Focus Group/Interview Instructional Guidelines from an IRB Perspective

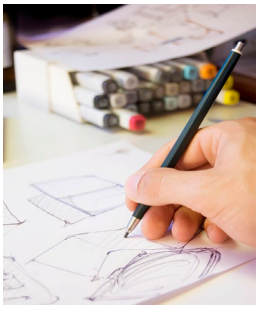
Focus group studies and/or individual-level interviews are commonly used in social and behavioral research to bring out insights and understandings that regular questionnaires may not offer. Engaging in this type of research, from an IRB perspective, requires certain considerations and safeguards to protect participants. The following are some guidelines to help investigators as they are designing a focus group/interview protocol that considers the rights and welfare of the subjects.

Designing a Focus Group/Interview Protocol:

Addressing these questions (where appropriate) in the protocol synopsis can help the IRB efficiently and effectively review the research protocol to determine risk to subject and level of category review.

Purpose of the Study:

- What is the main goal or aim of this study? (Describe in the Specific Aims section of the Protocol Synopsis)
- Is there a scientific or qualitative reason for designing the study as a focus group (instead of individual interviews)? (Describe in the Background Section of the Protocol Synopsis)



Target Subject Population (Describe within the Human Subject section of the Protocol Synopsis):

- 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:

- 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 to identify potential subjects? Will these 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.

- Will you being using protected health information (individually identifiable health information) to identify potential subjects? If so, federal regulations require investigators to request a HIPAA waiver (see NTR IRB website, in the "IRB Forms" section) in order to access identifiers for subject recruitment.

- Who will be contacting the prospective subjects? Remember, recruitment is part of the consenting process; therefore, human subject protection 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 NTR IRB website under "Instructional Guidelines" for IRB guidance on recruitment material.

Location/Setting (Describe within the Methods/Procedures and Setting section of the Protocol Synopsis)**:**

- 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/interview 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).

- Think about a location that will be convenient for the subjects. This is important to consider especially if no compensation for transportation or parking fees will be provided to the subject.

- For sessions conducted virtually, the protocol and relevant study documents (consent form, etc.) should address the following points:

  - Specify the platform researchers intend to use (Zoom, Teams, Skype, Google Meet, etc.).

  - Provide subjects with specific instructions on how to access the virtual session (e.g. login handout, email script with instructions, consent document). Additionally, where appropriate, describe any housekeeping items involved with delivering the session virtually (e.g., mute/camera on). This can be done in the Focus Group/Interview script (see below for additional information regarding this).

  - If you intend to audio-record the focus group/interview session, please bear in mind that most platforms will automatically video-record the session as well (given the nature of using a virtual platform). Therefore, researchers should inform participants in the consent document regarding both audio and video features. If researchers opt-out of the video-recording, or develop another way to avoid video-recording while audio-recording (e.g., use a handheld audio-recorded), this should be specified as well in the protocol and consent documents.

  - Data storage and security: In the event the focus group/interview sessions involve the (intentionally or unintentionally) collection of health information, and identifiers, please ensure that the platform being used is HIPAA complaint. Please recall that audio and video recordings are considered to be HIPAA identifiers.

  - For projects involving minors (i.e., individuals who are under 18 years of age), consider and describe how you will verify parental permission prior to initiating the study. Please note that you will need to obtain parental permission (from the minors' parents/guardians) and child assent (from the minors) prior to participation.

- Will refreshments be provided during the focus group session?

  - Although this is not an IRB requirement, investigators may consider this an option as a courtesy for lengthy sessions or in lieu of compensation.

Focus Group Discussion

Methods/Procedures – Study Protocol (Describe within the Methods/Procedures section of the Protocol Synopsis)**:**

- How many focus groups/interviews will you have?
- For a focus group, how many subjects per group session? Provide only a range/estimation. Being too specific may narrow your flexibility in structuring the groups.
- What will be the procedure followed during the focus group/interview?
    - How and 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.
        - If the focus group will be conducted virtually, will the consent document be emailed to the participants ahead of time? Or, will consent be provided online/electronically (e.g., Qualtrics). Guidance note: To satisfy regulatory guidance, please note that any electronic/digital signature must be accompanied by a computer-generated time/date stamp.
    - Who will consent the subjects? (Guidance Note: Anyone involved in the consent process must be listed as research personnel in the protocol synopsis).
    - Will the subjects have to fill out a demographic sheet, or any type of survey prior to or after the focus group discussion? Describe how the survey will be distributed.
        - Additionally, explain whether or not the focus group/interview responses will be linked to the survey data. If linked, describe how researchers plan to link and track individual-level data.

