

Focus Group Guidelines

This document provides guidelines for how to design focus group protocols and how to describe focus groups in the consent form. Focus group studies are commonly used in social and behavioral research to bring out insights and understandings that regular questionnaires or individual interviews may not offer. Engaging in this type of research, from an IRB perspective, requires certain considerations and safeguards to protect participants. The following are some guidelines to help investigators as they are designing a focus group protocol that considers the rights and welfare of the subjects.

A. Designing a Focus Group Protocol

The protocol should include the following information under the appropriate section-Objectives, About the Subjects, Risks to Participants, etc. Addressing these questions in the protocol document can help the IRB efficiently and effectively review the research protocol to determine risk to subject and level of category review.

OBJECTIVES section:

What are the main topics or ideas that will be discussed during the focus group? The nature of focus groups is usually designed to remain open-ended and allow free discussion regarding a particular topic. However, the IRB needs to know the main focal points of the discussion in order to assess risk to subject and ensure that discussion topics do not deviate from the proposed research plan.

- What is the main goal or aim of this study?
- Is there a scientific or qualitative reason for designing the study as a focus group (instead of individual interviews)?

ABOUT THE SUBJECTS section:

- How many subjects per focus group? Provide only a range/estimation. Being too specific may narrow your flexibility in structuring the groups. However, a maximum number of subjects for the overall study must be described, and should not be exceeded without prior IRB approval.
- What are the inclusion/exclusion criteria for this study?
- What is the general description of the subject population?
- What is the subject age range for the study?

RECRUITMENT METHODS section:

- How will you be recruiting subjects (i.e. phone call, email, send recruitment letter, advertisement, etc.)?

- What is the origin of the contact information (e.g., address, email address, phone number or name)?
- Does the information come from a database or registry? Do you have permission to access this database or registry? If so, please submit a letter which grants this authorization.
- Are you collaborating with a foundation or government program that already has a list of prospective subjects?
- Will you be doing a secondary data analysis in order identify potential subjects? Will this data come from a publicly available data source? If so, please attach a copy of the catalog/website page indicating where the data can be located.
- Who will be contacting the prospective subjects? Remember, recruitment is part of the consenting process; therefore, CITI training is required for those involved in subject recruitment.
- What is your target recruitment number?
- Will advertisements be used as a recruitment tool? If so, please visit the IRB website under “Info Sheets” for IRB guidance on Advertising and Recruitment

PROCEDURES section:

- How many focus groups will you have?
- Where will the focus group session be located?
- The session should be held in an area that will be comfortable for the subjects to interact and discuss the research topics.
- The location should also be secure and private as the information being discussed by the subjects can be considered sensitive and personal. Holding a focus group session in open or high traffic areas may not only discourage subjects from talking but also cause potential harm to subjects. Here, harm is not physical but rather a potential injury to a person’s reputation or confidentiality (or also known as informational risk).
- Duration of the discussion:
 - How long will the focus group session be?
 - Will the focus group session be a one-time visit? Or, will there be more than one focus group session?
 - What will be the procedure followed during the focus group?
 - Will there be a break offered to the subjects?
- Will the subjects have to fill out a demographic sheet or any type of survey prior to or after the focus group discussion?

- If set questions are being used to facilitate the focus group discussion, these should be attached for review with your submission. Otherwise, a general outline of the topics and prompts should be provided.
- If discussing sensitive topics, have a counselor or trained individual in the room or readily available during the discussion.
- Train the moderator to handle an emotional crisis or response.
- Will the group discussion be recorded? If so, this should not only be mentioned to the subject in the consent form but also prior to the recording actually beginning.
- Will the subjects be compensated for their time and effort?

CONSENT PROCESS section:

- When will the subjects be consented? A week or an hour before the focus group discussion? Just before the session begins? Be clear and specific.
- Who will consent the subjects (e.g. investigator or moderator)?

DATA MANAGEMENT section:

- If focus group sessions are recorded, how will you ensure subject confidentiality?
- Limiting the types of identifiers can minimize the risk of identification. Remind subjects not to use their last names.
- Keep recordings in a secure and locked area with access limited to designated researchers.
- Destroy recordings after data analysis or completion of the study.

RISKS TO PARTICIPANTS section:

Risk in terms of human subject research may not always involve physical harm. Rather and usually the case in social behavioral research, risk to subjects may involve informational or emotional risk. Investigators must consider the risks that maybe associated with the focus group study as they are designing their protocol. These risks should be mentioned in the protocol, consent form and, if applicable, briefly in a cover letter (used *in lieu of* informed consent).

