Social and Behavioral Research for Biomedical Researchers

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This Module consists of 9 sections, and will take you between 15 and 25 minutes to complete. You will then be directed to take a short quiz before proceeding to the next Module.

Introduction

This part of the training program will:

- Characterize social and behavioral research, presenting the most likely and typical risks.
- Extend the basic concepts of human subjects protection to these situations for biomedical researchers.

What is social/behavioral research (SBR)?

Social and behavioral research (identified in this module by the acronym "SBR") refers broadly to research that deals with human attitudes, beliefs, and behaviors. Biomedical and clinical researchers often incorporate SBR goals and methodologies into their physiological research. SBR is often characterized by data collection methods such as questionnaires, interviews, focus groups, direct or participant observation, and non-invasive physical measurements. Examples of the ways biomedical researchers use these techniques in their research include health histories, quality of life assessments, family pedigrees, and outcomes studies.
SBR data collection methods often used by biomedical researchers.

Typical SBR data collection methods include:

1. Questionnaires (written questions) or interviews (oral questions, either by phone or in person). These may be open-ended or fixed-answer with pre-established categories such as a Likert scale. Medication diaries and behavior logs are actually special forms of open-ended questionnaires. Some biomedical researchers may also use standardized questionnaires such as intelligence tests or psychiatric diagnostic assessments.

2. Opinion data and other oral data from key informant interviews, focus groups, or group discussions. Biomedical researchers may use these data collection methods to provide qualitative data to develop or support a hypothesis.

3. Direct observation of behavior and interactions. This may involve a pre-coded form for noting observations, or recording (audio-, video-, or other) of actual behavior.

4. Data already collected for other purposes, such as records from education, health care, social service programs, employment, and insurance coverage. These kinds of data are often used by health researchers in outcomes studies and epidemiological studies or as adjuncts in clinical or basic science research.

5. Non-invasive physiological measurement, such as skin impedance and pupil dilation as reflection of emotional arousal or attention. Although these are considered physiological measures, they are often used by social and behavioral researchers to document the physiological components of behavior.
Examples of biomedical researchers use of social/behavioral research methodologies.

- Descriptive or exploratory research involving detailed observation, often in the real world, and often of a culture, family, group, or individual. Records-based research that does not involve direct contact with subjects can be included in this category.
  **Examples include:**
  - Collection of family pedigrees for genetic studies.
  - Description (from videotaping of family interactions) of the behavioral effects of drugs or devices.
  - Epidemiology of farm accidents from an analysis of state workers’ compensation and medical records.

- Evaluation of existing programs of care, service, and education. Distinguishing between program evaluation and research can be difficult. If the intent of the data collection is to contribute to "generalizable" knowledge, or if the results are going to be applied outside of the setting or population, the activity is usually classified as research. If the results stay entirely in-house and are used for administrative purposes only, many institutions do not consider it research.
  **Examples include:**
  - Examination of the impact of a computer-generated information sheet given to people picking up asthma medications from a pharmacy.
  - Evaluation of on-call nursing services for the elderly living at home.
  - Assessment of the effectiveness of a manufacturer’s marketing strategies.

- Comparison of competing types or programs of information, education or treatment. These research projects usually randomize participants between experimental and standard approaches, sometimes with a third, control group.
  **Examples include:**
  - Massage versus education for low back pain.
  - Diet versus diet plus coached exercise for control of diabetes.
A new medication vs. a standard and widely used medication vs. talk therapy for treatment of depression.

Experimental manipulations of belief, attitude, emotion, or behavior, that affects subjects in ways that would not occur in their normal experience outside the research setting. Research of this type typically comes from academic areas such as psychology, communication, speech and hearing, or education, as well as nursing or medicine. If deception is employed, additional consent issues become important and must be addressed.

Examples of these kinds of studies include:

- Creating emotional stressors to measure cortisol levels.
- Use of placebo in clinical drug trials.
- Evaluating virtual reality as a means for pain management.

**Risks and benefits unique to SBR**

The risks of harm associated with SBR are different from those associated with traditional biomedical research.

- They may include psychosocial stress and discomfort, disruption of personal and family relationships, economic, and even political harms that may result from identifiable data falling into the wrong hands. Stress and discomfort may result from being asked personal questions, from being deceived, or from being subjected to research procedures designed to manipulate emotions, feelings, and thoughts.

- They may be less predictable, more subjective and variable, and less remediable than physiological harms. For example, it is more difficult to predict how an individual will respond to answering a question about childhood sexual abuse than to predict an individual's reaction to having blood drawn. Questions about certain behavior, attitudes, and beliefs may result in "inflicted insight." This can cause distress of realizing something about oneself that one would not have learned without having taken part in the study.

- They may be more dependent on socio-cultural factors than physiological harms. For example, collecting demographic information from illegal immigrants may be more risky than collecting the same information about
Reporting adverse events or reactions is as important in SBR as in any other human subjects research. Check with your local IRB to make sure that you understand these reporting requirements.

Managing and Minimizing Risks of Harm from SBR

1. **Data management.**
   - Many risks of SBR are the result of breaches of confidentiality involving sensitive data. Coding data, securing the master list linking the code to the subject identifier, maintaining the data in a secure environment, or de-linking data from identifiers can minimize risks resulting from breach of confidentiality.

2. **Debriefing.**
   - If distress or deception must be experimentally induced, as in some psychological and physiological measurement research, the research design usually requires withholding certain information from the consent process in order to obtain unbiased results. After they have completed participation, it is important to provide this information to subjects from whom it was withheld, and to provide an opportunity for subjects to express their concerns and ask questions about the research.
   - Strategies to accomplish this might include:
     1. Debriefing subjects with a description of what really happened.
     2. Explaining why the research could not otherwise be conducted.
     3. An apology.
   - If possible, researchers should debrief the subjects while they still have an opportunity to withdraw their data should they feel offended and not wish to continue participation or have their data excluded.

3. **Adequate informed consent.**
   - Making sure that potentially disturbing experiences and questions are identified during the consent process before the subject agrees to participate can minimize the likelihood that subjects will experience stress and discomfort.
Key Points about Informed Consent

1. The statement "there are no risks" should not be used. Although some SBR might have no physical risks, it is always necessary to consider whether there is a possibility (even if not a high likelihood) of emotional/psychological risk, loss or breach of confidentiality or stigmatization.

2. Describe the content of questions, interview topics, etc., and give specific examples of the MOST personal, sensitive, or distressing questions that will be asked. Sometimes it is appropriate to reassure subjects that there is no "right" or "wrong" answer.

3. State that participants have the right to refuse to answer any question for any reason. This statement should not impute to subjects a specific sensitivity or emotional state (e.g., it should not say, "You have the right to skip any questions that make you uncomfortable").

4. It may be difficult to advise subjects about emotional distress without increasing the likelihood of experiencing it. This is a judgment call that needs careful consideration in wording of consent forms.

5. If recordings are used, the consent should state that subjects have the right to review and delete recordings that will be kept indefinitely or shared outside of the research team.

6. If focus groups are used, subjects should be reminded that the identities of fellow participants and the information exchanged are confidential.