



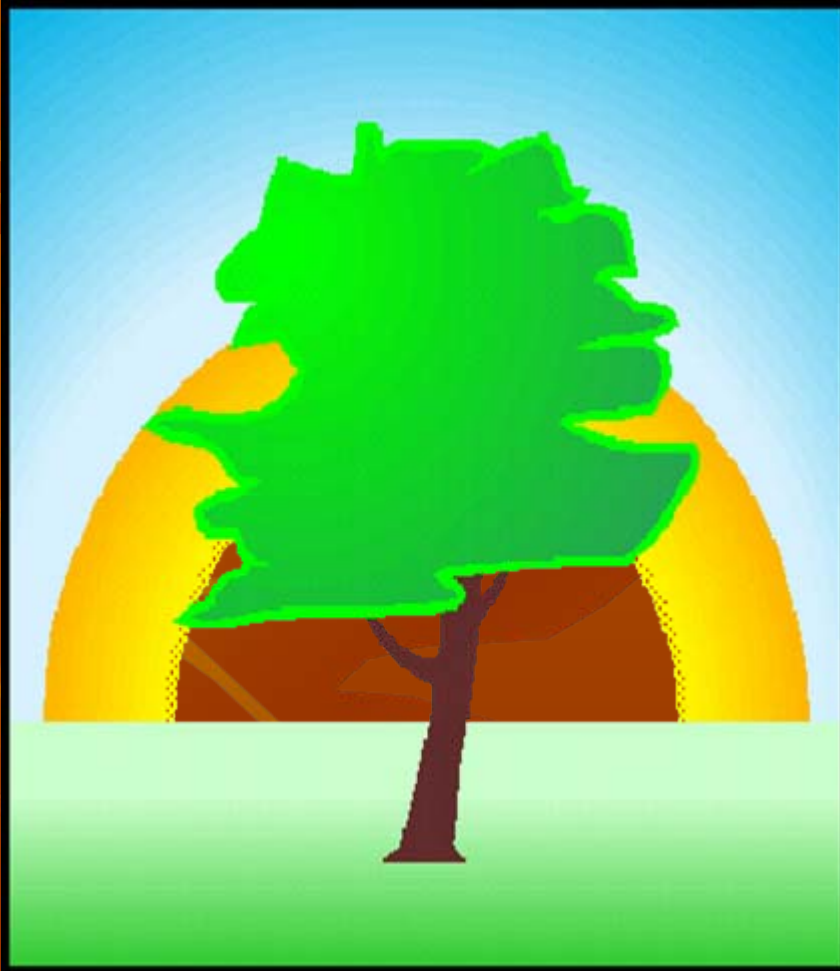
COMMUNITY RESEARCH WORKSHOP

Community Research Workshop

Activity: Opinions & Attitudes

Source: Family Health International, 2004

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.

Goal



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

Objectives



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

CONTENT OVERVIEW



Module I

Branch 1: Health Research

Branch 2: Community Participation

Branch 3: History – Past & Present

CONTENT OVERVIEW



Module II

Branch 4: Research Ethics Principles

Branch 5: Institutional Review Board/Ethics
Committee

Branch 6: Research Process

HEALTH RESEARCH

- What is research?
 - Organized way to gather information to answer questions
- What is a research subject or participant?
 - Anyone for whom information is gathered

Source: E. Eng, Protecting People Who Participate in Research, 2004

Health Research

What are some medical or health related benefits of research?

Health Research

- **Medical Benefits**
 - Vaccination
 - Recognition of tobacco use as a health hazard
 - Decline in deaths from coronary heart disease and stroke

Source: National Institute of Health, 2001.
Center for Disease Control, 2006. AHQR, 2006.
Wenger, et al, CVD in Women, 1993



Health Research

- Policy & Policymaker Benefits
 - Unequal Treatment Study by the Institute of Medicine

Source: Rural Health Research Centers, 2006

Health Research

Comments & Questions

Community Participation

What is a community?

