



COMMUNITY RESEARCH WORKSHOP GUIDE

Submitted by the

**University of Arkansas Fay W. Boozman College
of Public Health**

**Marvell Nutrition Intervention Research
Initiative (NIRI) Workshop Advisory Committee**

Table of Contents

Acknowledgement
[3]

Introduction
[4]

Workshop Opening & Overview
[6]

Content-Module I
[8]

Content-Module II
[23]

Additional Resources
[45]

Acknowledgement

The authors thank the United States Department of Agriculture (USDA) Agriculture Research Service (ARS) for funding this project (ARS Cooperative Agreement no. 6251-52000-0020-00D.)

We would like to acknowledge that much of the material included herein is adapted from the Family Health International (FHI) Research Ethics Training Curriculum for Community Representatives. Any part of this guide may be used on the condition that the UAMS Fay W. Boozman College of Public Health and the Delta NIRI is credited as the source on copies, reproductions, distributions and adaptations and no financial benefit is accrued.

Introduction

The University of Arkansas for Medical Sciences (UAMS) Fay W. Boozman College of Public Health (COPH) was established as the sixth and newest academic unit at UAMS in July 2001. Our mission is to improve health and promote the well-being of individuals, families and communities in Arkansas.

Community-Based Public Health Research

The Office of Community-Based Public Health was established to provide a resource to support efforts by the College to promote community-based public health among faculty, staff and student body.

There is increased recognition of the importance of involving community members in developing and implementing public health research projects and health promotion/disease prevention programs. Past experiences, perceptions of research and community capacity have been cited as factors which limit community participation in research activities.

Purpose of the Guide

Our goal in developing this guide is to facilitate community members' participation as equal partners in decision-making concerning either participatory or traditional research projects. Our objectives:

- Increase community knowledge about health related research
- Decrease negative attitudes and/or perceptions about research
- Improve researchers' understanding of community knowledge, perceptions and experiences with research

We used the "Tree" as a metaphor to describe principles to strive for in the research process. The tree symbolizes strength, healing and fruitfulness in some cultures; in other cultures, it symbolizes wisdom and support.

How to Use This Guide

The Community Research Workshop Guide is designed for small and large groups. The guide is divided into 2 modules, each containing 3 branches (sections):

Module I

- Branch 1: Health Research
- Branch 2: Community Participation
- Branch 3: Research History

Module II

- Branch 4: Ethics Principles
- Branch 5: Institutional Review Board
- Branch 6: Research Process

This workshop can be conducted in one day or two half day sessions.

This guide contains the following:

- Introduction
- Content-material to be learned
- Additional resources - research definitions, history of research and internet research related resources.

Terms Used in This Guide

- *Research, health research* and *study* are used interchangeably.
- *Research subject or participant* is used to describe a person who is participating in a research study.
- *Community representative/s* is used to describe a person or group who is representing the community in which the research is being conducted.

Other terms that are explained in the guide include:

- Special research communities
- Community-based participatory research
- Justice
- Beneficence
- Respect for persons
- Informed consent process

Community Research Workshop Opening

Icebreaker:

Participant introductions

Participants & facilitators list ground rules (list answers on flip chart)

Administer Pre-Questionnaire

Introduction to Workshop

Activity – discussion of opinions and attitudes about research

People should be grateful for the research coming into their communities
Do you:

- Strongly agree
- Agree
- Disagree
- Strongly disagree

This activity provides a useful context for people to discuss their opinions and attitudes about research, as well as a framework for the upcoming discussion of ethics in research. This is not a test of getting the “correct” answer. Rather, it should help us talk honestly about the many different attitudes and an opinion we may have about what is right for our communities and us. All opinions are welcome, and it is likely that you will have participants strongly react against the word “grateful.” One may not agree with what is being said, but one can listen and work to understand differing opinions. ¹

Discuss – the term “guinea pig” as it relates to how some people may feel about research.

Tree Metaphor

The tree symbolizes strength, healing and fruitfulness in some cultures; in other cultures, it symbolizes wisdom and support. These are principles to strive for in the research process

Workshop Goal

Our goal is that community members will participate as equal partners in decision-making concerning either participatory or traditional research projects.

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

Workshop Objectives

1. To increase community knowledge about health-related research.
2. To decrease negative attitudes and perceptions about research.
3. To improve researchers understanding of community knowledge, perceptions and experience with research.

Workshop Content Overview

Module I

Health Research Branch

Community Participation Branch

History Branch

Module II

Ethics Principles Branch

IRB Branch

Research Process Branch

MODULE I

Branch: Health Research

Objectives: To define health research
To describe benefits

Sub-branches

Health research defined

Benefits of research

1. medical
2. policy

Question – What is research? What is a research participant?

Research is an organized way to gather information that is useful for as many people as possible. By organized, researchers mean that there is a structure and a plan for doing the project. Information is anything that can be observed or measured about a person. As many people as possible means that research is meant to help other people who are not involved in the project. If the research is not going to help anyone after it is done, it should not be done. Research is done to answer one or more questions.

A research participant is anyone the researcher gathers information about. Anyone who can be observed or measured. An example would be reviewing health department records. Anytime something is recorded from an organization's records, information about someone is being collected. ²

Question – What are some medical or health related discoveries you know of that have helped save lives or helped someone live longer?

Public Health Achievements—United States, 1900-1999

Vaccination

Vaccines are an example of a research benefit. They have been and continue to be powerful public health tools that provide safe, cost effective and efficient ways of preventing illness and death from infectious diseases. Vaccines have greatly changed the control of infectious diseases, nearly putting an end to polio, smallpox and measles. ³ How was this done? It all started with research - Researchers developed & produced a vaccine; then they conducted studies in the laboratory or with animals to help decide how vaccines will act on humans.

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

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).

In these studies, the researchers checked for side effects, effectiveness, to what degree it may be poisonous and other drug effects. Then they had to test it in humans to see if it was effective. To do this they had to give it to some people and not give it to others and look to see if it made a difference.

Recognition of tobacco use as a health hazard

Recognition of tobacco use as a health hazard is an example of research benefits. Many research studies have been done to measure how tobacco affects the body; researchers have discovered that some cancers are caused or related to tobacco use, blood vessels that carry blood to different parts of our bodies are negatively affected, and emphysema and pulmonary disease are related to tobacco use.

