸

Question - What does this term mean?

Community-based participatory research!



Research that gets people involved is called participatory. Research becomes community-based when “a collaborative (joint) approach to research is used.” This approach must “equitably (fairly) involve everyone in the research process. It recognizes the unique strengths that each partner brings.”⁹

The key words here are “collaborative,” “equitably,” and “partners.” The goal is for researchers to work side-by-side with community members. They must do this in a way that is fair, and respectful of the needs of the community.

Helpful hint: For more information be sure to use the Community Tool Box located at <http://ctb.ku.edu/> . This helpful Internet site has over 6,000 pages dedicated to improving community development and health.

⁸ FHI, 10-15

⁹ LW Green, as cited in Meredith Minkler, Ethical Challenges for the “Outside” Researcher in Community-Based Participatory Research (Health Education & Behavior, 2004) 686.

We will use the term participatory research to mean research that is also community based.

Differences between Traditional Research & Community-Based Participatory Research

Traditional Research

Scientists usually decide which issues should be studied. Scientists make these decisions from their own point-of-view. First they read many scientific articles. They consider all the past studies. Then they do an analysis of what we know or don't know about a topic. This helps scientists understand what has been done so far.

Researchers follow demanding scientific standards and methods to collect data. Most of the funding is used to pay for research expenses. Researchers manage all the resources.

Scientists often recruit people to be in a study by following a research formula. A scientist may not really know the community that well. When scientists have not taken the time to find the information they need about a community then they take their best guess.

Researchers sometimes create new tools to help them measure behavior. They often adapt these tools by looking at other similar studies. Most research studies use scientific methods to analyze and study data.



Some scientists use statistics to measure abilities. This involves learning about a person's knowledge, or personality. One example of this type of study is IQ testing. These scientists are concerned with differences between individuals and groups. They compare each person's responses to a normal pattern. They compute any differences mathematically.

Other scientists prefer to observe behavior. They analyze what happens when people interact with their environment. These studies help them decide how to achieve better outcomes. Teachers may use this approach to decide how to help a student learn.

Researchers also investigate important issues. This is called qualitative research. Scientists take the role of the learner in this type of research. They design a study that will help them learn more about someone's personal experiences. For example, researchers recently interviewed Hurricane Katrina survivors with disabilities. They wanted to learn how they dealt with survival and coping issues.

Traditional researchers decide what question they want to answer. They figure out the best methods to use. They make these decisions based on their knowledge and expertise. They review the published findings and theory for the methods they plan to use.

Researchers report findings from statistical analysis, behavioral observations, or qualitative studies. They publish their findings in peer-reviewed journals. These articles are reviewed by other researchers with knowledge of the topic before they can be accepted by the science community.

Participatory Research: Benefits to Communities and Researchers

The table below shows some common methods used in Participatory Research. It lists the benefits of each.

When community representatives. . .	We see . . .
Help identify which issues are most important,	People who are motivated to participate
Help to design and submit a proposal;	People who accept the study's approach; Funds for the community.
Suggest ways to recruit and retain participants	Better success in finding people who participate for the life of the project.
Have input in creating measurement tools that are tested in the sample population;	Better ways to handle sensitive issues. Increased reliability and validity of data.
Help guide project activities	Research that has cultural and social meaning for people; Research that is more likely to produce positive change.
Assist researchers to interpret, share and translate the findings	A study that limits group harm and whose results are more likely to be used. ¹⁰

Special note: Many agencies that fund research issue a request for proposal or RFP. The RFP already states the priorities for research. This limits the influence that communities can have on the direction of the research. The purpose has already been decided broadly by the funding agency.

Summary: Community Participation in the Research Process

A community is a group of people who often share the same place. They often have similar beliefs and cultures. Many share similar ideals or goals. Sometimes people are alike in age or gender. They may come together because of a common lifestyle, health condition or disability. All of us belong to many communities. We share common bonds.

The members of any community can promote their interests. They may ask important questions and voice their concerns. Researchers can invite people to join formal groups to review research. They may also bring in different people to participate across all stages of the study.

Research that involves community representatives is more likely to respond to community health needs and expectations. This approach helps to make sure that

¹⁰ Agency for Healthcare & Quality Research, Evidence Report on Community-Based Participatory Research, Publication No. 04-E022-2, August 2004, <<http://www.ahrq.gov/clinic/tp/cbprtp.htm>> (19 January 2006)

what we do is in the best interests of both science and the community. ¹¹ When we do this, everyone wins.

Comments & Questions

¹¹ FHI, 15

3. The Importance of the History of Research

Objectives:

To understand the history that shaped key research ethics
To be able to identify key ethics documents

Past Research History



The period of time in Germany during World War II is called the Third Reich. Many people have heard about the way the Nazis treated the Jewish people at that time. The second story is about how the Nazi's treated people with disabilities.