What kind of community do you belong to?

What are some characteristics of your community?

Source: Family Health International, 2004

COMMUNITY PARTICIPATION

Characteristics of a Community

- A group linked by:

- Location

- Common perspectives

- Joint action



Source: Family Health International, 2004

Characteristics of a Community

- Special research communities
 - Persons with the same disease
 - Persons with the same profession

Source: Family Health International, 2004

Characteristics of a Community

- Special research communities
 - Persons from the same population
 - Persons living in a specific geographic community

Source: Family Health International, 2004

Community Participation

Why is it important
that community
members
participate in the
research process?

Activity:
Small Group Discussion



Source: Family Health International, 2004

Community Participation

WHY?

- Protects research subjects or participants
- Helps researcher develop goals
- Improves the way research is designed
- Increases chances of sustained effort

Source: Family Health International, 2004

Roles & Responsibilities of Community Representatives

- Ensure research is responsive to community needs & expectations
- Advocate for research participants or subjects well-being



Source: Family Health International, 2004

Roles & Responsibilities of Community Representatives

- **Ensure appropriate informed consent**
- **Secure access to research benefits**

Source: Family Health International, 2004

Community Representatives' Role

Rumors !!!!!!!!!



Community-Based Participatory Research (CBPR)

What is Community-Based Participatory Research?



Community-Based Participatory Research (CBPR)

- Collaborative approach to research
- Equitably involves all partners
- Recognizes unique strengths

Source: LW Green (cited), 2004

Community-Based Participatory Research

Traditional Research	CBPR
<ul style="list-style-type: none">■ Identifies issues based on study of disease, how it spreads & funding priorities	<ul style="list-style-type: none">■ Community identifies issues of greatest importance <p data-bbox="1489 1136 1818 1172">Source: AHQR, 2004</p>

Community-Based Participatory Research

Traditional Research	CBPR
<ul style="list-style-type: none">■ Academics make design decisions■ Approaches to recruitment & retention based on scientific issues	<ul style="list-style-type: none">■ Community involved with design decisions■ Community provides guidance in recruitment & retention strategies

Source: AHQR, 2004

Community-Based Participatory Research

Traditional Research	CBPR
<ul style="list-style-type: none">■ Measurement instruments are adopted/adapted from other studies■ Manage all resources	<ul style="list-style-type: none">■ Community helps develop measurement instruments■ Co-manage resources <p data-bbox="1489 982 1818 1018">Source: AHQR, 2004</p>

Community-Based Participatory Research

Traditional Research	CBPR
<ul style="list-style-type: none">■ Researchers design intervention based on literature & theory■ Researchers report findings from analysis & publish in peer review journals	<ul style="list-style-type: none">■ Community help guides intervention development■ Community assist with interpretation & dissemination of findings <p data-bbox="1489 1206 1818 1243">Source: AHQR, 2004</p>

Community Participation

Comments & Questions

RESEARCH HISTORY



Research History

- World War II - 1939-1945
 - Freezing experiments – Nazi Germany
- Nuremberg Code - 1946

Source: E. Eng, Protecting People Who Participate in Research, 2004
BC Cohen, Jewish Law, 2006

Research History

- Nuremberg Code of Principles
 - Researchers are responsible for obtaining voluntary informed consent
 - Experiments should benefit society
 - Research should not cause unnecessary physical or mental suffering

Source: Human Subject Protection, Harvard University, 2001

Research History

- Nuremberg Code of Principles
 - Risks should be reasonable
 - Researchers should be qualified & professional
 - Research subjects or participants must be able to stop participation

Source: Human Subject Protection, Harvard University, 2001

Research History

- Nuremberg Code of Principles
 - Researcher should stop study any time research subjects or participants may be harmed

Source: Human Subject Protection, Harvard University, 2001

Research History

- 1964 World Medical Association
 - Declaration of Helsinki
 - Document focused on ethical principles

Source: Human Subject Protection, University of Arkansas, 2005

Research History

- United States 1950's to 1970's
 - Wichita Jury Study - 1953
 - Munson Jewish Chronic Disease Study – 1963

Source: Human Subject Protection, Harvard University, 2001

Research History

- Tuskegee Study
1932-1971
- Belmont Report
1974
 - Federal
regulations
 - Ethical principles

Source: Human Subject Protection, University of Arkansas, 2005. Family Health International, 2004.



