



## A SOCIAL, BEHAVIORAL, & EDUCATIONAL RESEARCH (SBER) CASE STUDY OF FOCUS GROUPS

### USING FOCUS GROUPS TO PERFORM A NEEDS ASSESSMENT WITH CAREGIVERS OF PERSONS WITH PSYCHOTIC DISORDERS

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#### **OVERVIEW**

The social, behavioral, and educational research (SBER) case studies provide education and guidance on how to identify and mitigate risks associated with SBER. These studies may be used by both IRB administrators and investigators when reviewing and designing research studies that involved SBER components.

Case studies follow a standard format that includes: 1) a fact pattern, 2) regulatory, cultural, and ethical issues, and 3) a risk/benefit analysis and risk management options. This format was created to allow for flexibility in applying the case studies.

By identifying common themes, linking them directly to federal regulations and guidance, and outlining risk mitigation options, the case studies can be used in a variety of ways, which include: 1) as an education tool for training individuals in human subjects research, 2) as a basis for developing reviewer checklists/worksheets, and 3) as a tool in designing research projects.

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#### **CASE STUDY**

##### **SCENARIO/FACT PATTERN:**

A researcher at a community hospital with a psychiatric emergency department would like to perform a needs assessment with caregivers and first-degree relatives of people with psychotic disorders. Specifically, the researcher is interested in learning about the needs of the families who provide support to patients with mental illness (e.g., those with psychosis, schizophrenia, bipolar, etc.). The researcher is especially interested in learning about how family members provide support during exacerbated psychiatric symptoms that can lead to hospitalization, and how they learned to do so. The researcher is also interested in learning how the family member identifies the warning signs, and how they discuss this topic as a group. The researcher proposes convening several small groups of four or five people from different families to discuss:

- 1) What types of vigilance (in terms of day-to-day activities, caregiver watchfulness, etc.) is needed
- 2) How to detect worsening symptoms before they become too severe, and
- 3) What information or education is needed to assist in early symptom management?

A clinician with experience counseling caregivers and families of psychiatric patients will facilitate the focus groups with the aid of a junior researcher and medical student. Groups will meet for 1½ - 2 hours, during which the facilitator will use several open-ended questions to guide the flow of the conversation.

During the consent process, and prior to the beginning of the discussion, participants will be instructed on using the appropriate etiquette of focus group participation and informed that while the group will together acknowledge and affirm the privacy of group discussions, no guarantee of privacy can be made.

There is no funding for this research and the participants will not be compensated for their time. The researcher intends to publish the study in a peer-reviewed journal.

# USING FOCUS GROUPS TO PERFORM A NEEDS ASSESSMENT WITH CAREGIVERS OF PERSONS WITH PSYCHOTIC DISORDERS-DISCUSSION

## DISCUSSION

*Questions/Comments for the researcher:*

- How do you plan to screen and recruit study participants?
- What are the qualifications/training of the facilitators?
- What questions will be asked?
- How will the group conversation be managed?
- What steps will be taken if a member becomes agitated or upset?
- What if participants report elder abuse, assault, child abuse, or imminent harm to self or others? How are mandatory reporting requirements disclosed to study participants?
- Will there be any de-briefing or post-discussion survey (e.g. time to allow respondents to indicate if they felt they were able to openly discuss their opinions)?
- Will information be given to the participants about available resources/assistance?
- Is this the right method for getting this information? How will you assure confidentiality in a group setting? Can this be obtained via interview without as many risks (while still obtaining research data useful to the researcher)?
- What is the sample size? Is it sufficient to reach saturation?
- Will the focus groups be audiotaped or videotaped?
- What will happen if participants share information about a family member who has not consented to this research study?
- Should the family member be told about the subject's participation in the research?

## **REGULATORY, CULTURAL, & ETHICAL ISSUES:**

- **Secondary participants:** Participants in this focus group may be asked to provide potentially sensitive information about a family member with a psychotic disorder. If the information provided about the family member is private, individually identifiable information, that person becomes a secondary participant.
- **Recruiting participants** into this study must be done carefully. The study seeks participants who have a family member receiving treatment at a particular hospital, but researchers must be careful to appropriately approach potential participants. Recruitment materials that allow interested participants to contact the research group (but are not targeted based on medical record information) may be useful to consider in this study. Recruitment that utilizes targeted outreach based on medical record information poses additional challenges and will require careful consideration.
- **Confidentiality:** The nature of a focus group is such that confidentiality cannot be guaranteed. For studies, which involve sensitive information, researchers must consider which types of procedures (i.e. use of pseudonyms, data security plan) are required to minimize breach of confidentiality or violation of privacy.
- **HIPAA:** The researcher conducting this study is an employee of a covered entity (the hospital) under the HIPAA Privacy Rule. If the focus group elicits individually identifiable health information

(protected health information) the researcher must seek written authorization from the individual or a waiver of authorization; however, if no individually identifiable health information is elicited the requirements of HIPAA do not apply.