- Informational risk involves the probability of breach of confidentiality or loss of privacy. Accidental disclosure of research information (e.g. responses, data, identifiers, etc.) allows for subject identification outside of the research study. This could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.
- Emotional risk can be associated with a study if the focus group discussion involves a sensitive research topic that can trigger an unwanted emotional response (e.g. sexual, child or spousal

abuse, alcoholism, teen pregnancy, sexuality, STDs, etc.). Emotion is relative and varies from person to person. An investigator cannot assume they will not encounter this possibility. In sensitive focus group discussions, investigators should consider their subjects' experiences, culture and environmental setting as well as how a subject might react in "public" (a room full of other people).

- What services or counsel will you offer in case the focus group discussion triggers an emotional response from a subject? This often occurs with sensitive topics and an investigator must be prepared to manage this type of harm (emotional).
- Have a crisis hotline number or the contact information for other counseling services available to subjects in case an emotional response occurs after the discussion ends.
- Note that in a focus group setting, even if all participants are reminded not to share the information discussed in the focus group, it is always a possibility that some may breach this trust. Complete confidentiality must never be guaranteed to subjects in a focus group.

PROVISIONS TO PROTECT THE PRIVACY INTERESTES OF PARTICIPANTS section:

- Sensitive information can be revealed during focus group discussion. What measures will you take to ensure the discussion will remain private and confidential?
- Remind subjects that the information discussed during the focus group needs to remain confidential.

B. Waiver of Informed Consent/Documentation in Focus Group Settings

The type of risk level (minimal or more than minimal) can dictate whether an informed consent document or a waiver of written consent is needed.

Federal regulations define minimal risk to be "the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests."

The required elements of informed consent can be found on the IRB website under the Info Sheets tab. See the Informed Consent and Assent document.

To qualify for a waiver or alteration of Informed Consent, the following requirements must be met [45 CFR 46.116 (d)]:

- (1) The research presents no more than minimal risk to subjects
- (2) The waiver will not adversely affect the rights and welfare of the subjects
- (3) The research could not practicably be carried out without the waiver; and
- (4) Whenever appropriate, the subjects will be provided with additional pertinent information after they have participated in the study

It is important to note that numbers (1), (2), (3) and (4) must all apply and must be cited as justification for waiver of informed consent. Number (4) is particularly important in Social Behavioral Research, for example, in the following types of situations:

- There may be new information as a result of a survey or focus group that would be relevant to the subjects.
- The purpose of the research may require elements of deception, in order to obtain a natural response that the subject would not display if those elements of deception were disclosed prior to the exercise. However, after the completion of the study, pertinent information must be disclosed to the subject. See the IRB website under Info Sheets for guidance on Research Involving Deception.
- Subjects may be undergoing some moderator or investigator “manipulation” to elicit emotional responses.

An investigator who qualifies for an alteration of federal required elements of consent must still disclose to subjects pertinent study information. This consent can be in form of a recruitment/cover letter, which includes:

- (1) A brief explanation of the study
- (2) The procedures
- (3) Highlight the risks (breach of confidentiality or emotional response) associated with the study
- (4) Option to withdraw
- (5) Voluntary participation
- (6) Measures to maintain confidentiality, and
- (7) Appropriate contact information (Principal Investigator and IRB Office).

If a research study qualifies for a waiver of informed consent, CU-Boulder requires an investigator to have an oral or written script containing core information about the research study. This script must be submitted for review as an attachment in eRA.

Investigators must formally request a waiver of informed consent in the protocol document/eForm and receive approval from the IRB. This request must also include a justification explaining the need for a waiver of informed consent or documentation

C. Informed Consent in Focus Group Settings

Use the Consent Form Template, Informed Consent Guidance, and Language Resource Text available on the IRB website. All consent statements should be consistent with the procedures and risks described in the protocol. Be sure to include the following as it applies:

CONFIDENTIALITY section:

For minimal risk focus group research:

The researchers will try to maintain confidentiality of the data. However, the nature of focus groups means that we cannot guarantee confidentiality. Please respect the privacy of the other participants and not repeat what is said in the focus group to others.

For research that is greater than minimal risk it may be necessary to include a statement of non-disclosure that participants would agree to in the informed consent. This should be added to the Signing the Consent Form section of the Informed Consent template available on the IRB website..

Example:

Non-Disclosure Statement:

____I agree to maintain the confidentiality of the information discussed by all participants and researchers during the focus group session.

If you cannot agree to the above stipulation please see the researcher(s) as you may be ineligible to participate in this study.

Risk and Discomforts section:

Some of the questions the researchers ask you may be upsetting or make you uncomfortable. If you do not wish to answer a question, you can skip it and go to the next question. If you do not wish to participate you can stop.