Research has also discovered that public health anti-smoking campaigns have resulted in delayed initiation of tobacco use, cessation of use, and reduced exposure to environmental tobacco smoke (second hand smoke). Since the 1964 Surgeon General's report on the health risks of smoking, the prevalence of smoking among adults has decreased, and millions of smoking-related deaths have been prevented.⁴

Decline in deaths from coronary heart disease and stroke

Decline in deaths from coronary heart disease and stroke have resulted from risk-factor modification, such as smoking cessation and blood pressure control coupled with improved access to early detection and better treatment. Since 1972, death rates for coronary heart disease have decreased 51%. This is certainly an improvement; however, 250,000 women are dying each year from coronary heart disease. Much of the research in the last 20 years on the diagnosis and treatment of CHD has either excluded women entirely or included only limited numbers of women. As a result, many of the tests and therapies used to treat women for CHD are based on studies conducted predominantly in men. Research does show that women may not be diagnosed or treated aggressively as men, and their symptoms may be very different from those of men having a heart attack.⁵

There is research now in progress to study treatments that benefit women, differing symptoms of heart attacks among women and other disparities. New approaches are needed to bring high-quality clinical care to women who are at risk for cardiovascular disease or who have such disease already. In addition to incorporating information about the prevention and treatment of cardiovascular

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).

disease in women into the standard medical school curriculum, postgraduate training of physicians should also include information about sex-specific aspects of cardiovascular care. Finally, an increase in educational messages focusing on cardiovascular disease in women could promote the overall objective of enhancing the cardiovascular health of women in the United States.

6

Influence on Policy & Policymakers: Funding and allocation of resources

Example: Rural Health Research Centers (RHRC)

These centers help policymakers, both in Washington and throughout the Nation; better understand the problems that rural communities face. RHRCs produce policy-relevant research on health care in rural areas. Each year research topics are selected by the research center directors and policy staff. The emphasis is on research that will have a timely impact on policy issues. Issues such as public health, health care access and chronic illness to name a few.

The centers provide technical assistance to health care policymakers, helping them to understand the unique characteristics of rural health care systems and to implement programs and interventions that address rural health care needs. This is important because the research findings are disseminated to local, state, and federal policymakers who play key roles in the development of legislation and the administration of programs and interventions that require funding.⁷

Another example of how research has had a beneficial impact is the study by the Institute of Medicine published in a book called Unequal Treatment. This study compiled results from hundreds of other studies that showed consistent disparities in the quality of healthcare provided to minorities in the U.S. This book presented the research in a combined and comprehensive manner that made it hard to ignore. This and other research has had a huge impact on funding and attention to eliminating racial and ethnic health care disparities.

Comments & Questions

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.

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

Branch: Community participation

Objectives:

To define community

To explain why community participation is important in the research process

To identify differences between traditional and community-based participatory research

Sub-branches

Define community & special research communities

Roles and responsibilities of community representatives

Community-based participatory research

Questions – What is a community? What are some communities you belong to? What makes you a member of a community? Why is it important for you to belong to a community? What are some characteristics (uniqueness) of communities?

Characteristics of a community

In 2001, a study of 118 persons with different social and ethnic backgrounds defined community as “a group of people with diverse characteristics who are linked by social ties, share common perspectives, and engage in joint action in geographical locations or settings.” One element of community was identified as a “sense of place, something that could be located and described, denoting a sense of locale or boundaries.” A community is an identifiable area or location, such as a city, a village, a neighborhood, or even a workplace.

This study also identified “sharing common interests and perspectives” as part of belonging to a community. As members of a community, we share our values, norms, religion, interests, worries, needs, happiness, and suffering with the other members of our community. Many times these commonalities have existed for years, if not for centuries. Other identified elements of community were joint actions that bring people together or social ties such as family, friends, and diversity.

Define- special research communities

Special Research Communities

Some research projects may target participants who belong to special communities. Examples include:

- Persons with the same disease. Examples: AIDS or breast cancer.
- Persons with the same profession or method of earning a living. Examples: health care providers, teachers, or sex workers.
- Persons from the same population. Examples: adolescents, older persons, persons in prisons, or injecting drug users.

- Persons living in a specific geographic community. Examples: cities, small towns, or specific settings, such as health clinics, bars, nightclubs or truck stops.

In all of these examples, individuals representing these communities should participate in the design, review, and conduct of the research to ensure that the views and needs of the community are considered. Often the benefits and risks of the research affect not only the individual participants, but also the entire community from which they are drawn.

Question – Why is it important to have community members participate in the research process? (process meaning: before the study, during the study and after the study). What are some barriers to community participation?

To build a bridge between the community and the research staff, it is important to involve the community in the entire research process. Community involvement:

- Optimizes the protection of research participants
- Enhances investigators' perceptions of the research goals
- Improves the way research is designed
- Increases chances of sustained effort

Community participation in the research process can happen in many ways. Sometimes

community representatives form a group to advise the research process, as the voice of local questions and concerns. Other times, an ethics committee—formed of members not based in the community—will ask a local community representative to be a voice for all participants.

There are various names for a formally established group representing the community, such as a community advisory board (sometimes referred to as a CAB), community-working group, or community advisory group. Such groups are usually empowered to advise the research study throughout the research process, representing the interest of the research participants. Although established international guidelines require community participation, they do not define exactly how a community and its representatives are involved in research studies. Sometimes representation is on a local level, while other times it could be on a national or international level.

Roles and Responsibilities of Community Representatives

1. One of the responsibilities of a community representative is to ensure that the research addresses a local need and is not conducted only to find answers to scientific questions.
2. When research is conducted among individuals with a specific disease, a community representative should make sure that the research design is

sensitive to the needs and expectations of the individuals with the disease.

3. In any type of health research, community representatives should advocate for the well-being of Participants. Potential research participants must receive and understand all important information through the informed consent process before deciding to participate in a research study. Details about informed consent are presented later in this curriculum. Community representatives can work with the researchers in the development of the informed consent process to make sure that this process is complete, comprehensible, voluntary, and culturally appropriate.
4. Particular importance is given to the benefits that participants and their communities receive once the study is completed, as well as what treatment participants in the study will receive. Important sample questions for a community representative to ask include:
 - Is the issue being studied of importance to the community?
 - Will the study, drug, treatment, or intervention be made available to the participants?
 - Who will make it available? Under what conditions?
 - How long will it be available in the community where it is being tested?
 - Will the quality of health care in the community improve as a result of the research?
 - Will the research result in desirable behavior change in the community?
 - What other benefits will the community receive as a result of the research?⁸

Discuss “rumors”

How could a community representative help prevent rumors from spreading?

Why should a community representative alert the study staff if he or she hears rumors about the study?

How could a community representative help ensure that accurate research results reach the study participants?

