Human Subjects Guidelines for Community-based Work

Ensuring our Community Members are Protected

Human Subjects Protection Training

- Introduction
- What is Research?
- Privacy and Confidentiality
- Informed Consent
- Working with youth
- Incentives vs. Coercion
- Conclusions

Suggested Citation:
Introduction

• Prevention is about improving the wellbeing of individuals, families, and communities.

• Much of the work we do in prevention involves gathering information from people. From them, we need to know community readiness, individual usage, levels of knowledge about risk and harm...

Whenever organizations ask individual to provide information about themselves, certain protocols should be followed in order to protect those individuals from any harmful effects of providing that information.

Suggested Citation:
“The Common Rule”

• The “Common Rule” is set of regulations developed by the U.S. Department of Health and Human services and other agencies in order to prevent harm to persons (human subjects) who provide personal information or opinions for a research study.

• Harmful effects include violations of privacy, undue stress, coercion, economic or personal hardship.

What is Research?

Research means a systematic investigation designed to develop or contribute to generalizable knowledge. It includes experiments, observational studies, surveys, test, and recordings.

Suggested Citation:
Universities and other research entities are required to have an IRB to review all proposed research.

Much of the data gathered from individuals as part of the SPF-PFS is not considered research. It is not going to be published or disseminated as generalizable knowledge in journal articles or at conferences.

Protecting Our Communities

Program evaluation data or data that is gathered as part of a needs assessment or planning process is usually not considered research, so does not need to be reviewed by an Institutional Review Board.

However, any data collected from or about individuals should be gathered, analyzed, and reported using appropriate guidelines to protect human subjects!
BUT we still need to ensure participants are protected

Further Resources

- Our primary activity is not to contribute to generalizable knowledge – it is to help our communities!

What Falls under Human Subjects Protection?

Human Subject Means a living individual, about whom you obtain either:
1. Data through intervention or interaction with the individual, including:
   – Human participant surveys, interviews, focus groups
   – Collecting data through observations
   – Use of human tissues/specimens
2. Private information about a living individual, including:
   – Observation of behavior when the individual doesn’t know it
   – Medical or academic records that an individual can reasonably expect will not be made public

Privacy and Confidentiality

- Participants should be informed of how the project will ensure privacy and confidentiality, including:
  - how you will report the data,
  - where it will be stored,
  - who will or will not have access to the information,
  - how the identity of participants will be kept private.
- Those working with participants must always be aware of these policies.
What to do when your project does not meet the requirements of research and does not need an IRB...

....you still should protect humans as subjects

What to do:

• Still need to ensure informed consent of people who participate in our data gathering processes.
• Still need to ensure that data are handled appropriately to ensure individual confidentiality.
• All organizations that collect data from human subjects need to follow protocols related to informed consent and individual confidentiality.
Informed Consent

- Only someone over the age of 18 can give informed consent to participate.
- In order for someone to give informed consent to participate your organization is obligated to ensure they have:
  - Information
  - Comprehension
  - Voluntariness

Consent Forms

- Check SPF-PFS website for sample consent forms:
  - http://pfs.ohio.gov/
  - Adults
  - Consent/assent for children
    - Since only someone over the age of 18 can give informed consent, children can only assent to participate, but collecting child assent is still important. As we will discuss later, involving youth in research involves the same concerns as involving adults. Children should still be informed of the procedures and their rights as participants, but you must obtain parental consent for them to participate.
Information

• Participants should have information about the study or project in order to make an informed decision about participation.
• Researchers must provide certain essential points of information:
  – purpose of the research,
  – description of what the subject will do,
  – any foreseeable risks of harm,
  – benefits,
  – Who to contact with questions
  – Compensation...

Comprehension

• Comprehension is the ability to understand what one is being asked to do, as well as the implications of any risks of harm associated with participating in the research.
• Participants should be able to comprehend the information about the study or project and their role in it.
• This is a function of intelligence, rationality, maturity and language, presentation of information must be adapted to the subject’s capacity.