Research History

Comments & Questions

Principles of Research Ethics

What is research ethics?

Standards that affect how research is
conducted

Three Principles of Research Ethics



1. Respect for persons

2. Beneficence

3. Justice



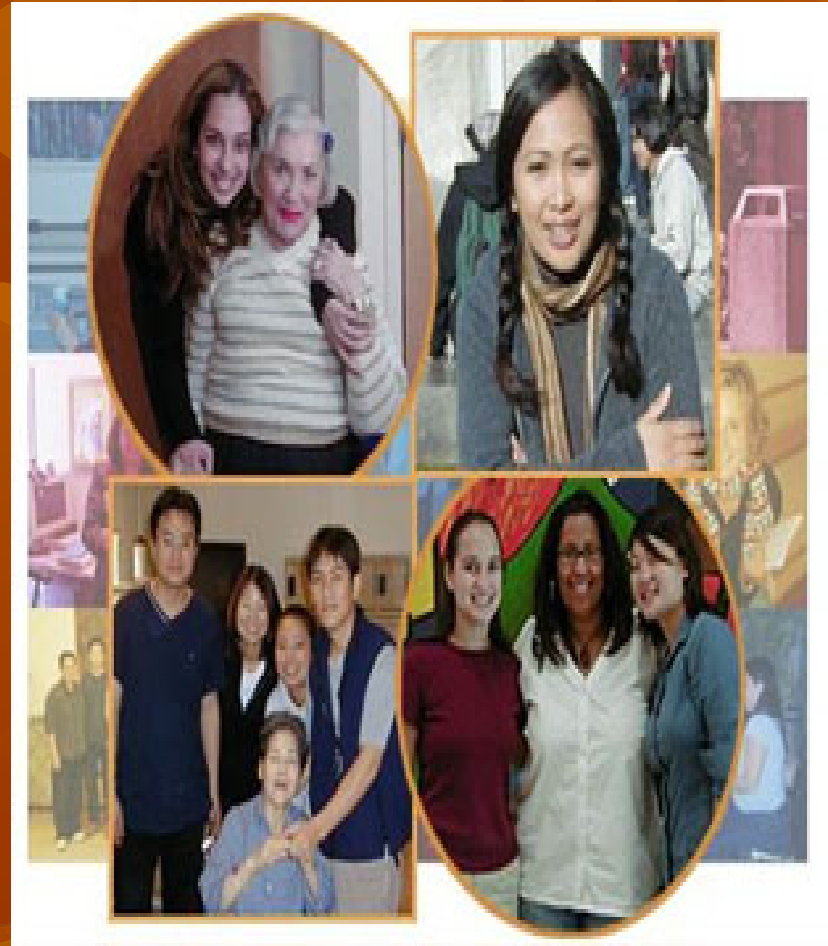
Research Ethics

Principle 1

Respect for Persons

What words or sentences
can you think of that
define respect for
persons?

Source: Family Health International, 2004





Principles of Research Ethics 1

- Respect for persons
 - Self-Determination
 - Unique
 - Free

Source: Family Health International, 2004

Principles of Research Ethics 1



What is a vulnerable persons?