    - Will there be a break offered to the subjects? Guidance Note: Depending on the length of the session, or even type of discussion (e.g., emotionally charged/sensitive discussion topics) researchers may consider providing a break.
- 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 available to subjects in case an emotional response occurs **after** the discussion ends.
    - 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 audio recorded (and/or video recorded)? If so, this should not only be mentioned to the subject in the consent form but also **prior** to the recording actually beginning (i.e., include information about this topic in the Focus Group/Interview Guide).

- Guidance Note: For projects being conducted virtually, please bear in mind that most platforms will automatically video-record the session as well (given the nature of using a virtual platform). Therefore, researchers should inform participants in the Consent and Focus Group/Interview Guide script documents regarding both audio and video features. If researchers opt-out of the video-recording, or develop another way to avoid video-recording while audio-recording (e.g., use a handheld audio-recorded), this should be specified as well in the Protocol Synopsis and Consent documents.

General Discussion Topics (Describe within the Methods/Procedures section of the Protocol Synopsis):

- What are the main topics or ideas that will be discussed during the focus group/interview? The nature of focus groups and semi-structured interviews is usually designed to remain open-ended and allow free discussion regarding a particular topic. However, the NTR IRB needs to know the main focal points of the discussion in order to assess risk to subject and ensure that discussion topics to do not deviate from the proposed research plan/aim. Please summarize the main discussion topics and provide the base/structured questions within a Focus Group/Interview Guide Script (see example at the end of this document).

    - Guidance note: Researchers can provide additional provisions or reassurances to the IRB by specifying within the Protocol Synopsis that any follow-up prompt will be in line with the IRB-approved study topics and will be within the realm of minimal risk. Further, key personnel delivering the session will be appropriately trained regarding study procedures/protocol and topics. This specific information/content can be incorporated into the Risk/Benefit section of the Protocol Synopsis.

Moderator of the Focus Group Discussion (Describe within the Methods/Procedures section of the Protocol Synopsis):

- Who will be heading or directing the focus group discussion (e.g. investigator, volunteer, health care educator or counselor)? Recall that those involved in carrying out research activities should be listed as research/key personnel in the protocol synopsis.

- If the Principal Investigator will not be leading the discussion, will the investigator train the moderator? If not, will the moderator receive any type of training in dealing with consenting and handling the research discussion? Remember that the principal investigator is responsible for everything, regardless of their actual "real-time" level of direct or indirect involvement in the study.

Confidentiality (Describe in the Data Storage and Confidentiality section of the Protocol Synopsis):

- If focus group sessions are recorded (video or audio), 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, or use pseudonyms.

- Keep recordings in a secure and locked area with access limited to designated researchers.

- Destroy recordings after data analysis or completion of the study.

- Sensitive information can be revealed during focus group discussion (e.g. criminal activity, suicide/mental health, risk to reputation or employability, etc.). 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. Researchers can also specify or include this prompt in the Focus Group/Interview Guide script.

    - Specify an approximate timeline for transcribing and destroying the recordings.

- **Data Storage and Confidentiality**. Please include the following standardized language in the protocol synopsis (in the Data Storage and Confidentiality section):

  "Research data, in hard copy or electronic form (CDs, DVDs, digital or magnetic tape/files, hard-drives, flash-memory drives, recordings, etc.) will be stored and managed in a secure manner following federal, state, institutional and sponsor (if applicable) policies, practices and guidelines. Further, research documents including electronic documents containing subject data, identifiers and linked data will be securely stored (locked file cabinets, lockers, drawers; password-protected file server, software system; etc.) in accordance with standard document management practices. At all times, only listed key personnel specifically designated and authorized by the Principal Investigator shall have access to any research related documents. All such personnel will be properly trained and supervised regarding the management and handling of confidential materials. The Principal Investigator assumes full responsibility for such training, supervision, and conduct. Any identifiers (if collected and retained) will not be published and will be removed, destroyed or stripped from the research data upon study closure."

Duration of the Discussion (Describe in the Estimated Time to Complete the Study section of the Protocol Synopsis):

- How long will the focus group/interview session be?

- Will the focus group session be a one-time visit? Or, will there be more than one focus group/interview session?

- What is the duration of the study? Overall? (One time, several different focus groups over 1 month, 3 months, a year?)

Compensation (Describe in the Compensation section of the Protocol Synopsis):

- Will the subjects be compensated for their time and effort?

Will subjects be compensated if they do not complete the focus group/interview session (e.g., if they leave early)?

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Risk associated with Focus Group/Interview Studies

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.

