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
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
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
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

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

<table>
<thead>
<tr>
<th>Traditional Research</th>
<th>CBPR</th>
</tr>
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<tbody>
<tr>
<td>• Identifies issues based on study of disease, how it spreads &amp; funding priorities</td>
<td>• Community identifies issues of greatest importance</td>
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</table>

Source: AHQR, 2004
# Community-Based Participatory Research

<table>
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<th>Traditional Research</th>
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<tr>
<td>- Academics make design decisions</td>
<td>- Community involved with design decisions</td>
</tr>
<tr>
<td>- Approaches to recruitment &amp; retention based on scientific issues</td>
<td>- Community provides guidance in recruitment &amp; retention strategies</td>
</tr>
</tbody>
</table>

Source: AHQR, 2004
## Community-Based Participatory Research

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<td>- Measurement instruments are adopted/adapted from other studies</td>
<td>- Community helps develop measurement instruments</td>
</tr>
<tr>
<td>- Manage all resources</td>
<td>- Co-manage resources</td>
</tr>
</tbody>
</table>

Source: AHQR, 2004
# Community-Based Participatory Research

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<th>Traditional Research</th>
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<td>- Researchers design intervention based on literature &amp; theory</td>
<td>- Community help guides intervention development</td>
</tr>
<tr>
<td>- Researchers report findings from analysis &amp; publish in peer review journals</td>
<td>- Community assist with interpretation &amp; dissemination of findings</td>
</tr>
</tbody>
</table>

Source: AHQR, 2004
Community Participation

Comments & Questions
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

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

- 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
What kinds of risks are acceptable or unacceptable in a study?
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
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/ethic/cultural background

Source: Family Health International, 2004
Institutional Review Board

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

Develop Research Study Plan or Protocol

IRB Study Review
- Exempt
- Expedited
- Full Committee

NO Approve Study Plan YES

Revise & Resubmit

Decline Study

Proceed

Continuing Review

Close study

NO

Approve Study Plan YES

Revise & Resubmit

Decline Study

Proceed

Continuing Review

Close study
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
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 (HIPPA)

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

Source: HIPAA Training, University of Arkansas, 2005
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