A person who have decreased ability to make decisions for themselves

Source: Family Health International, 2004

Principles Research Ethics 1

- Vulnerable persons

- Minors

- Pregnant women

- Prisoners

Source: Family Health International, 2004



Principles of Research Ethics 1



- Persons with limited education
- Persons with few economic resources
- Persons with mental disabilities

Source: Family Health International, 2004

Principles of Research Ethics 1



- Drug users
- Women in some settings

Source: Family Health International, 2004

Principle of Ethics Research 2



Beneficence

What does beneficence mean?

Principle of Ethics Research 2

- Beneficence
 - Do no harm
 - Maximize possible benefits & minimize possible harm

Source: Family Health International, 2004



Principles of Ethic Research 2



What kinds of risks are acceptable or unacceptable in a study?

Principle of Ethics Research 3

Justice

How do you define justice?





Research Ethics Principle 3

■ Justice

- Fair & equal distribution of benefits & risks of subjects or participants
- Fair & equal subject or participant recruitment

Source: Human Subject Protection, Harvard University, 2001

Family Health International, 2004

Research Ethics Principle

Comments & Questions

Institutional Review Board/Ethics Committee



**What is an Institutional Review Board
(IRB)?**

**A committee of people whose goal is to protect
human research subjects or participants**

Institutional Review Board

Facts about the committees



Institutional Review Board Committee Selection



- Appointed by Vice chancellor for academic affairs and research administration
- Four year periods
- Federal requirements at least five members

Source: IRB Committee, University of Arkansas, 2006

Institutional Review Board Committees



- Biomedical/clinical research
 - Examines the medical results of using different drugs/medicines or medical interventions that have a possibility of helping to diagnosis or prevent disease
 - Measure the effectiveness of the drug/medicine

Source: IRB Committee, University of Arkansas, 2006

Institutional Review Board



- Behavioral research
 - Primarily studies human behavior
 - Open-ended questions, interviews or focus groups, or surveys
 - Studies test educational, motivational and/or behavioral intervention

Source: IRB Committee, University of Arkansas, 2006

Institutional Review Board



What are the qualifications of committee members?



Institutional Review Board Members

- Qualifications
 - Background in science or research
 - Community or religious leaders
 - Former study subjects or participants
 - Local community representatives

Source: Family Health International, 2004

Institutional Review Board Members



- Diverse

- Gender

- Age

- Racial/ethnic/cultural background



Source: Family Health International, 2004

Institutional Review Board



How does the IRB committee protect human research subjects or participants?

Institutional Review Board



- Committee makes decisions about the research study based on:
 - Design & conduct of the study
 - Community considerations
 - How participants are recruited

Source: Family Health International, 2004

Institutional Review Board



- Care & protection of research participants
- Confidentiality issues
- Informed consent

Source: Family Health International, 2004

Institutional Review Board



What happens if a researcher does not follow the protocol or plan?

Institutional Review Board Policy on Misconduct



- Suspension or termination
 - Inappropriate involvement of participants in research
 - Serious or continuing non-compliance with federal regulations or IRB policies
 - New information regarding increased risk to participants

Source: IRB Policies & Procedures, University of Arkansas, 2004

Institutional Review Board



Comments & Questions

Research Process

What is the research process?

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

Research Process

- Issue selection
 - Identify the problem
 - Define the research question



Research Process

- Study design
 - Experimental
 - Researchers randomly assign research subjects or participants to receive an intervention or not receive an intervention
 - Example: Diabetes Prevention Study

Source: W. Trochim, The Research Methods Knowledge Base, 2004

Research Process

- Study Design

- Quasi-experimental

- A study design that in which two groups of subjects or participants are studied but not randomly assigned

- Example: researcher studies smoking on respiratory function

Source: Teaching & Learning Research Methodologies, University College Dublin, 2006

Research Process

- Study Design
 - Non-experimental
 - Researcher observes & measures an event but does not intervene
 - Example: researcher does not decide who smokes when comparing the amount of lung cancer between smokers & non-smokers

