

APPENDIX D: ETHICAL CONSIDERATIONS IN HUMAN SUBJECTS RESEARCH

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Now that you are about to plan and conduct a community assessment, including collecting data from community members, it is important that you read this section in order to identify any potential risks or ethical considerations. This appendix covers Institutional Review Boards (IRB), the research approval process, and has some useful resources at the end to help if you need to gain IRB approval as part of your community assessment.

What are the key principles of ethical research I should be familiar with?

There are six key principles that provide a good framework for the ethical development of research:

1. **Value:** the research must aim to enhance health or knowledge.
2. **Scientific validity:** the research must be methodologically sound, so that research participants don't waste their time with research that has to be redone.
3. **Fair subject selection:** research participants should be selected fairly and equitably, and without personal bias or preference.
4. **Favorable risk-benefit ratio:** risks to the research participants should be minimized, and potential benefits should be maximized—the potential benefits to individuals and knowledge gained for society must outweigh the risks.
5. **Informed consent:** individuals should be informed about the research and provide their voluntary consent before becoming research participants.
6. **Respect for enrolled subjects:** research participants should have their privacy protected, the opportunity to withdraw, and their well-being monitored.

The concept of trust is the cornerstone of ethical research. The dignity and welfare of individuals who participate in research should be a central concern of everyone involved in the research project. The head researcher (sometimes called the "Investigator") is ultimately responsible for the conduct of the research, the ethical performance of the project, and the protection of the rights and welfare of the subjects.

Additional care must be taken with these special classes of research subjects who are potentially more vulnerable to risks than the rest of the community:

- Children
- Prisoners
- Pregnant Women
- Mentally Disabled Persons
- Economically Disadvantage Persons
- Educationally Disadvantaged Persons
- Terminally Ill Persons

- Students
- Employees

What is research?

Research with human subjects is a systematic investigation—including pilot testing, research development, and evaluation—with one or more participants designed to develop or contribute to generalizable knowledge.

Research may involve activities such as the analysis of data collected from people. Participation in these kinds of activities, particularly if you plan to publish the results, is considered human subjects research.

What is a human subject in research?

A human subject is a living individual about whom an investigator conducting research obtains data or identifiable private information. They are more commonly called research participants.

What are the potential risks for human subjects involved in research?

Risk: The probability of harm occurring as a result of participation in a research study. This harm could be physical, psychological, social, or economic.

Minimal Risk: A risk is minimal where the probability of harm or discomfort anticipated in the proposed research is not greater than what is ordinarily encountered in daily life—or during the performance of routine physical, psychological or educational examinations or tests.

The potential risks or harms of social-behavioral research include an invasion of privacy or a violation of confidentiality. It is important to consider these risks ahead of time, as they could result in:

1. **Social risks:** disclosure of personal or group attitudes, behaviors or preferences that may lead to stigmatization, discrimination, or prejudice.
2. **Psychological harms**, which may include:
 - Stress
 - Depression
 - Confusion
 - Guilt
 - Embarrassment
 - Loss of self-esteem

3. **Economic risks:** disclosure of an individual's personal information that may, if revealed to others, negatively impact employment, insurance coverage, or academic status.
4. **Physical harms:** could occur either by or against the research participant if exploring sensitive topics—such as domestic violence—or illegal activities such as drugs, gangs or other crimes.

Privacy refers to the rights of a research participant to limit the access of their personal information to others.

Confidential data refers to personal or identifiable information about oneself given with the understanding that it will not be disclosed to others without consent.

Identifiable information refers to any information that could later identify the research participant to others, so that their responses could be linked back to themselves. Identifiable information could include: first or last name, address, phone number, place of work, job title, visible community position, or any other shared information that could identify the participant amongst their peers from the information they shared.

Confidentiality refers to the obligation of the researcher to restrict access to personal or identifiable information about the research participant.

Anonymous data refers to data collected without any personal or identifiable information. Ethical and legal concerns about confidentiality may be easily addressed by collecting only anonymous data from research participants.

- ⇒ In order for research to preserve a subject's privacy or confidentiality, it must include sufficient safeguards to ensure against potential harms resulting from an invasion of privacy or a violation of confidentiality. This can occur by collecting only anonymous data, or presenting individual data only in a summarized form.

What is informed consent?

Ethical research requires that research participants, to the degree that they are capable, be given the opportunity to consent to participating in the research. This is called "informed consent". Any informed consent process should include these three main components:

1. **Information.** This includes information about the research procedure, its purposes, risks and anticipated benefits, and a statement offering the subject the opportunity to ask questions and to withdraw at any time from the research. Many informed consent processes also include information about the organization or institution conducting the research.