⁸ FHI, 10-15

Question - What is community-based participatory research?

“A collaborative (joint) approach to research that equitably involves all partners in the research process and recognizes the unique strengths that each brings”.⁹

Key words here are “collaborative,” “equitably,” and “partners.” The goal is for researchers to work side by side with community members in the research process.

Other terms: action research, rural participatory appraisal & community-based research.

Difference between Traditional Research & Community-Based Participatory Research

Traditional Research

Issues identified based on a study of disease, how it spreads and funding priorities.

Design based entirely on demanding scientific standards and something that can be achieved; funding requested primarily for research expenses.

Approaches to recruitment and retention based on scientific issues and "best guesses" regarding reaching community members and keeping them involved in the study.

Measurement instruments adopted/adapted from other studies. Tested chiefly with psychometric analytic methods. Psychometrics is the field of study (connected to psychology and statistics) concerned with the measurement of "psychological" aspects of a person such as knowledge, skills, abilities, or personality. Psychometrics is primarily concerned with differences between individuals and employs statistical tools such as normal distribution and factor analysis.

Researchers design interventions based on literature and theory.

Researchers report findings from statistical analysis and publish in peer-review journals.

Researchers manage all the resources.

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

Community-Based Participatory Research

Full participation of community in identifying issues of greatest importance.

Benefit: Increased motivation to participate in research process.

Community representatives involved with study design and proposal submission.

Benefit: Increased acceptability of study approach, include funds for community.

Community representatives provide guidance regarding recruitment and retention strategies.

Benefit: Enhanced recruitment and retention.

Measurement instruments developed with community input and tested in similar population.

Benefit: Potentially sensitive issues handled better and increased reliability and validity of measures.

Community members help guide intervention development.

Benefit: Assures greater cultural and social relevance to the population served, increasing the likelihood of producing positive change.

Community members assist researchers with interpretation, dissemination and translation of findings.

Benefit: Assures greater sensitivity to cultural and social norms and climate and potential group harm and enhances potential for translation of findings into practice.¹⁰

Community members co-manage the resources

Summary: Community Participation in the Research Process

A community can be defined as a group of people sharing the same location, beliefs, culture, ideals, goals, age, gender, profession, lifestyle, or disease. All of us belong to many communities, bonded by common interests.

When researchers decide to study a specific community, members of that community can

come together to promote their interests, ask questions, and voice any concerns. Community representation can occur in the form of formally established groups of individuals who take part in the research at all stages of the study.

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)

Community representation ensures that the research responds to community health needs and expectations, involves appropriate informed consent, and provides access to research benefits. Community representation benefits the community and can ensure that the research is designed and implemented in the best interests of science and the community.¹¹

Comments & Questions

¹¹ FHI, 15

Branch: Research History

Objectives:

To understand the history that influenced development of key research ethics documents.

To be able to list the research ethics documents.

Sub-branches

Research ethics documents -Nuremberg Code, Declaration of Helsinki & Belmont Report

Research history in the U.S.

Past History

Past events lead to rules that now protect research participants. Many people have heard about the way the Nazi regime treated the Jewish people. One particularly horrifying part of that history is what some of Hitler's doctors did to prisoners of war during World War II.¹² One experiment was called the freezing experiment and prisoners were immersed into tanks of ice water for hours at a time, often shivering to death, to discover how long German pilots downed 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 immersion in the North Sea for more than one to two hours.

Doctor Sigmund Rasher attempted to duplicate these cold conditions at Dachau, and used about 300 prisoners in experiments recording their shock from the exposure to cold. About eighty to ninety of the subjects died as a result.¹³

In 1946, at the end of World War II, 23 Nazi doctors and scientists were put on trial for murder of concentration camp inmates who were used as guinea pigs. Because of these horrifying experiments, there was a military tribunal, known as the Nuremberg Trial. When the facts came out several people got together to make the **Nuremberg Code**.

Principles Taken from the Nuremberg Code

- Researchers are responsible for obtaining voluntary informed consent from their subjects. They should not delegate this responsibility to others.
- Experiments should be designed to benefit society, and not be random or unnecessary.

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).

- Precede human research with animal experiments and studies on the natural history of disease whenever this is possible, so that the anticipated results will justify the performance of the experiment.
- Research should involve no unnecessary physical or mental suffering or exposure to harm. In particular, the experiment should not be conducted if there is reason to believe it may lead to death or disabling injury of a subject, "except, perhaps, in those experiments where the experimental physicians also serve as subjects."
- Risks should be reasonable based on the possible benefits of the research, which should take into account the humanitarian importance of the problem being studied.
- Researchers must be scientifically qualified and should perform professionally at every stage of the experiment.
- Subjects must be at liberty to withdraw at any time of their own free will.
- The experimenter should stop the study at any time if in his opinion subjects may be harmed by continuing to participate.¹⁴

These standards are rules for how we treat participants in research and during the 1950's and 1960's were widely recognized. However, this document was often ignored in the United States. Most scientists and doctors felt that points outlined were common sense and were written more as an argument to be made about the crimes committed by the Nazi doctors.

In 1964, the World Medical Association developed a code of research ethics call the **Declaration of Helsinki that** was based on the principles set forth in the Nuremberg Code. The focus of this document was on true medical research with a therapeutic intent.

These principles became the required method of conducting human subject research in an ethical manner. In principle, the declaration became the ancestor and paved the way for the implementation of an Institutional Review Board.

¹⁴ Human Subject Protection Power Point (Harvard University Kennedy School of Government, 2001) <<http://www.ksg.harvard.edu/research/KSGHumanSubjectsnov2001.ppt>> (4 April 2006).

Research History in the US

From the 1950s to the 1970s in the United States, there were a number of abuses of human subjects committed by US researchers that came to public attention. These included:

- The Wichita jury study (1953) – six jury rooms were bugged to study how juries deliberate. The violations included lack of consent, deception, and violation of the juror’s rights.
- The Munson Jewish Chronic Disease Study (1963) – Senile patients were injected with live cancer cells to study a person’s immunity to cancer without any notification or consent of the patients.
- The Public Health Service Syphilis Study of “Tuskegee Study” (1932 – 1971).¹⁵

The Wichita Jury Case

In 1953, University of Chicago researchers tape-recorded the deliberations of juries in six civil cases, with the consent of the judge and counsel for both sides, but without the jurors’ knowledge. The researchers were investigating whether the comments of some lawyers might have inappropriately affected the deliberative process. When word of the

research leaked out (one of the tapes was played at a Bar Association conference), public outrage led to Senate hearings chaired by James O. Eastland.