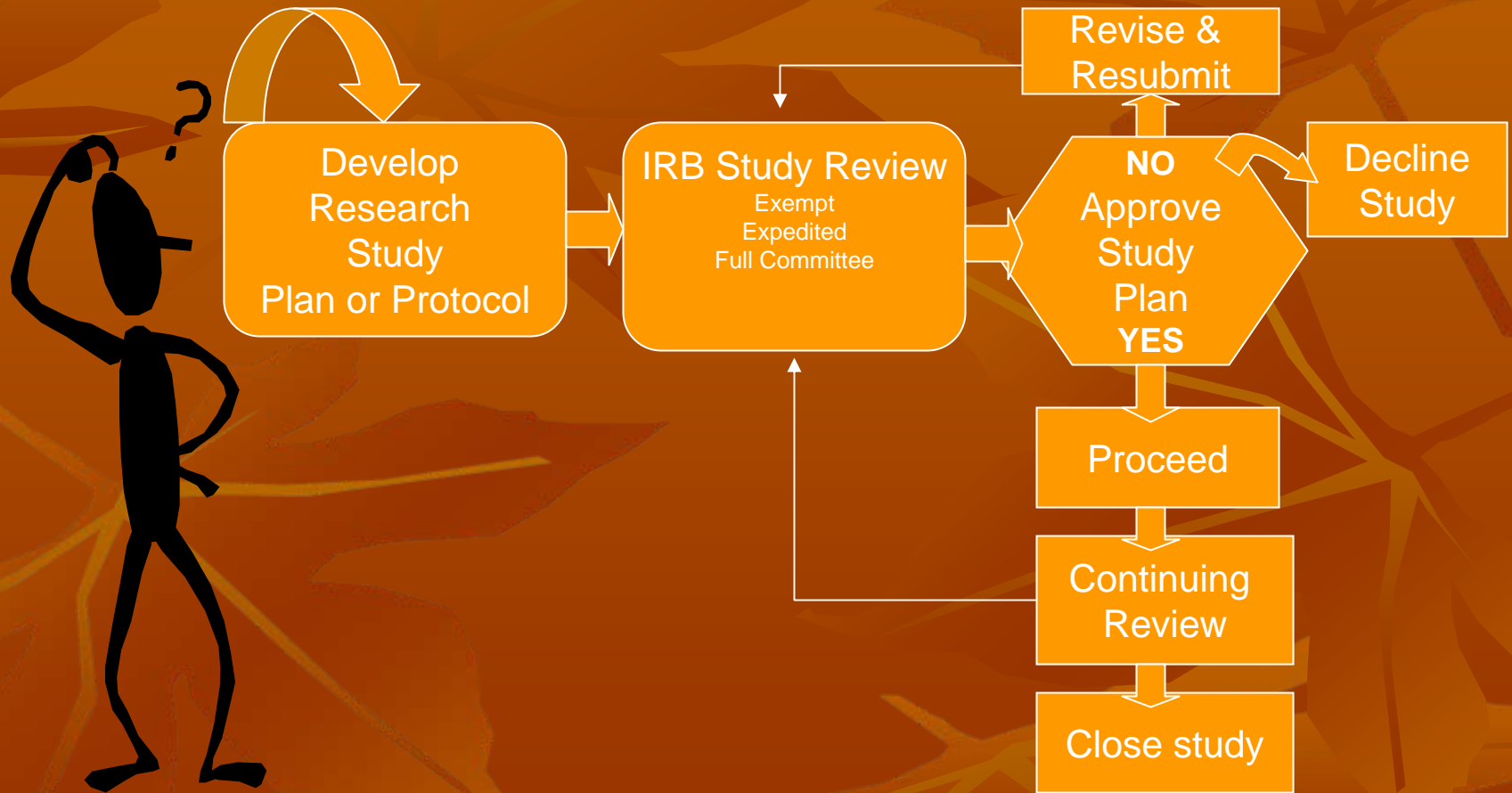
Source: Teaching & Learning Research Methodologies, University College Dublin, 2006

Research Process

- Secure funding
 - Call for proposals by funder
 - Community & researchers solicit funds
 - Research projects funded by government agencies, universities, corporations, or foundations



Institutional Review Board (IRB) Process



Research Process

- Recruitment
 - Community partners
 - Advertising
 - Medical records or other databases of patient information
 - Primary care physicians

Source: IRB Recruitment Practices, University of Arkansas, 2002





Research Process: Informed Consent

■ What is informed consent ?