Suggested Citation:
Voluntariness

- Voluntariness requires conditions free of coercion and undue influence.
  - Coercion includes pressure, threat of harm, or large compensation for participating.
- Participants must be free to choose to participate in research.
- They also must be free to end their participation for any reason, without consequences.

Involving Youth in Evaluation

- Based on concerns for the welfare of children as research subjects, protections for children that exceed those for adults were incorporated into the federal regulations for protecting research subjects.
- It is important to involve young people in deciding how they will be involved and to ensure their participation is not token or manipulated by adults.
- When working with children (under the age of 18) it is important to obtain both parental consent and youth assent to participate.

Suggested Citation:
Key ethical considerations

• **Avoiding harm to participants**
  – Assess the risks of harm to participants through your research and plan to minimize these.
  – Be prepared to deal with any distress participants may express during the research process.
  – Make arrangements for further ongoing support to individual participants who need it.

Key ethical considerations (cont.)

• **Child protection**
  – Consider child protection issues in daily practice and in the recruitment of research staff.
  – Discuss how you would handle situations where risks of serious harm to participants is disclosed.

Suggested Citation:
Key ethical considerations (cont.)

• **Informed Consent**
  - Ensure that all participants give informed consent to their involvement.
  - Provide information about the research that is understandable and attractive to participants and include their rights as participants and how the data they provide will be handled.
  - Seek the informed consent of youth, ensuring they know they can withdraw their consent at any point.
  - Parental Consent (and how you request it) depends on the sensitivity of the research, the potential risks involved and your organization’s/the setting organization’s policies.
  - Seek the support of community organizations, school and other settings where research will take place.

Key ethical considerations (cont.)

• **Inclusive approach**
  - Make sure your methods maximize the chances of males and females to participate fully.
  - Consider how to include the voices of participants who face discrimination.
Key ethical considerations (cont.)

- **Confidentiality** - Make practical arrangements to protect the confidentiality of respondents.
- **Fair return** - Consider whether there is need to offer compensation to those helping you with your project— including youth researchers and participants and in what form.
- **Safety of research staff** - Assess possible risks to the safety of research staff and take steps to prevent them.

Key ethical considerations (cont.)

- **Wider accountability**
  - Ensure that you properly consult with communities in planning your research and contribute where possible to capacity building.
  - It is important to explain the potential benefits of the research to participants but avoid raising unrealistic expectations.
  - At the end of the process, bring the results of the research back to the communities which participated.
Incentives vs. Coercion

- Providing incentives for participation can help you get a large enough sample but precautions need to be taken to ensure that you are not coercing subjects into participating.
- Providing too great of an incentive, particularly among youth or economically disadvantaged populations can create undue influence to participate.
- When working with these populations, it is important to consider the local research context, the needs of the population, and what passes for an acceptable incentive.

Good Practice

- All public and nonprofit organizations should carefully follow established guidelines that protect human subjects, even though much or all of our work is not considered research.
- If your organization is involved in research (meaning you plan to generalize about a larger population, publish our findings for a general audience), then it is important to collaborate with a university or research organization that has an established Institutional Review Board and follow their procedures.

Suggested Citation:
It is important that all employees who are directly or indirectly dealing with data collected from individuals be trained in the appropriate human subjects protocols.

Good Practice!

When in doubt, consult your friendly OSET team member!
References

- Code of Federal Regulations, Title 45, Part 46: Protection of Human Subjects:
- SAMHSA Confidentiality and Participant Protection Requirements and Protection of Human Subjects Regulations:
  - https://www.federalregister.gov/articles/2003/04/29/04‐9656/notice‐of‐request‐for‐applications‐for‐strategic‐prevention‐framework‐state‐incentive‐grants‐spf‐sig#h‐37
- Save the Children Sweden (2004). So You Want to Involve Children in Research? A toolkit supporting meaningful and ethical participation in research relating to violence against children.
  - http://jme.bmj.com/content/34/5/389.short