Even though there was no evidence that the recordings had influenced the actions of the jury, it was felt that the *possibility* of further recordings being made might affect jurors’ statements or deliberations. A federal law was passed in 1956 banning all recording of jury proceedings.

The Jewish Chronic Disease Hospital

In 1963, researchers from The Sloan-Kettering Institute began a study at Brooklyn’s Jewish Chronic Disease Hospital to investigate certain aspects of the body’s reaction to foreign tissue. The protocol involved injecting a culture of cancerous cells under the skin of elderly, disabled patients with compromised immune systems. Many patients were incapable of giving informed consent and even those who were capable were told the doctors were conducting a “harmless skin test.”

Similar studies had been performed in healthy individuals and in cancer patients and the researchers had no reason to believe that their actions would lead to the development of cancerous tumors in their subjects. Nevertheless, when members of the hospital’s board of directors learned of the study, they

¹⁵Word Human Subject Protection Behavioral Course, Lesson 2 (University of Arkansas Medical Sciences)

took the hospital to court to force disclosure of the study records. Subsequent headlines blared that “Live Cancer Cells” had been injected into helpless elderly patients, and led to the termination of the study. Two of the physicians responsible for the research were put on probation for a year. Three years later, despite these sanctions, one of the researchers was elected president of the American Association for Cancer Research.¹⁶

The Tuskegee Syphilis Study continues to emerge again and again as an example of research gone wrong. From 1932 to 1972 three hundred ninety-nine poor black sharecroppers in Macon County, Alabama, were denied treatment for syphilis and was deceived by physicians of the U.S. Public Health Service. As part of the study, designed to document the natural history of the disease, these men were told that they were being treated for “bad blood.” In fact, government officials went to extreme lengths to insure that they received no therapy from any source. On July 26, 1972, *The New York Times* described the study as “the longest no therapeutic experiment on human beings in medical history.” The disclosure of this study by the press was a major scandal in the United States.¹⁷

The project ended in 1972 after details were reported in the press. Senator Edward Kennedy held hearings on the study, and a class action suit was later brought against the government (including the Department of Health, Education, and Welfare (DHEW) — now known as the Department of Health and Human Services — the Public Health Service, the Centers for Disease Control, and several other government agencies). The case was settled for \$10 million in 1974, to be shared among the surviving subjects and the families of those no longer living.

Because of the Kennedy hearings, the National Research Act of 1974 authorized the DHEW to issue completely redesigned regulations on the use of human subjects in federally funded research.¹⁸ Also, in 1974 congress formed the National Commission for the Protection of Human Subjects in Biomedical and Behavioral Research. The commission wrote the **Belmont Report**, which they issued in 1979. This report is a cornerstone document of ethical principles and federal regulations for the protection of research participants. It is based on respect for persons, beneficence and justice.¹⁹

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

Comments & Questions

¹⁶ Human Subject Protection Power Pt.

¹⁷ Word Human Subject Protection Behavioral Course, Lesson 2.

¹⁸ Human Subject Protection Power Pt.

¹⁹ FHI, 70.

MODULE II

Branch: Research Ethics Principles

Objectives:

To learn the 3 fundamental principles of research ethics

To identify vulnerable research participants

Sub-branches

Respect for persons

Beneficence

Justice

Three Fundamental Principles of Research Ethics

Ethical principles

On July 12, 1974, when the National Research Act was signed into law, the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research was created. A primary charge to the National Commission was to identify ethical principles to guide research involving human subjects. The Commission's *Belmont Report* (formally titled *Ethical Principles and Guidelines for the Protection of Human Subjects of Research*) was published in 1978.

The Belmont Report enumerates three basic principles for investigators conducting research with human subjects:

- **Respect for persons**
- **Beneficence**
- **Justice**²⁰

These principles are considered to be universal—they apply everywhere in the world. These principles do not have national, cultural, legal, or economic boundaries. Everyone involved in human research studies should understand and follow these principles.

Although these principles are universal, the availability of the resources needed to maintain these principles throughout the research process are not universal or evenly distributed. For instance, financial resources available to an ethics committee or a community advisory board may be limited. However, these principles should guide the thinking and behavior of all individuals involved in planning, conducting, and sponsoring research that involves human participants, regardless of limitations.

²⁰ Human Subject Protection Power Pt.

1. Respect for Persons

Question - What words define respect?

Respect for persons is one of the fundamental principles in research: It is the recognition of a person as an autonomous (self-determination), unique, and free individual. It also means that we recognize that each person has the right and capacity to make her or his own decisions. Respecting a person ensures that dignity is valued. Individuals should be empowered to make free decisions and be given all the information needed to make good decisions. To conduct a research project when some of the potential participants do not have the right or the capacity to make a decision is a violation of research ethics and basic human rights. Community representatives can help recognize the unique decision-making process of individuals and communities and suggest the best ways to empower participants to make voluntary decisions.

Define vulnerable people: people who have reduced ability for self-determination

Vulnerable Persons

Some groups are traditionally considered vulnerable research participants. They include:

- Minors
- Pregnant women (avoid unnecessary risk to fetus & additional concerns women face when pregnant)
- Prisoners (confinement & limited freedom)
- Persons with mental disabilities (may lose ability to decide what is best for their health)

In recent years, attention has been given to other types of vulnerable persons (including but not limited to):

- Persons with limited education or illiterate persons who may find it difficult to understand informed consent information.
- Persons with few economic resources who may have limited access to health services and may see their participation in a research study as the only opportunity to obtain needed health care.
- Women in some settings (some women must ask their husbands before consenting to participate in a study).
- Drug users or others who engage in illegal activities.

Vulnerable persons can still participate in a research study; however, they need special protections. The informed consent process, conducted with special care for vulnerable persons, promotes respect for persons. Researchers and community representatives should understand that even small gifts or tokens to research participants could influence decisions, making persons vulnerable.

2. Beneficence

Define Beneficence; Belmont Report that involves an obligation to protect people from harm. Two general rules: 1) do no harm and 2) protect from harm by maximizing benefits and minimizing possible risks of harm.

Discuss kinds of risks that are acceptable or unacceptable in a study

The principle of beneficence makes the researcher responsible for the physical, mental, and social well-being of the research participant. Community representatives can provide input to ensure that the benefits to the research participant are optimal while the risks are reduced to a minimum. The commitment to avoid risks or reduce them as much as possible is also referred to as non-maleficence, from the classic medical profession's promise to "first do no harm."

