

Informed Consent Guidelines for Community-Based Work

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...

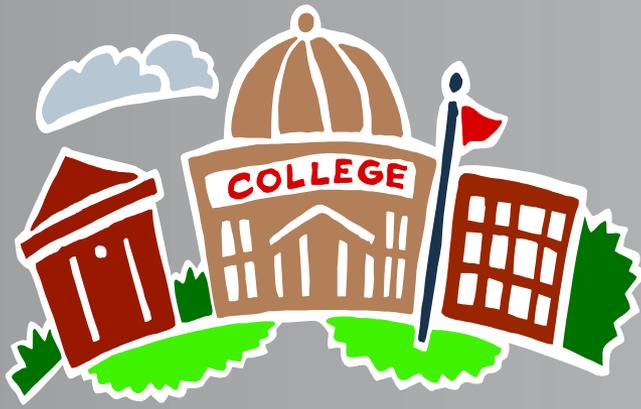


Whenever organizations ask individual to provide information about themselves, certain protocols should be followed in order to protect those individuals from any harmful effects of providing that information.

“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.
- Risks of participation include violations of privacy, undue stress, coercion, economic, or personal hardship.



Universities and other research entities are required to have an Institutional Review Board (IRB) to review or declare exempt from review all proposed research or evaluation and ensure that guidelines protecting individuals are being followed.

What is Research?

- A research project is a systematic investigation designed to develop or contribute to general knowledge. It includes experiments, observations, surveys, tests, and recordings.
- Much of the data gathered from individuals as part of the SPF or any prevention work is not considered “research.” It is not going to be published or disseminated widely outside of the entities involved.

What is Research?

Program evaluation data or data that are gathered as part of a needs assessment or planning process are not considered to be research and do 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 participants!

What data should fall under regulations protecting individuals?

- Data through intervention or interaction with the individual (including asking for information through surveys, focus groups).
- Private information about a living individual (including observing behavior, reviewing medical or academic records).

If you don't have an Institutional Review Board

- Most community-level agencies do not have Institutional Review Boards.
- You still need to ensure informed consent from people who participate in your data gathering processes such as surveys, focus groups, interviews...

All organizations that collect data from individuals or use records containing private information about individuals need to follow procedures for informed consent and confidentiality.

Questions about Confidentiality and Informed Consent?



If you have any questions about confidentiality or informed consent processes, consult your friendly OSET team member!

What is Informed Consent?

In order for someone to give informed consent to participate in a survey, focus group, interview, or other data gathering process, your organization is obligated to ensure the individual has:

1. Information
2. Comprehension
3. Voluntariness

Components of Informed Consent

Information-

Participants should have information about the study or project in order to make an informed decision about participation. ***Information*** includes procedures, purpose, any risks, benefits, compensation, etc. Potential participants should also know who to contact for more information.

Components of Informed Consent?

Comprehension-

Participants should be able to comprehend the information about the study or project and their role in it. ***Comprehension*** is a function of intelligence, rationality, maturity, and language. Information must be adapted to the prospective participant's capacity to comprehend.

Components of Informed Consent

Voluntariness-

- Participants' decision to participate must be under conditions free of coercion and undue influence to participate. Coercion includes pressure, threat of harm, or large compensation for participating.
- Volunteer participants should be told that they may still receive services (if applicable) even if they do not participate in or complete the data collection component of the project.
- Volunteer participants should be told that they have the right to end their participation at any time without problems.

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, and how the identity of individual participants will be kept private.

Sample Informed Consent Language for Community-Based Work

Here is a sample Informed Consent document.
Click on the document to view it in larger format.

SAMPLE CONSENT FORM

___ County Alcohol and Prescription Drug Use Focus Group (or Interview)

Statement of Informed Consent

The _____ is collecting information to help guide a planning process for reducing high risk alcohol use and the misuse of prescription drugs within the 18-25 year-old population in _____ County. We are hoping to gain insight into _____ that will inform efforts to develop programs to reduce the use of alcohol and prescription drugs.

In order to gain more in-depth understanding about how 18-25 year-olds in _____ County view _____, we are conducting # of focus groups/interviews across the county. You have been selected to participate in this group discussion/interview on the basis of your role in _____. During this discussion/ interview, we will ask you questions about what you think about _____. There are no right or wrong answers. We are only interested in your opinions. The focus group/interview should last about _____ minutes.

Participation in the group discussion/interview is voluntary. You may choose not to answer any questions or choose to quit the discussion/interview at any time. We do not anticipate that you will experience any risks or discomforts from participating in this focus group/interview.

The group's discussion/interview will be recorded, but be assured that information gathered in this group discussion/interview is *confidential*. Only members of _____ will see or listen to the information obtained from these discussions/interviews. The recording will be stored on a secure computer server and will be destroyed at the completion of the project. All names will be removed prior to any reporting and sharing of information.

All information obtained from the # focus groups/interviews will be combined to develop a summary report, and no information from the report will identify you as an individual. Summarized results of these focus groups/interviews also may be presented in publications, professional meetings, or at conferences.

The results of this data collection may not benefit you directly. However, they will contribute to a body of knowledge concerning _____, its impact on _____, and its potential for _____ across the county.

If at any time you have any questions or concerns, please feel free to contact one of the individuals listed below:

Name _____	Affiliation _____
_____	Email/phone _____
Name _____	Affiliation _____
_____	Email/phone _____

Your signature below indicates that you have read this consent form and that you voluntarily agree to participate in this group discussion. You will receive a copy of this consent form for your reference. Thank you!

Print Participant Name _____	Signature _____	Date _____
Name of Interviewer _____	Signature _____	Date _____

Good Practice!

- All public and nonprofit organizations should establish and follow guidelines that protect individuals (human subjects), even though much of our work is not considered research.
- It is important that all employees who are directly or indirectly dealing with data collected from individuals be trained in the appropriate human subjects procedures.

Good Practice!

- If your organization is involved in research (meaning you plan to generalize about a larger population/publish 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.

Remember!

When in doubt,
consult your
friendly OSET team
member!



References

Code of Federal Regulations, Title 45, Part 46: Protection of Human Subjects:

<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html>

SAMHSA Confidentiality and Participant Protection Requirements and Protection of Human Subjects Regulations:

<https://www.federalregister.gov/articles/2004/04/29/04-9656/notice-of-request-for-applications-for-strategic-prevention-framework-state-incentive-grants-spf-sig#h-37>