2. **Comprehension.** The way in which informed consent and research information is shared is as important as the information itself. Researchers are responsible for making sure the potential research participant has comprehended the information before giving informed consent, has been provided information in a way that allows time for consideration or questioning, has been presented information in the preferred language, and makes sure that it doesn't require high-level literacy skills.
3. **Consent is voluntary.** Consent to participate in research is valid only if voluntarily given, without coercion, undue influence, or pressure.

What is an Institutional Review Board (IRB)?

An Institutional Review Board (IRB) is an entity created to review proposed research in order to protect the rights and safeguard the welfare of human subjects.

IRBs are responsible for reviewing and approving research involving human subjects, and are charged with a twofold mission:

1. To determine and certify that all projects reviewed conform to the regulations and policies set forth by the Department of Health and Human Services (DHHS) regarding the health, welfare, safety, rights, and privileges of human subjects.
2. To assist researchers in conducting ethical research that complies with the DHHS regulations in a way that permits accomplishment of the research activity.

Most large research hospitals, universities, and other research organizations have IRBs. In order to maintain a review process that is responsive to the concerns of all involved, federal regulations require that the IRB committee membership reflect the experience, expertise and diversity in academic, research and professional backgrounds, racial and cultural heritage, and a sensitivity to community attitudes. In addition, some communities have set up their own IRBs, in order to approve, negotiate and oversee all research conducted within their community.

If you collaborate with any researchers from any of these types of institutions for your community assessment, it is important to find out ahead of time if your community assessment needs to go through an IRB approval process. If you do need to gain IRB approval, then you will want to look further into the following resources to get more information about this process. In general, it is helpful to know that seeking and receiving IRB approval entails the following steps:

- Contacting the IRB to get the appropriate research approval application forms and instructions.
- Sharing research plan, data collection instruments, and relevant human subjects issues to the IRB review committee.

- Negotiating for approval of research by ensuring that the research is safe and ethical, and will protect the rights and welfare of human subjects.

What is HIPAA?

HIPAA, or the Health Insurance Portability and Accountability Act, is a federal medical privacy rule which took effect in April of 2003. HIPAA provides new federal protection to the privacy of *medical records*. If you are using clinic, hospital, or other records that were created when people were receiving medical treatment, there may be an extra level of consent that you need to obtain.*

What Research is covered by HIPAA?

1. Research that includes the review of medical records or biological materials with attached information; or
2. Research that results in the addition of new information to a medical record e.g., research in which a health care service is performed, such as testing a new diagnostic method, or a new drug, biologic, or device, creating new information in a medical record.

What is required?

In general, if you are going to obtain information from medical records, and the information you obtain can in any way be traced back to the person (via their name, address, phone number, social security number, etc.), you must first obtain specific permission from the person whose medical record you are going to use. If you would like to become more informed about the specifics of HIPAA, please consult the resources listed below.

* From <http://www.oprs.ucla.edu/human/NewsLetters/041103.htm>

Where can I go for more information?

1. American Health Information Management Association, "Online HIPAA Resources": http://www.ahima.org/pdf_files/HIPS_Resources.pdf
2. The Belmont Report: Ethical Principles and Guidelines for the Protection of Humans Subjects of Research: <http://ohsr.od.nih.gov/mpa/belmont.php3>
3. California HealthCare Foundation: Health Currents, "HIPAA Privacy: Separating Myths from Facts": <http://www.californiahealthline.org/index.cfm?Action=dspltem&itemID=102470>
4. *HIPAA Made Simple: A Guide to Fast-Tracking Compliance, Second Edition* by Margaret Amatayakul; published by HCPro, Inc. Available on Amazon.com.
5. Los Angeles Unified School District IRB, the Program Evaluation and Research Branch: <http://www.lausd.k12.ca.us/lausd/offices/perb/>
6. National Institutes of Health, Office of Human Subjects Research: <http://www.nihtraining.com/ohsr/site/>
7. Title 45 Code of Federal Regulations Part 46, Protection of Human Subjects (45 CFR 46): <http://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm>
8. UCLA's Office for the Protection of Research Subjects: <http://www.oprs.ucla.edu/>
9. UCLA's on-line education and certification program for human research investigators and key personnel: <http://www.oprs.ucla.edu/human/certificate.htm>. Anyone can take this on-line course and get certified. Even if you aren't going through UCLA IRB approval, it's a great course on human subjects approval and how to design an ethical project.
10. U.S. Department of Health and Human Services, Office of Human Research Protections: <http://ohrp.osophs.dhhs.gov/index.html>
11. U.S. Department of Health and Human Services, Office of Human Research Protections, IRB Guidebook: http://ohrp.osophs.dhhs.gov/irb/irb_guidebook.htm
12. World Health Organization, Scientific and Ethical Review Group: http://www.who.int/reproductive-health/hrp/SERG_guidelines.en.html