The risks to a person participating in a research study must be weighed against potential benefits and knowledge to be gained. In addition to benefits and risks to individuals, recent attention has been given to possible benefits or risks to the communities where the research will be conducted.²¹

3. Justice

Define Justice

Justice requires that the burdens and the benefits of research be distributed equitably. This means that research procedures should be carefully chosen and administered, and that costs and benefits should be equitably distributed among persons and groups. Subject selection should not be based solely on convenience to the investigator. Ordinarily, those who bear the risks of research should be those who benefit from it.²²

²¹ FHI, 32-39

²² Human Subject Protection Power Pt.

1. Justice requires the fair and equal distribution of benefits and risks of participation in a research study.
2. Recruitment and selection of participants must be done in a fair and equal manner. Justice forbids exposing one group of people to the risks of the research solely for the benefit of another group.

Community representatives have the responsibility to ensure that community participation in a research study is justified. Community representatives need to be aware of the need for appropriate protections for research participants. They must pay special attention to the benefits that the participants or their communities will receive because of their participation in the research and advise the research team so that incentives offered by the research will not influence the decision to participate. The principle of justice establishes special protections for vulnerable persons. Justice does not permit using vulnerable groups—such as low-resource persons—as research participants for the exclusive benefit of more privileged groups.

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 populations that participate in their studies.

These principles were developed to provide guidance and ensure 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.²³

Comments & Questions

²³ FHI, 40-41.

Branch: 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

To describe who makes up the IRB committees

Sub-branches

IRB/Ethics committee

 selection process

 members' qualifications

Research approval

 biomedical

 behavioral

Research review

Misconduct policies

Because of the ethical documents, codes & regulations IRB or committees were formed. These committees are known by various names, such as a research ethics committee (sometimes referred to as an EC) or an institutional review board (sometimes referred to as IRB). This committee is a group of people from different backgrounds that conduct an independent review of proposed studies on human subjects or participants. The main purpose of ethics committees is to protect human research subjects or participants. This is more important than the interests of the researcher or the institution in which a study will take place.

IRB/Ethics Committee Members

How is the committee selected?

The vice chancellor for academic affairs and research administration appoints members of the IRB, including the chairperson/s. These appointments are for four-year periods and federal requirements mandate that the IRB must have at least five members of various backgrounds. Generally, there are two IRB committees, biomedical & behavioral. At UAMS, there are 20 voting members and 4 alternates on the biomedical committee; 10 voting members nine alternates on the behavioral committee.

Biomedical & Behavioral Committees

Biomedical IRB - Biomedical research is a study that examines the medical results of using different drugs/medicines or medical interventions that have a possibility of helping to diagnose or prevent disease. The idea is to measure how effective the outcome of the drug/medicine.

Example: Diabetes prevention program, major clinical trial.²⁴

Behavioral IRB - Behavioral research primarily examines human behavior. This includes interactions between people, observations of people, or group/individual behavior relating to interventions or experiences. Researchers may use open-ended questions, interviews or focus groups, or surveys inquiring about individual or group knowledge attitudes, perceptions, experiences, or behavioral activities. These studies may test educational, motivational and/or behavioral intervention effectiveness.²⁵

Example: Walking Compared with Vigorous Physical Activity & Risk of Type 2 Diabetes in Women

Committee Members

Both of these committee review studies to decide if they are ethical or governed by principles, respect, beneficence & justice. In order to do this, each committee needs a good mix of people. The guidelines state:

- Some members should have a background in science or research. Members should be qualified to review specific research activities as well as the acceptability of the proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice.
- Some members should have a background that is not scientific so that the review is balanced. An ethics committee may also include religious or other community leaders or former study participants. These members help the ethics committee consider how the research might affect the community in which the study will take place. These members must receive the same level of respect as the scientific members. These representatives are not representing specific communities the same way community partners should in a CBPR project, but rather are there to voice the outside, non-institutional community perspective.

²⁴ Diabetes Prevention Program Research Group. (2002). New England Journal of Medicine, Volume 346, Number 6

²⁵ Institutional Review Board Committees, (University of Arkansas for Medical Sciences) <http://www.uams.edu/irb?IRB_Comm.asp> (14 March 2006)

- Diversity of gender, age, race and ethnic/cultural background among ethics committee members.
- Outside consultants with knowledge of research & ethics if necessary.

Ethics Committees: Review of Research

To decide if proposed studies are ethical, the ethics committee should look at six basic issues:

- Scientific design and conduct of the study. The ethics committee should consider the impact on the safety of the participants in the design of the study. A study design is an outline of a study and how you think it will work;
- Recruitment of research participants. The ethics committee should examine how participants are recruited. Recruitment is the process of enrolling people in research projects; people could be different ages, cultures, gender, etc.
- Community considerations. The study should address a local need or problem and be designed with an understanding of the local community. Input from community representatives can help the ethics committee to do this.
- Care and protection of research participants. The ethics committee must look at how the study positively or negatively affects participants or their communities.
- Informed consent. The ethics committee must decide if the consent forms and process are adequate. 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 of participants. In some research, the greatest participant risk is having confidentiality broken.

Only when these concerns have been addressed should the ethics committee grant approval for the study to begin. Additionally, some ethics committees also review other aspects of the research such as ownership of the data or budgets.²⁶

²⁶ FHI, 25-28

Policy on Misconduct

The Institutional Review Board (IRB) has the authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB Policies, is not in compliance with federal regulations, or has been associated with unexpected serious harm to subjects.

An example of suspensions or terminations *for cause* might include inappropriate involvement of human subjects in research, serious or continuing noncompliance with federal regulations or IRB policies, new information regarding increased risk to human subjects, etc.

Any letter of suspension or termination of approval to an Investigator must include a statement of the reasons for the IRB's action.

If current participants must be withdrawn from the research, the IRB and Investigator will work together to notify the participants, address the procedures necessary to take into account their rights and welfare; and inform participants when follow-up for safety reasons is permitted.

Investigators must continue to report any adverse events or unanticipated problems involving risks to the participants or others.

In addition to the IRB, the Vice Chancellor of Academic Affairs and Research Administration (VCAA/RA) may suspend or terminate approval of research studies or privileges of individual investigators.²⁷

Summary: Ethics Committees

The primary role of ethics committees is to protect human research participants. These mandatory committees meet at least once annually to approve or disapprove new research projects and review the progress of ongoing studies. An ethics committee has a minimum of five members, some of whom have a background in research or science, while others are nonscientists and represent community interests.