In Nazi Germany the government began what is called "mercy" killing. They killed many people with disabilities. Doctors hired by Hitler were authorized to kill or experiment on anyone they believed to be "unworthy of life." This included men, women and children with disabilities. A man named Hugh Gallagher wrote about these practices. His book is titled *By Trust Betrayed: Patients, Physicians and the License to Kill in the Third Reich*.

The Nazi's were careful not to call these actions murder. They tried to justify, and hide what they were really doing. Instead they called this practice giving "final medical assistance." Many German physicians and others knew what was really happening. They knew that people with disabilities' were being experimented on and murdered. They did nothing! Finally the parents of these people, their friends, and the Church ended this policy. By then over 200,000 men, women and children with disabilities had been murdered.

Some German doctors also did brutal experiments on prisoners of war.¹² These prisoners were trapped. If they refused to participate they were killed. One experiment was called the freezing experiment. Prisoners were placed into tanks of ice water for hours at a time. They often froze to death. The scientists did this to discover how long German pilots who were shot down by enemy fire could survive the frozen waters of the North Sea. It was generally known at the time that human beings did not survive in the North Sea for more than two hours. Doctor Sigmund Rasher decided to repeat these experiments at Dachau (a prison camp). He used about 300 prisoners. He observed and recorded their symptoms of shock from the exposure to cold. About eighty to ninety of the people died.¹³ In 1946, at the end of World War II, 23 Nazi doctors and scientists were put on trial for murder of prisoners. The trial was held by a military tribunal. It came to be known as the Nuremberg Trial. After the facts came out, several people got together and wrote the Nuremberg Code. This code is still used to guide humane research today.

¹² E. Eng, *Protecting People Who Participate in Research* Power Point (University of North Carolina, 2004)

¹³ BC Cohen, *Jewish Law Home Page*, <<http://www.jlaw.com>> (25 January 2006).

Principles Taken from the Nuremberg Code

Researchers must obtain voluntary informed consent from people (subjects). They should not delegate this responsibility to others.

Experiments should be designed to benefit society, and not be random or unnecessary.

Animal research should come before human research whenever scientists need to study the natural history of a disease. Animal research should be done first whenever this is possible. This helps make sure that the expected results will justify the performance of the experiment.

A research study should never involve unnecessary physical or mental suffering or exposure to harm. The experiment should not be conducted if there is reason to believe it may lead to death or disabling injury. "

Any risks should be reasonable and based on the possible benefits to humanity.

Researchers must be scientifically qualified and should perform professionally at every stage of the experiment.

People must be free to withdraw at any time.

The experimenter should stop the study at any time if the subjects may be harmed by continuing to participate.¹⁴

These standards are rules for how we should treat people in research. They were widely read by people who worked in hospitals and universities. Sadly, these rules were still often ignored. Most scientists and doctors felt that the rules were common sense. They dismissed the document as something written about the crimes committed by Nazi doctors. They did not believe the really applied to them.



In 1964, the World Medical Association developed another code called the Declaration of Helsinki. This code was based on the principles set forth in the Nuremberg Code. It described how true medical research should be done. All doctors were now required to follow these rules when conducting research on any humans. The declaration led to creation of ethical review boards that operate today at our colleges and medical schools. These boards are called Institutional Review Boards.

Setting the Stage - Past Research History in the US

After the Declaration of Helsinki was made, some researchers still harmed people. New rules are made each time harmful research is discovered. These rules make sure that past mistakes are not repeated. The rules protect everyone.

¹⁴ Human Subject Protection Power Point (Harvard University Kennedy School of Government, 2001) <<http://www.ksg.harvard.edu/research/KSGHumanSubjectsNov2001.ppt>> (4 April 2006).

It is important to study past research practices that caused problems. The stories we will learn about are worst-case examples. They are not very common. Most researchers don't plan to harm people. Yet strong rules are still necessary. It is always easy for researchers to believe that they will not harm anyone. The truth is that unless we are careful we still may.

Isolation creates conditions where harm becomes easier.

From the 1940's through the 1970's a "medical" model of disability prompted states to build institutions. Disability was viewed as an illness or disease. People with disabilities were gathered into large sterile environments where they could be kept away from others. Their future was grim. They had little hope of reaching their fullest potential.

People with disabilities were viewed as someone who:

- Was sick and needed care
- Might be dangerous to themselves or others
- Was either evil or innocent
- Should be pitied
- Could only be the object of charity
- Could not learn much, if at all
- Would never be normal
- Was less than human

Children and adults who lived in institutions were separated from their families. They were denied civil rights. They could not get a good education or good health care. The institutions became over-crowded. By the late 1960's, living conditions in these institutions had become very bad. Yet many state officials and doctors looked the other way. They denied that problems existed. Under these isolated conditions many people were harmed.

