

## Guidance Document:

### Focus Groups

#### Overview:

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 requires certain considerations and safeguards to protect participants. This document provides guidelines for how to describe focus group research procedures in a research Protocol. A Consent Form for focus group research should contain similar, consistent information.

#### What information should be included in a Protocol involving Focus Groups?

The protocol should include the following information under the appropriate sections. Addressing these issues in the Protocol document can help the IRB efficiently and effectively review the research protocol to determine risk to subject and level of review.

#### STUDY DESIGN:

- Discuss the data to be collected as a result of the focus group procedures. How will this information be analyzed in support of the research questions?
- 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 should be described, and not exceeded without prior IRB approval.

#### CONSENT PROCESS:

- When will the subjects be asked to provide their Consent to participate? Be clear and specific. Describe any provisions to conduct the consent process with subjects individually, in private. This reduces undue influence or pressure to agree to participation if a group is already present.
- Who will consent the subjects (e.g. investigator or moderator)?

#### PROCEDURES:

- How many focus group sessions 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 if 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 (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.
- 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.

#### **DATA MANAGEMENT:**

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

#### **RISKS TO PARTICIPANTS:**

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 discussed in the Protocol and Consent Form.

- Informational risk involves the probability of breach of confidentiality or loss of privacy. Accidental disclosure of research information (e.g. responses, data, identifiers, etc.) can allow for subject identification outside of the research study. Depending on other information collected, this could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation. When using focus group procedures, it is important not to appear to promise complete confidentiality due to the

possibility that, although it may be discouraged, members of the group may disclose information discussed in the focus group outside of the research context, thereby breaching confidentiality. Information about this possibility should be included in the Consent Form as well.

- 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.). In sensitive focus group discussions, investigators should consider their subjects' experiences, culture and environmental setting as well as how a subject might react in a "public" setting (a room full of other people). Investigators conducting focus groups must be trained and prepared to manage emotional harms if they occur. If appropriate, ensure services or counseling, a crisis hotline number or the contact information for other counseling services are available to subjects both during and after their participation.