In order to grant approval to initiate a study, close examination of scientific design and conduct of the study, participant recruitment measures, community considerations, care and protection of participants, informed consent, and confidentiality issues is necessary. It may be in the interest of the community that a formally established community-working group contact the local ethics committee and express readiness to help.²⁸

Comments & Questions

²⁷ Institutional Review Board Standard Operating Policies & Procedures, (UAMS) <http://www.uams.edu/irb/IRB_Policies.asp> (14 March 2006).

²⁸ FHI, 29

Branch: Research Process

Objective: to identify basic components of the research process

Sub-branches

What is the research process?

Research process is the route researchers take to get answers to questions.

1. Issue selection

Question: How is an issue selected?

If the community is already involved in a research project research **discuss** how their issue was selected.

If not:

The first step in the research process begins with an idea. Someone wants to find out about a particular “issue” or improve “something.” Typically, researchers ask the questions about a specific issue based on their interest, knowledge of the issue and resources (time, finances, etc.)

Questions to ask about an idea:

Is it practical?

Has it been done before?

How much time do we have?

Can it be done?

What might the results be?

2. What method do we use to study the issue? There are three study designs: Experimental, quasi-experimental and non-experimental.

Experimental

In the simplest type of experiment, two groups are created who are alike – the special research groups we discussed earlier. Similar people, living in similar environments, having similar backgrounds, and so on. One group (the program or the treatment group) gets the program and the other group (the comparison or control group) does not. In all other respects the groups are treated the same. How do you create two groups that are equivalent? The approach used in experimental design is to assign people randomly from a common pool of people into two groups; the key to the success of the experiment is in the random assignment. Experimental designs are the most

“rigorous” (accurate, careful, exact, and precise) of all or are the “gold standard” against which all other designs are judged.²⁹

Example: diabetes prevention study (3 year study, findings published February 7, 2002, issue of the New England Journal of Medicine) participants from 27 clinical centers around the country were randomly split into two different treatment groups. There were three groups of people; one group received a diabetes drug, one group received lifestyle intervention & the other received placebo pills (a harmless material given as medicine).

Quasi-experimental

A study design that in which two groups of subjects or participants are studied but not randomly assigned. An example of a quasi-experimental design would be a study in which you examine the effects of smoking on respiratory function. You might have people who smoke one pack a day and two packs a day smokers, but you can't really assign them into these groups (is it ethical to make people who smoke 1 pack a day now smoke 2?). You would then run your study, but when you make a conclusion, you cannot make any cause and effect conclusions.

Non-Experimental or Observational

In an observational study, the researcher measures but does not intervene; a study of something that can be observed as it really is and there is no attempt made to change the subject or participant in the research process.³⁰

Example: the rate of occurrence of lung cancer among smokers may be compared to the rate among nonsmokers; the researcher does not decide who smokes.

3. Secure funding. Doing research costs money – so at some point, you have to find some money to support the work. Government agencies, universities, corporations, or foundations of various kinds usually fund research projects. Sometimes funders have their own ideas and questions about particular issues and will provide resources for a study. In that case, community members and researchers respond to a request for proposals. At other times, community members and researchers may solicit funds for study topics that are on their agenda.

²⁹ William M. Trochim, “The Research Methods Knowledge Base,” August 16, 2004, <<http://trochim.human.cornell.edu/kb/index.htm>> (3 March 2006).

³⁰ Teaching & Learning Research Methodologies, (University College Dublin, 2006), <<http://www.ucd.ie/teachings/res/non.htm>> (30 March 2006).

4. IRB - Flow Chart for Study Submission Process

Protocol: a detailed research plan that gives information about how the research will be done; includes purpose of the research, the research question, why the study is important, results we anticipate, and all materials that will be used in the study (questionnaires, surveys).

Exempt research: type of research study that involves educational tests, surveys, interviews or observation of public behavior and does not require approval by the IRB; research using existing information on records, samples of body material if publicly available or unidentifiable; written consent is usually not required.

Expedited review– type of research study that does not have to be reviewed by the entire IRB committee; the IRB chairperson or one of the members of the IRB committee may approve study; examples of expedited studies include: records, specimens or documents not used for research & information from voice video, digital or image recordings made for research purposes.

Full or Standard Committee Review - type of research that does not qualify for expedited or exempt review; research study will be reviewed at the full committee meeting and the study must receive the approval of the majority of those members present at the meeting; quorum is met; the committee meets once a month.³¹

Personal story from community or academic researcher

Discuss frustrations, length of time for approvals, etc.

5. Recruitment

- Community partners can help with recruiting participants into community studies.
- Advertising for research subjects in a variety of media outlets: newspapers, email, radio, television, bulletin boards, poster, etc.³² Advertisements used to recruit subjects should be seen as an extension of the informed consent and subject selection processes. Therefore, the UAMS IRB will review all advertisements to ensure that the information is not misleading to subjects, especially when a study will involve persons with acute or severe physical or mental illness or persons who are economically or educationally disadvantaged.

³¹ IRB, 7.3, 7.4 & 7.5

³² Acceptable Methods to Recruit Subjects for Research, (University of St. Louis, 2006), <<http://www.slu.edu/research/irb/documents/RecruitmentMethods.doc>> (20 March 2006).

- Mining Databases. Searching Medical Records or other Databases of Patient information looking for potential participants requires IRB approval prior to the search. (NOTE: A search to find out if a patient population exists in anticipation of a research project would not be considered recruitment provided no identifying information was retained to be used later.)
- Primary Care Physicians. Contacting primary care providers (PCP) for access to potential participants from the patient population of the PCP is another method of potential recruitment. This would require IRB approval prior to initiation and the PCP may be subject to HIPAA restraints that would prevent him/her from sharing PHI with the Investigator.³³

6. Informed consent

Objectives:

To explain the concept of informed consent

To name and discuss the 8 essential elements of informed consent

Sub-branch

Goals of the informed consent process

Children in research

Community representation & informed consent

Creation of informed consent documents

Essential elements of informed consent

Goals of the informed consent process:

- the subject or participant gets information about the study
- the subject or participant has time to consider all options
- questions that the subject or participant has are answered
- all information is understood by the subject or participant
- the subject's or participant's voluntary informed consent to participate has to be obtained
- the subject or participant has to be informed throughout the research study

³³ Institutional Review Board Recruitment Practices, 14.3 <http://www.uams.edu/irb/IRB_Policies.asp> (University of Arkansas Medical Sciences, 2002)

- continue to confirm subject or participant consent to participate throughout the research study³⁴

Children in Research

There are special regulations in place to keep children safe and protected from harm when they participate in research. The IRB approves research involving children under particular guidelines. In Arkansas, children include all those who have not yet reached their 18th birthday. Children under 18 and beginning at 7 can agree to participate in research; this is called assent. When children are recruited, it should be done so they do not feel pressured; they should be informed in language and terms they understand. Consent from parents or legal guardians must be gotten before children can be enrolled as research a subject or participant. The child must be informed about the purpose of his/her voluntary participation. There are individuals who called emancipated minors; they are under 18, living on their own, financially independent, have a child or are married.