- **Existing Stress/Distress:** Family members of people with severe and persistent mental illness experience significant life stress that is associated with caring for a family member with mental illness. They may suffer from conditions of their own that may be difficult to manage in a group setting.
- **Access to care and discussion of mental illness:** The researchers must take into consideration the culture of the participants and placement of the mental health clinic, as well as the fact that participants may have limited access to care, and/or be less comfortable sharing information about mental illness and treatment options.

#### *Questions/comments for the IRB:*

- How best can the researchers pre-screen participants?
- What procedures are in place to protect the privacy of participants and confidentiality of data collected? Do these procedures protect both the participant and the family member with the psychotic disorder?
- Are the family members with a psychotic disorder considered secondary participants? Consider regulations and guidance regarding subjects who are decisionally impaired or incompetent adults
- If they are considered secondary participants, can the IRB waive the requirement to obtain informed consent (45 CFR 46.116(d)) from them by documenting:
  - The research involves no greater than minimal risk to the secondary participants
  - The waiver will not adversely affect the rights and welfare of the secondary participants
  - The research would be impracticable without the waiver
  - If possible and appropriate, the secondary participants will be informed of the study when it is over.
- Does the researcher address how the study will respond to social and psychological harms related to participation in the focus group?

#### **RESOLUTION & DISCUSSIONS:**

##### *Risk/Benefit Analysis:*

Can this study be considered “minimal risk”? This study may qualify for expedited review under Category 7 if sufficient steps are taken to avoid breach of confidentiality through the disclosure of sensitive information and the facilitator’s questions are determined to have minimal risk. The study might qualify for expedited review if the research team carefully designs a plan of action for if participant becomes distressed or discloses reportable information, (e.g., child abuse, elder abuse, neglect, harm to self or others, etc.) and provides resources and follow-up (if necessary/applicable).

Given that this group maybe a fragile population, steps should be taken to ensure that participants are screened and determined to be capable of engaging in focus group discussions without experiencing distress.

##### *Mitigation/Management of Risks:*

#### **Privacy/Confidentiality:**

- Within the focus group, use first names only and consider using pseudonyms for family members, ask participants not to talk specifically about what others say, and emphasize that the PI cannot guarantee that the group discussion will be kept private.

- Protect against inadvertent disclosure of recorded information to the media or the public. If use of this information is intended, it must be viewed and authorized by the participant and institutional communications.
- Explicitly state in the consent form that certain information (e.g. statements regarding assault/abuse/neglect) will be reported to authorities, as required by law.

**Consent:**

- Make clear to participants that they may excuse themselves from the focus group (and participation in the study) at any time, and that by doing so, this decision will not affect their relationship with the investigators, the institution, or any services that the institution provides.
- Clearly state in the consent form when and why the participants may be asked to leave, and have a method of seeking assistance if necessary.

**Study Design:**

- Be careful to present questions to the group in a respectful way, and vet the study design with a patient advocate or family specialist who can suggest topics and/or language to avoid.
- Limit the sensitive information elicited about family members with a psychotic disorder. Avoid questions which ask participants to provide information about the family member's health or history with mental illness.
- Screen participants carefully, and provide information in the consent process to ensure that participants understand the study procedures, how their data will be used, and that they may withdraw from the study at any time for any reason.
- Be sure that participation does not put subjects at risk for harm from family members or others.

*Alternate Details:*

- The focus group starts with each participant writing for ten minutes in response to a prompt "what is the hardest part about knowing when a family member should be hospitalized?" Participants write their names on the paper but the moderator reads answers to the group without identifying who wrote them.
- The investigators intend to recruit children under 18, who will attend focus groups with adults because of the logistical difficulty of conducting an under-18-only focus group.

*Other Events:*

- The family member of a subject calls the PI to complain that she is upset that her family member is participating in this study and feels that her own privacy is being invaded by her family member participating. She demands to know what her family member is saying about her in the focus group sessions.
- A subject in the focus group discovers that another subject has been secretly taping the focus group sessions on his phone. The subject reports this to the PI. When the PI confronts the other subject, that subject denies that he has been taping the sessions.

## **REFERENCE(S)**

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