

Understanding and Reviewing an IRB Application

It is important for community partners to understand the **Institutional Review Board (IRB)** process involved in the research project. An institutional review board is a committee that has been formally designated to approve, monitor, and review research involving humans with the aim to protect the rights and welfare of the research subjects.

Additional resources related to Institutional Review Boards:

- Training unit on Ethics and IRBs and CBPR: <http://depts.washington.edu/ccph/cbpr/u1/u13.php>
- What is an IRB and what purpose does it serve? <http://depts.washington.edu/ccph/irbcalls2.html#1>
- CBPR and Research Ethics Webpage: <http://depts.washington.edu/ccph/irbhome.html>

Adapted from Sinai Urban Health Institute: www.suhichicago.org and www.CBPRcurriculum.info

Ask academic researchers to see a copy of the IRB application.

IRB Application Components

Background, purpose and objectives: This section describes the background and setting to the project, its rationale, purpose, objectives and hypothesis for research.

Questions to consider:

- *Is this research really justified?*
- *Who benefits? How?*
- *Was the community involved or consulted in defining the need?*
- *Who came up with the objectives and how?*
- *Are there concrete action outcomes? How will they affect the community?*

Research methods: This section describes how the research will be done. It indicates what procedures will be used to collect data (e.g., surveys, interviews, focus groups), the frequency of these procedures and the number of people involved. It indicates the period of time the research will be carried out and how long each phase will last.

Questions to consider:

- *How will the community be involved? At what levels?*
- *Are there training or capacity building opportunities built in?*
- *Will the methods used be sensitive and appropriate to various communities (consider literacy issues, language barriers, cultural sensitivities, etc.)?*

Population targeted or research participants: This section describes who the participants are and why they were selected. It states the proposed “sample size” (e.g., how many people will be involved) and how that size was determined. It provides any relevant inclusion or exclusion criteria for who can be involved in the study and describes any special issues with the proposed study population, (e.g., incompetent patients or minors).

Questions to consider:

- *How will vulnerable groups be protected?*
- *Who speaks for the community?*
- *Are the potential research benefits and harms likely to be shared relatively equally among all participants?*

Recruitment: This section describes how and by whom participants will be approached and recruited. It includes copies of any recruiting materials (e.g., letters, advertisements, flyers, telephone scripts). It states where participants will be recruited (e.g., hospital, clinic, school). It provides a statement of the investigator's relationship, if any, to the participants (e.g., physician, teacher, community public health representative).

Questions to consider:

- *What is the power relationship between the investigator(s) and participants? Is there potential for coercion?*
- *Are the service providers and researchers different people?*
- *Is it clear to the population that they may still receive services even if they choose not to participate in the research?*
- *Who approaches people about the study and how?*
- *Are your recruitment strategies and materials culturally appropriate and adapted to the participants?*
- *How will you assure confidentiality?*

Risks and benefits: This section describes the anticipated risks and benefits to research participants. It explains how these risks and benefits are balanced and what strategies are in place to minimize and manage any risks.

Questions to consider:

- *What are the risks for communities? For individuals?*
- *How will the risks be minimized?*
- *Are your recruitment strategies and materials culturally appropriate and adapted to the participants?*
- *Is it clear and transparent who will benefit from this research and how?*
- *How do you distribute the benefits most equitably?*

Privacy and confidentiality: This section provides a description of how privacy and confidentiality will be protected.

Questions to consider:

- *What processes will you put in place to be inclusive about data analysis and yet maintain privacy of participants?*
- *Where will you store data? Who will have access to the data? How? Is it clear and transparent who will benefit from this research and how?*
- *How will the data be shared with the community upon study completion? The researcher should have a detailed plan of how the data will be shared with the community.*

Compensation: This section describes any reimbursements, remuneration or other compensation that will be provided to the participants, and the terms of this compensation.

Questions to consider:

- *Are people being reimbursed for their time and effort? If so, how can this be done without being “coercive”?*
- *Has the participant been assured that the research and service delivery are not being linked?*

Conflicts of interest: This section provides information relevant to actual or potential conflicts of interest (to allow the IRB to assess whether this information should be shared with participants as part of the informed consent process).

Questions to consider:

- *What happens when you are the researcher and the friend, peer, service provider, doctor, nurse, social worker, educator, or funding agency?*

Informed consent process: This section describes the procedures that will be followed to obtain informed consent from participants. It includes a copy of the information letter(s) and consent form(s). If written informed consent is not being obtained, it explains why. Where minors are to be included as participants, a copy of the assent script to be used is provided. If you are dealing with a population with special needs (e.g., illiterate) or with a different language base, how these differences will be addressed to assure that they are fully informed is explained.

Questions to consider:

- *What does this mean for “vulnerable” populations (e.g., children, mentally ill, developmentally challenged)?*
- *What does it mean to inform?*
- *What does it mean to “consent”?*
- *How do you do this in a culturally sensitive manner?*
- *Whose permission do you need to talk to whom?*

The informed consent is one of the most important components of the application. Every study participant will be required to use this document to consent to the research study.

Questions to consider:

- *Are you able to understand the purpose of the study just by reading the consent?*
- *Do you think it’s appropriate for your community members?*