Permission: the agreement of parent(s) or guardian to allow their child to participate in research.

Parent: a child's biological or adoptive parent.

Guardian: an individual who is authorized by state or local law to consent on behalf of a child.

Emancipated Minors

There exceptions to the rule of obtaining assent and seeking parental consent for individuals considered emancipated minors. Emancipated minors may include individuals who are under the age of 18, living on their own and financially independent from their parent(s) or legal guardian(s), have borne a child, or who are married. Consent is sought from an emancipated minor; not assent. ³⁵

Community Representatives and the Informed Consent Process

1. Community representatives can offer culturally appropriate guidance when researchers are developing the informed consent process. Involvement at this stage safeguards each potential participant's ability to make an informed, voluntary choice to participate or not to participate in the research. The information provided during the informed consent process must be carefully

³⁴ A Guide for Researchers, (Western Institutional Review Board, 2006), <<http://www.wirb.com/download/guide%20for%researchers%20090605.pdf>> (16 March 2006)

³⁵ Word Human Subject Protection Behavioral Course, Lesson 5

selected based on the needs of both the researcher and the research participants.

2. Since the information the researcher considers essential may be extensive or difficult to understand, it is necessary to include evidence or indicators that the participant has understood this information. Information that is not understood is the same as no information, and the informed consent is meaningless. Community input is particularly valuable in selecting the type and sufficiency of the information provided and the indicators that confirm that the potential participant can understand the information. Rumors may surface at any time in the research process. Community representatives can work with the research team to help resolve them.

Once people start hearing about a new study, the informed consent process is under way. What people hear from this point on could influence what they think about the project and their decision to be involved. For this reason, it is important for community representatives to help to plan how to introduce a new study.

Creation of Informed Consent Documents

- written so a person with no medical background can understand
- written to the appropriate reading level
- It is strongly advised that materials and forms be tested for appropriateness before they are used in screening or actual enrollment. This practice, called pilot testing, involves a person who knows the materials and uses them with someone who is very similar to the individuals to be recruited for the study. Based on results from this test, the materials may need to be revised to make them more understandable.

Activity: pass out local sample consent form to participants; ask them to take 10 minutes to read it individually or in a group. Discuss essential elements of the form noting any weaknesses.

Discuss participants' observations.

Essential Elements of Informed Consent

Developing or selecting the information to be included in the informed consent process is very important. The process benefits from the involvement of community representatives and usually includes an 8-point framework:

1. Description of the research and the role of the participant, including an explanation of all procedures relevant to the participants

A description of the research is commonly presented at the beginning of the informed consent process and documentation. It should clearly explain that the potential participant is being asked to participate in a research study. It is common for participants to mistakenly believe they will receive a free and effective treatment. It must be clear that the safety and efficacy of such treatment is not known and is precisely the reason why the research is being conducted. Potential participants must understand that they will not be receiving standard or routine care services. The purpose and objectives of the research must be clearly presented, explaining the new information being sought.

All the procedures involved in the research, e.g., number of blood samples, diagnostic tests, number of follow-up visits, or interviews, must be detailed to ensure that the participant understands that she or he is agreeing to undergo such procedures, particularly to those procedures that are experimental. The anticipated duration of the person's participation must be clearly stated.

When the research requires the use of a placebo, it is essential to confirm that the potential participant has understood that she or he may actually not receive any treatment at all. The use of placebos often requires special attention in the informed consent document and process, because many people have difficulty understanding the concept. It is also important to disclose the names of the institution(s) responsible for the research, the sponsors, and the members of the ethics committees and community advisory boards that reviewed approved the research.

2. Description of reasonably foreseeable risks

The informed consent process must make the potential participant well aware of all anticipated or foreseeable risks associated with the study. Consideration must be given not only to physical, but also to mental and social risks, e.g., social stigmatization to participants in HIV/AIDS prevention or treatment studies. Participants must be notified promptly if any new risks are identified during the conduct of the study. The amount of information on the possible risks, likelihood of such risks occurring, and their severity and duration, require careful consideration in the planning of the informed consent

process. The challenge is to present no more or no fewer risks than is necessary.

3. Description of expected benefits

The informed consent documentation must include a description of any benefits to the participant or others that may reasonably be expected from the research.

Benefits must be presented without overstatement or exaggeration with the intent to induce participation. The provision of health care to which the potential participant is entitled without participating in the research must not be presented as a research benefit.

Persons with limited access to health care services are vulnerable research participants. Offering health care to individuals who otherwise do not have access to this care is potentially coercive. Researchers are responsible for ensuring that the potential participant's decision is not unduly influenced by the opportunity to receive health care.

Benefits are commonly presented as available only during the study. In other words, when the research is finished, the benefits also end. The duration of any benefit associated or derived from the research participation must be clear to the potential participants beforehand. What benefits or services will be available to participants when the research is ended, or if she or he decides to withdraw from the study, should be explained in the informed consent process. This is particularly important in studies of new treatments. If the treatment proves to be safe and effective, the participant must be informed of availability when the study is terminated.

4. Alternatives to participation, such as other studies or services in the area

It is important to present to the potential participant the existing alternatives or choices other than participation in the study. The participant should be given information on the advantages and disadvantages of the alternatives and allowed the opportunity of choosing between participating in the study or the alternatives. For some research, there is no alternative—the only choice would be to not participate. In biomedical research, the potential participant must be informed of the regular health care options available compared to the research options. In essence, the information gives the person the choice not to participate.

5. Explanation of confidentiality

In the informed consent process, they must be informed about the degree of confidentiality throughout the study and once the study is over. This section should mention all the persons or organizations who may review or have access to the research records. If the researcher's capability to protect any confidential information is limited, the extent of this limitation must be disclosed. Special attention to confidentiality is necessary when public knowledge of participation is potentially damaging to the participants or their community.

6. Explanation of compensation for injuries or health problems resulting from participation in the study

Any compensation of economic value associated with participation in the research must be explained. No compensation of any type should have any coercive effect to participate in the study. It is common to compensate participants for their time, travel, and inconvenience. The amount or value of this compensation should not be so high as to unduly influence a potential participant's decision to participate in the study.

