Community Engagement Research
The Responsibilities, The Risks, and The Rewards

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Community Engagement
- "The process of working collaboratively with and through groups of people affiliated by geographic proximity, special interest or similar situations affecting the well being of those people"

Characteristics
- Equal contribution between researchers and community members (equal discussion of relevant research questions)
- Trust, shared decision making
- Long standing relationship
Three Basic Ethical Principles
Respect for Persons: Protect the autonomy (freedom) of all people, treat with courtesy, obtain informed consent
Beneficence: Minimize risks, maximize benefits and having the best interests of the participants in mind
Justice: How are burdens and benefits distributed? (One group shouldn’t bear the cost of research)

Validity of Community Engagement Research
What does it mean?
What does our office look for in an application?

When the IRB application is submitted, please make sure that the following questions have been addressed by the Principal Investigator before the scientific review of the study:

• Does the planned study address a significant question? (Are we asking participants to undergo risks associated with research that will not contribute or help the development of knowledge?)
• Is the study design appropriate to answer that question?
• Is the methodology adequately explained?
• Are the response criteria and endpoints clearly identified? (What are you measuring and how are you measuring it? How will you know whether your hypothesis is true or false?)

• Is the sample size appropriate to answer the research question? (Again, are we asking individuals to undergo risks for research that may not provide any significant information?)

• Are the data collection, analysis methods, and statistical tests described adequately?

Helpful Hints

• Plan early: Establishing a good match with any community partner is a process and takes time
• Always remember the plan: Outreach should make sense and integrated as part of your work in the research
• It's a two way street: Discussion and confirmation as to a mutual fit is essential
• Commitment: invest in these relationships and preserve them.

Investigator Top 10 Responsibilities

1. Design Ethical Research
2. Protect participants by complying with federal regulations/institutional policies
3. Obtain prior IRB Approval
4. Comply with all IRB conditions & requirements
5. Obtain Informed Consent/Assent
**Investigator Top 10 Responsibilities**

6. Document Informed Consent/Assent
7. Implement Research As Approved and Obtain Prior Approval for Modifications
8. Submit Progress Reports
9. Report Unanticipated Problems
10. Retain Records for a minimum of 3 years after study is completed (6 years if HIPAA/PHI is collected)

**PI’s are responsible for**
appropriately training community personnel serving as research personnel

Train individuals obtaining informed consent (they should be able to answer questions the potential participants may have about the research)

Use technology or innovative approaches in obtaining informed consent

**Respect**

- Both the PI and the research personnel who interact with the participant must build a relationship with that person
- Each person comprehends differently, responds differently, and has different needs
PRINCIPAL INVESTIGATOR'S RESPONSIBILITIES FOR KEY PERSONNEL

- Ensures that each person working on the research project has completed human research protections training within the past 3 years
- Maintains all educational certificates for each key personnel involved in the research

PRINCIPAL INVESTIGATOR'S RESPONSIBILITIES FOR KEY PERSONNEL

- Ensures that each person interacting with research participants (e.g., recruiting individuals and/or collecting data) are properly trained about the specific study so to be able to answer questions and deal with unanticipated events
- If working with community services, make sure the personnel understand their dual roles and how they need to differentiate between what is being done in research and what is offered as standard service

Informed Consent

- Informed consent begins with advertising and recruitment of participants
- Researcher vs. Intern
- Relationship between Researcher and Participant
  - Mind set of subject
  - Opportunity for coercion
Basic Elements of Informed Consent

- Purpose of research & research plan (include a statement this makes it clear the activity is research)
- Identification of risks and benefits
- Statement about confidentiality

Basic Elements of Informed Consent

- Explanation that participation is voluntary
- Right to refuse to participate or to withdraw after participation begins
- Names of person to contact with questions and concerns
- Name of person to ask questions about research
- Name of person to ask questions about rights

Institutional Review Board

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