Social and Behavioral Research (SBR) for Biomedical Researchers

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Introduction

Biomedical researchers employ and, therefore, must understand the variety, risks, and benefits of SBR techniques used within the framework of biomedical research. In appreciating the subtleties associated with SBR, this module also presents important points to consider in relation to informed consent.

Learning Objectives

By the end of this module, you should be able to:

- Describe some of the areas of study where SBR techniques are used.
- Discuss the types of data collection associated with SBR.
- Identify the risks and benefits that are unique to SBR.

What Is SBR?

SBR refers broadly to research that deals with human attitudes, beliefs, and behaviors. Biomedical and clinical researchers sometimes incorporate SBR questions and methodologies into their physiological research. SBR is characterized by data collection methods, such as:

- Questionnaires
- Interviews
- Focus groups
- Direct or subject observation
- Non-invasive physical measurements

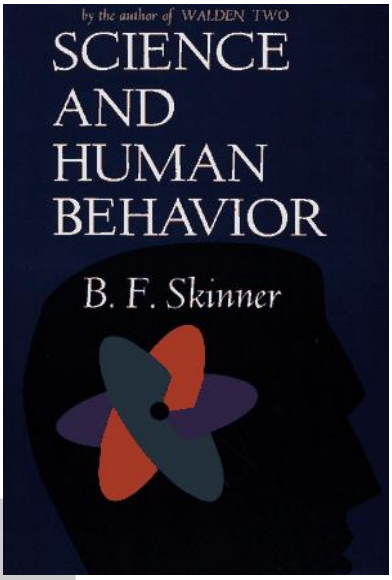
Examples of the ways biomedical researchers use these techniques in their research include health histories, quality-of-life assessments, family pedigrees, surveillance, and outcomes studies.

SBR Data Collection Methods Often Used by Biomedical Researchers

Typical SBR data collection methods include:

- 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).
- 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 enrich or support their physiologic data in testing hypotheses.
- 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.
- Data already collected for other purposes (such as, records from education, healthcare, 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.
- 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 SBR researchers to document the physiological components of behavior

Examples of Biomedical Researchers' Use of SBR Methodologies



Examples of SBR methodologies used by biomedical researchers include:

- 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, devices, or other physiologic interventions
    - 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 applicable outside of the research 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 organizations do not consider this to be research. Examples include:
    - Evaluation of the effect 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 subjects between experimental and standard approaches, sometimes with a third control group. Examples include:
    - Massage versus education for lower back pain
    - Diet only versus diet plus coached exercise for control of diabetes
    - A new medication versus a standard and widely used medication versus talk therapy for treatment of depression
- Experimental manipulations of belief, attitude, emotion, or behavior, that affect 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 and medicine. If deception is used, additional consent issues become important and must be addressed. Examples include:

- Creating emotional stressors to measure cortisol levels
- Using a 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 harms, 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 from learning 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 undocumented immigrants may be more risky than collecting the same information from citizens.

Reporting adverse events or reactions is as important in SBR as in any other human subjects research. Check with the applicable Institutional Review Board/Independent Ethics Committee (IRB/IEC) to ensure that these reporting requirements are understood.

Managing and Minimizing Risks of Harm from SBR

Data Management

Many risks of harm from 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.

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 subjects 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:

- Debriefing subjects with a description of what really happened
- Explaining why the research could not otherwise be conducted
- Issuing 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.

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

Key points to understand about informed consent include:

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 subjects 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 (for example, 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 subjects and the information exchanged are confidential.

Social and Behavioral Research (SBR) for Biomedical Researchers

Dr. Rosen is the program director for the Pediatric Residency Program at an academic medical center that specializes in caring for critically ill children. He wishes to evaluate the effectiveness of the training program that uses simulation sessions designed to develop intubation skills. He plans to randomize pediatric residents to an initial faculty-led or fellow-led simulation laboratory experience. Residents will return to the simulation laboratory one week later to complete another simulation laboratory session to evaluate their skills. Dr. Rosen will observe the evaluation sessions and collect data on the numbers of failed attempts and successful intubations by each resident and by group assignment. Dr. Rosen wants to withhold information about the actual purpose of the research from both the residents and the faculty members to decrease any performance effects that may potentially bias the results.

- Is Dr. Rosen's study considered human subjects research?

  Whether this study is human subjects research, as defined in the federal regulations, depends on Dr. Rosen's intent in conducting the study. If Dr. Rosen is evaluating the training program solely for the purpose of improving the program, then it is probably not human subjects research but, rather, program evaluation. Although there are ethical concerns with regard to program evaluation, most organizations do not require IRB/IEC review for program evaluation.

If Dr. Rosen is conducting the study in order to contribute to the literature on medical education, then it would be considered human subjects research because it is designed to contribute to "generalizable knowledge."

The remainder of the questions will assume that Dr. Rosen's study is human subjects research.

- Dr. Rosen is using several SBR techniques in his study in a seemingly biomedical-oriented environment. What SBR methodologies are utilized in this research?

  Dr. Rosen's research is best categorized as educational research to compare two different types of teaching approaches and experiences. The research uses a randomization procedure, also frequently used in biomedical research, for the comparison. Observing the evaluation session without interacting with the residents or faculty members allows Dr. Rosen to use another SBR technique for data collection. Withholding information about the actual purpose of the research from both groups of subjects illustrates the use of deception, which is common in SBR research and can be appropriate to potentially reduce affects on performance.

- What could be the risks in this study and what steps should Dr. Rosen consider in order to minimize them?

  Even though the risk of a breach of confidentiality might be minimal, there is the possibility that Dr. Rosen would know how each resident performs, and that could influence his evaluation of them and his recommendations for their career advancement. A neutral party, who is not in a position of authority or part of the student-teacher relationship, could observe the evaluation sessions, collect the data, and record the data using an assigned code for each resident. The observer could provide Dr. Rosen the data without the linking code. Although the withholding of information about the research's actual purpose from both the residents and the faculty members is justified to decrease any performance effects that may

potentially bias the result, Dr. Rosen could hold a "debriefing session" after the data collection is complete. The debriefing session would inform the subjects of the research's actual purpose, outline the reasons for withholding certain information, and detail the precautions that had been taken to minimize risks of harm. The debriefing session also provides an opportunity for the residents and faculty to ask questions.

Summary

SBR techniques can enhance biomedical research studies by using non-invasive techniques of data collection. However, with all human subjects research, the risks of harm should be identified and mitigated by researchers. Understanding SBR techniques and possible risks of harm will help biomedical researchers better use the SBR techniques in the framework of biomedical research.

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