Families and advocates rallied against a system that pushed people with disabilities from the mainstream of society into institutions.¹⁵ In 1972, Geraldo Rivera (a TV reporter) took a camera into one institution. He showed the horrible conditions at the Willowbrook State School in New York. Poorly clothed children, youth and adults were housed in the crowded facility. Some were naked. Most were without appropriate care. Many people saw the TV report. They were angry. Families and advocates were able to close many similar institutions in the United States.

New ways of viewing disability

¹⁵ Source: Parallels in Time, Minnesota Governor's Council on Developmental Disabilities, 1999.

Today we are starting to view disability in a new way. People with disabilities came back into their communities. They began to reject the traditional 'sick' role. They asserted their right to full, active participation in their life, healthcare, and community. They were no longer the 'patient' in need of care. People with disabilities were not content to remain dependent. Instead, they began asserting their right to decision-making and active choice in their lives.

Today, disability is viewed as a natural part of the human condition. Individuals are seen as people first with abilities as well as limitations. They have the same rights as anyone else. This shift in thinking and attitudes has begun to change research and policy. Practices that were used in the late 1900's are no longer accepted as ethical. People with disabilities are now involved in all aspects of research and health care.¹⁶

Research History in the US

Several groups of people in the US were abused during the 1950s, 1960's and the 1970s. This eventually came to public attention. It is important to learn about these studies. Many rules were adopted to prevent this harm from being repeated. Three important studies are:

The Willowbrook Study (1963 – 1966)
US human radiation experiments (1944- 1974)¹⁷
The "Tuskegee Study" (1932 – 1971).¹⁸

The Willowbrook Study



This study involved a group of children who had mental retardation. They lived at the Willowbrook State Hospital in Staten Island, New York. These children were deliberately infected with the hepatitis virus. At first, the children were fed extracts of stools from infected individuals. Later children received injections of more purified virus preparations. Investigators tried to defend the study. They pointed out that most of the children got the infection anyway while at Willowbrook. They told people that their careful research conditions would help the children.

Doctors were hoping to study the history of the disease when left untreated. Later they tried to discover how gamma globulin impacts the disease. Gamma Globulin is a protein in human blood. It includes most antibodies (the cells that fight infection).

¹⁶ (DeJong 1979).

¹⁷ Radiation Experiments <http://gra.sdsu.edu/irb/tutorial/m2s2.htm>

¹⁸ Word Human Subject Protection Behavioral Course, Lesson 2 (University of Arkansas Medical Sciences)
Willowbrook Hepatitis Study. (1/21/01). <http://hstraining.orda.ucsb.edu>

This study raised many concerns. The children were deliberately infected with a harmful disease. The officials tried to convince the parents to enroll them in the study in exchange for admission. Space in the hospital was deliberately kept short.

Radiation Experiments

Thousands of dangerous experiments took place during the cold war. Many people were exposed to dangerous levels of radiation. This was done to gather safety data on the effects of the atomic bomb. Scientists also wanted to develop treatments for cancer. Many people agreed to participate. People who were sick, imprisoned or vulnerable could not give consent. At least 54 children with intellectual disabilities were fed radioactive breakfast cereal. Former President Clinton apologized to the people who survived and their families in 1993.

The Tuskegee Syphilis Study

From 1932 to 1972 three hundred ninety-nine poor black farmers in Macon County, Alabama, were denied treatment for syphilis. They were deceived by physicians of the U.S. Public Health Service who knew the men had this disease. Once again doctors were trying to study the natural history of a disease. They wanted a group of people that would be easy to follow in whom they could watch the disease progress. The men were told that they were being treated for “bad blood,” but were given a harmless substance that did not treat syphilis. In fact, government officials went to extreme lengths to insure that they received no therapy from any source. The study was exposed by the press. It was a major scandal in the United States.¹⁹

The project ended in 1972. Senator Edward Kennedy held hearings on the study. A class action suit was later brought against several government agencies involved. The case was settled for \$10 million. This money was shared among the survivors and families.

The National Research Act of 1974 authorized the government to issue new regulations for federally funded research.²⁰ Congress formed the National Commission for the Protection of Human Subjects in Biomedical and Behavioral Research. The commission wrote the Belmont Report, in 1979. This report is a cornerstone document of ethical principles and federal regulations to protect research participants. It is based on three important principals:

Treating people with dignity and respect.
Make sure you do no harm, especially to vulnerable people (beneficence);
Assure fair and equal treatment for all (justice).²¹

There are now Federal rules in place to protect the rights of people with disabilities in research settings. However new abuses sometimes still happen. Participatory Action Research or PAR, offers another layer of protection.²²

¹⁹ World Human Subject Protection Behavioral Course, Lesson 2.

²⁰ Human Subject Protection Power Pt.

²¹ FHI, 70.

How can we keep “bad things from happening again”?

What other safeguards can help protect people in the future?

Comments & Questions