Input from community representatives is needed at the beginning of the study to determine the appropriate amount and type of compensation. Information must be disclosed about available treatment, the degree and duration of treatment, and who would pay for it in the case of injury or complications related to the research. Community representatives need to be aware of the research, institution, national, or sponsor policies on compensations available to the research participants.

Sometimes treatment will be provided free of charge for injury or complications associated with the research. However, the resources available for this purpose may be limited.

Note: The difference between benefits and compensation should be made known to participants. Compensation, usually in form of payment for transportation expenses or a token of appreciation, is generally given at the enrollment stage or after a visit to the study clinic. Benefits, such as drugs, health care, and the like, are usually given only during the study.

7. Whom to contact about the research if the participant has questions or concerns

In the informed consent documentation, three groups of contacts should be considered:

- Research team
- Ethics committees

- Special groups (such as members of a community representative group or a special interest group)

Information should include name, address, phone number, or any other means to establish contact with these persons. The contact information must be realistic, economically viable, and culturally appropriate. The names of the responsible researcher/s should be provided to address participant questions, complaints, or any health care problems. The inclusion of the research sponsor can provide the participant with the option of direct communication with the sponsor.

However, it is generally easier for a participant to contact the research site before trying to reach the study sponsor directly. Contacts outside of the research team are needed to address possible concerns about participation or the quality of the care. Names of members of the ethics committee must be included.

In some types of research, contact information for counseling groups or groups of persons with the same disease may be appropriate.

8. Explanation that participation is voluntary

It is important to assure the potential participant that participation in the research is absolutely voluntary and that he or she will be free to discontinue participation at any time. The information should indicate that refusal to participate or decision to withdraw will not result in any penalties or loss of benefits to which the participant is otherwise entitled. However, it should be made clear how important the participant is and how much it means that he or she complete the study. If many of the participants do not follow procedures and the study is compromised, then opportunity, time, and money have been Lost.³⁶

Introduction to Health Insurance Portability and Accountability Act 1996 (HIPAA)

Question: What is HIPAA?

HIPAA, which stands for the American Health Insurance Portability and Accountability Act of 1996, is a set of rules to be followed by doctors, hospitals and other health care providers. HIPAA took effect on April 14, 2003. HIPAA helps ensure that all medical records, medical billing, and patient accounts meet certain consistent standards with regard to documentation, handling and privacy.

³⁶ FHI, 46-60

In addition, HIPAA requires that all patients be able access their own medical records, correct errors or omissions, and be informed how personal information is shared used. Other provisions involve notification of privacy procedures to the patient. HIPAA provisions that have led in many cases to extensive overhauling with regard to medical records and billing systems (hippa.101.com).

Question: How does HIPAA affect research?

The major areas of research affected are the informed consent process and the written informed consent document. It will also greatly affect review preparatory for research (pre-research) and sharing of research information with sponsors and any other person or group outside of the research institution. Research falls under the “covered entities” portion of HIPAA and therefore all people involved with research now have additional rules to follow to protect the confidentiality of medical and research information.

The HIPAA legislation covers all research that has any personal identifiers that can be used to trace research information back to an individual, whether living or dead. This includes research data that is written or electronic, and all human samples.³⁷

7. Data collection

Question: What are some ways that information is gathered?

There are many ways to get information. The most common ways are literature search, talking with people, focus groups, personal interviews, telephone, mail, surveys and administration data collection.

A literature search involves reviewing all readily available materials. These materials can include publications, newspapers, magazines, annual reports, on-line databases, and any other published materials. It is a very inexpensive method of gathering information, although it often does not yield timely information. Literature searches over the web are the fastest, while library literature searches can take between one and eight weeks.

Talking with people is a good way to get information during the initial stages of a research project. It can be used to gather information that is not publicly available, or that is too new to be found in the literature. Examples might include meetings with community coalitions, community-based organizations and associations. Although often valuable, the information has questionable validity because it is highly subjective and might not be representative of the population.

³⁷ Health Insurance Portability & Accountability Act Training for Community Connectors (University of Arkansas Medical Sciences-Office of Community-Based Public Health, 2005).

A focus group is used as a preliminary research technique to explore people's ideas and attitudes. It is often used to test new approaches. Groups of 6 to 12 people meet in a conference-room-like setting with a trained moderator. The moderator leads the group's discussion and keeps the focus on the areas you want to explore. The meeting is usually taped and written documentation is done. Their disadvantage is that the sample is small and may not be representative of the population in general.

Personal interviews are a way to get in-depth and comprehensive information. They involve one person interviewing another person for personal or detailed information. Typically, an interviewer will ask questions from a written questionnaire and record the answers verbatim. Personal interviews are generally used only when subjects are not likely to respond to other survey methods.

Telephone surveys are the fastest method of gathering information from a relatively large sample (100-400 respondents). The interviewer follows a prepared script that is essentially the same as a written questionnaire. However, unlike a mail survey, the telephone survey allows the opportunity for some opinion probing. Telephone surveys generally last less than ten minutes.

Mail surveys are a cost effective method of gathering information. They are ideal for large sample sizes, or when the sample comes from a wide geographic area. They cost a little less than telephone interviews, however, they take over twice as long to complete (eight to twelve weeks). Because there is no interviewer, there is no possibility of interviewer bias. The main disadvantage is the inability to probe respondents for more detailed information.³⁸

Administration data: office records - bills & claims

8. Intervention

Question: What is an intervention?

Taking action to change what is happening or might happen in another's affairs in order to prevent something unwanted.

Example:

We might do a health behavior intervention to decrease unhealthy diets and a couch potato life-style (sedentary) because diabetes is a big health issue in our community.

³⁸ Research Methods, (Stat Pac-Survey Software, 2006) <<http://www.statpac.com/surveys/research-methods.htm>> (8 February 2006).

9. Data analysis - Describes what we found out.

We've collected all this information. Now we have to organize and exam it so we can come to some conclusions. We might use charts, graphs, tables and narratives (give an account of events in the order they happened) to describe our findings. We also may use statistics (data with numbers) and logical techniques to describe, summarize and compare data/information

10. Dissemination

Question: Who gets the information about the findings of the research?

Study participants, community members, researchers, funders and the public.

Question: How do they they get it?

Through various mediums: community meetings, scientific journals and conferences, newspapers, television, radio.

Question: What is the purpose of this dissemination activity?

To ensure that information/knowledge is useful in reaching decisions, making changes, or taking specific action and is available to those who can most benefit from it.

Comments & Questions

Final Comments & Questions