“Consent given by a competent individual who”

- Has received the necessary information
- Has adequately understood the information
- After considering the information, made a decision without pressure

Source: A Guide for Researcher, Western IRB, 2006



Informed Consent Goals

- The subject or participant gets information about the study
- The subject or participant has time to consider all choices
- The subject or participant's questions are answered

Source: A Guide for Researcher, Western IRB, 2006



Informed Consent Goals

- The subject or participant understands all information
- The subject or participant's voluntary written informed consent to participate is obtained
- The subject or participant is informed throughout the research study

Source: A Guide for Researcher, Western IRB, 2006



Informed Consent Goals

- The subject or participant consent to participate throughout the research study is confirmed

Source: A Guide for Researcher, Western IRB, 2006



Informed Consent

- Children in research

- What is assent ?



- Children under age 18 and beginning at age 7 can agree to participate in research

- Written assent

Source: Human Subject Protection, University of Arkansas, 2005





Informed Consent & Children

- Guidelines
 - Children should not feel pressure when recruited
 - Children should be informed in language and terms they understand.

Source: Human Subject Protection, University of Arkansas, 2005



Informed Consent & Children

- Children should be informed about the purpose of his/her voluntary participation
- Consent from parents or legal guardians

Source: Human Subject Protection, University of Arkansas, 2005



Informed Consent & Emancipated Minors

- What is “emancipated minors?”
 - Individuals under the age of 18
 - Living independently of parent or legal guardian
 - Financially independent from parent or legal guardian



Source: Human Subject Protection, University of Arkansas, 2005

Informed Consent & Emancipated Minors



- Have borne a child
- Married.
- Consent not assent is sought from an emancipated minor

Source: Human Subject Protection, University of Arkansas, 2005



Informed Consent & Community Representative Role



- Participate in the draft & review of informed consent process
- Advice is essential for:
 - Review agreement or approval

Source: Family Health International,
2004



Informed Consent & Community Representative Role



- Participant understanding
- Vigilance

Source: Family Health International, 2004

Elements of Informed Consent Document



Activity: Review Sample Consent Form

Source: Family Health International, 2004

Health Insurance Portability and Accountability Act 1996 (HIPAA)

What is HIPAA?

Health Insurance Portability and Accountability Act

- Set of rules for doctors, hospitals and other health care providers
- Standards for medical records, medical billing, and patient accounts
- HIPAA took effect on April 14, 2003

Source: HIPAA Training, University of Arkansas, 2005

Health Insurance Portability and Accountability Act

- Requires patients access to medical records
- Correct errors or omissions in medical records
- Be informed how personal information is shared

Source: HIPAA Training, University of Arkansas, 2005

Health Insurance Portability and Accountability Act

- How does HIPAA affect research?
 - Informed consent process
 - Written informed consent document
 - Pre-research - sharing research information with funders & others

Research Process

- Data collection
 - Literature search
 - Focus group
 - Personal interviews
 - Telephone & mail surveys

Source: Research Methods, Stat-Pac Survey, 2006



Research Process

■ Intervention

- An action that changes the course of a disease process
- An activity that is designed to change behavior
 - Example: health behavior intervention to decrease unhealthy diets & couch-potato life-style

Research Process



- Data analysis
 - Collect
 - Organize
 - Exam
 - Make conclusions

Research Process

- Dissemination
 - Community meetings
 - Scientific journals & conferences
 - News media