- **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).

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 synopsis (in the Risk/Benefit section), the consent form/document (in the Study Risk section) and, where appropriate/applicable, briefly in the Focus Group/Interview Guide.

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Informed Consent in Focus Groups/Interview Studies

The type of risk level (minimal or more than minimal) and method of delivery/data collection can dictate whether a full-fledged informed consent document (which will be signed by the research subjects) or a verbal consent script (which will be accompanied by a request for a waiver of documentation of informed 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*."*"*

- Elements of informed consent are outlined in the "Informed Consent" link found on the NTR IRB website.

- For projects involving minors (i.e., individuals who are under 18 years of age), you will need to obtain parental permission (from the minors' parents/guardians) and child assent (from the minors) prior to participation. Please include information about this topic in the protocol synopsis.

- In certain circumstances, NTR IRB understands that a formal ***written*** consent process cannot take place (e.g., it may not be practical to obtain a subject's written signature on a consent form). For example, a telephone interview would be more advisable for specific or certain study populations. In this situation, researchers may seek a waiver of *documentation* of informed consent in order to carry out consent through a verbal consent script. To qualify for a *waiver of documentation of Informed Consent*, the following requirements must be met [45 CFR 46.117 (c)(1)]:

  > *An IRB may waive the requirement for the investigator to obtain a signed informed consent form for some or all subjects if it finds any of the following:*
  >
  > *(i) That the only record linking the subject and the research would be the informed consent form and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject (or legally authorized representative) will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern;*
  >
  > *(ii) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context; or*
  >
  > *(iii) If the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.*

  An investigator who qualifies for a *waiver of documentation of informed consent* must still disclose to subjects pertinent study information and include all the regulatory requirements of informed consent within their verbal consent script.

  Researchers may use the templates for the consent statement and full fledge consent document as guidance on how to craft a verbal consent script. To access these templates, please visit the NTR IRB website and navigate to the link titled "Informed Consent" or see below for direct links.

Bear in mind, if the subjects will not be signing a consent form, the principal investigator must formally request a *waiver of documentation of informed consent.* To request (and justify the need for) a waiver, please complete and sign the form titled "Waiver of Documentation of Informed Consent" (available on the NTR IRB website under the "IRB Forms") and include the form in the submission.

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Templates and samples of Consents & Research-related Materials for Focus Group Studies

Please note that any sample document provided should be modified or customized to meet the needs of your project.

Informed Consent Template

Sample of Consent Statement/Cover Letter (used in lieu of written informed consent)

Sample of Focus Group Guide Script and Discussion Topics*

Sample of Interview Guide Script and Discussion Topics*

We would like to extend our appreciation to Dr. Erika Thompson, Principal Investigator and associate professor (within the School of Public Health) at the University of North Texas Health Science Center, who allowed us to use her focus group and interview guide scripts for educational purposes.

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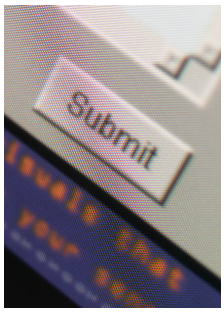
Submitting to NTR IRB

For a focus group/interview research project, please submit the following:

- IRB Wizard Application form (also referred to as the "North Texas Regional IRB New Protocol Application" form)
- Protocol Synopsis (see NTR IRB website under IRB Forms for general template)
- Focus Group/Interview Discussion Guide/Script



- Informed Consent document or Verbal Consent Script (if applicable)
    - If a verbal consent script will be used, please also submit a request for a waiver of *documentation* of informed consent. (This IRB form is available on the NTR IRB website, in the IRB Forms section.)
    - If minors (i.e., individuals under 18 years of age) will be participating in the study, please submit a copy of the parental permission form and the child assent form.
- Evidence of human subject protection training certificates for all key personnel (e.g., CITI).
- Conflict of Interest forms for all key personnel (see NTR IRB website link at "IRB Forms") if Expedited or Full Board is required.

If applicable…

- Any survey or data collecting instruments
- Any recruitment advertisements (see NTR IRB website link at "Instructional Guidelines" for guidance on designing recruitment material)
- A letter of collaboration from a foundation, other investigator or any other collaborator

The study must be submitted through IRBNet (the NTR IRB's electronic submission system). Please visit the NTR IRB website for specific guidance on how to submit a new project into IRBNet (or follow this link here). As a friendly reminder, the IRBNet submission package must be signed by the Principal Investigator. If you have any further questions regarding focus group/interview studies, please call 817-735-0409 for assistance.

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