Also of interest

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The Institutional Review Board Member Handbook

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that the IRB should not approve a consent document that contains inaccurate information. Specifically:

- The consent document should *never* be used as part of the deception and thus should not include anything that is untrue.
- The consent document should reveal as much as possible to the participant regarding the procedures in the study.
- The consent document need not explain the details of the study if this will eliminate the capability of the study to inform the process under investigation. A useful guideline to keep in mind is that the experimenter–subject relationship is a real relationship "in which we have responsibility toward the subject as another human being whose dignity we must preserve."

CHAPTER 3-7

QUALITATIVE SOCIAL SCIENCE RESEARCH

DEAN R. GALLANT AND ROBERT J. AMDUR

Qualitative Social Science Research

- Informed consent is an important part of qualitative research. Much qualitative research is exploratory, and the areas of inquiry may not be apparent even to the research team at the time the study is initiated. Qualitative research should be designed to sustain the consent process throughout the course of a subject's participation.
- Qualitative researchers may encounter reportable situations—evidence of child or elder abuse or neglect, or the likely prospect of harm to self or others. In most states, investigators have a legal obligation to report such situations to appropriate authorities. Researchers who are at all likely to uncover reportable situations must be prepared for the possibility. Appropriate consultation should be available if the researcher is not a trained clinician with relevant clinical experience. The IRB should consider the adequacy of the investigator's plans and may want to seek counsel from experts in the field.
- If identifiers must be retained (for longitudinal studies, or where subjects are videotaped or audiotaped), and if the research deals with very sensitive topics, it may be appropriate to seek a certificate of confidentiality to protect against compelled disclosure—by federal, state, or local authorities—of identifying information.

Not all research in the social sciences is laboratory-based experimental work. There is a long tradition of *qualitative research* by anthropologists, ethnographers, sociologists, survey researchers, psychologists, and others whose observations are typically conducted outside the laboratory. The purpose of their research is often to *develop* hypotheses rather than to test and validate them in controlled studies. Methods include observation (including participant observation), questionnaires or surveys, interviewing, or review and analysis of existing data. Because of the potential range of activities involved, qualitative research in the social sciences can present special problems for IRBs, for investigators, and for the subjects themselves.

TYPES OF RISK IN QUALITATIVE RESEARCH

Breach of Confidentiality

Subjects routinely share the stories of their daily lives with friends and colleagues. But, typically, a researcher collects information with the hope of publishing the results—if not necessarily attributing the subjects' comments directly (as a reporter might do), then at least revealing the cumulative knowledge gained from the research inquiry. If identities are poorly disguised, whether from others or from the participants themselves, subjects can risk embarrassment or more serious harm.

Violation of Privacy

Privacy refers to a state of being free from unsanctioned intrusion. Ordinarily, individuals have a right to privacy—that is, control over the extent, timing, and circumstances of sharing information about themselves with others. Violation of this right, although not necessarily a direct harm, contradicts the Belmont Report's principle of respect for persons.

Validation of Bad Behavior

Some research may unintentionally reinforce undesirable characteristics of research subjects. An investigator interviewing members of clandestine militant groups in a war-torn country worried about his ability to collect good data, thinking that subjects would be unwilling to reveal their "secrets." But to his surprise, and perhaps dismay, subjects reported that this interest from a faculty member at a major research institution gave an imprimatur of legitimacy to their anarchistic efforts! Another investigator studying recreational drug use among teens quickly learned it was necessary to develop a relationship of trust with his subjects, including being able to talk with them without criticizing their drug-taking behavior. A non-judgmental relationship like this, with a senior researcher at a prominent university, can have the unhappy effect of persuading subjects that their behavior is acceptable—if not fascinating—to wise adults. In such cases, it may be appropriate for the IRB to discuss its concerns with the investigator to help narrow the gap between strict scientific objectivity and responsible social values.

Risk of Harm to Others

Are possible harms to *secondary research subjects*—that is, individuals who do not themselves participate in the study but about whom the investigator obtains information via interview or other hearsay means—an appropriate area of concern for the IRB? In December 1999, the Office of Protection from Research Risks cited failure to obtain informed consent from secondary subjects as a finding in a letter of suspension of IRB authority. Oral historians and genetics researchers, among others, reacted promptly, insisting that extension of this regulatory interpretation would effectively halt much of their research, since they could not possibly obtain informed consent from everybody about whom they indirectly received information. As of this writing, the question is unresolved, but OPRR (now Office of Human Research

Protection [OHRP]) has not rescinded its interpretation, so IRBs should at least consider whether special consideration should be given to secondary subjects in studies where primary informants provide information about others.

INFORMED CONSENT

Although the content and issues may differ, informed consent is no less important in qualitative research than it is in clinical research. However, much qualitative research is exploratory, and the areas of inquiry may not be apparent even to the research team. How then can subjects truly be informed? Prior information about risks, insofar as they are known or can be anticipated, cannot be withheld. But if the range of possible risks is potentially very large, how can an investigator present accurate information about the study in a manner that will not simply frighten subjects away? One strategy is to sustain the consent process throughout the course of a subject's participation. As new data are acquired, and the researcher's overall knowledge of risks expands, subjects can be reminded that participation is voluntary, and their understanding of the risks and benefits of participation can be refreshed. This process should not be used to mask risks, nor to lure subjects into a relationship with the investigator before they fully understand the consequences, but it can help them develop an understanding of the research and the context of their role in it. Their continued participation is then based on active awareness of emerging developments.

REPORTABLE SITUATIONS

Much qualitative research deals with sensitive topics and looks deeply into subjects' daily lives. As a result, investigators may encounter reportable situations: evidence of child or elder abuse or neglect, or the likely prospect of

harm to self or others. In most states, investigators have a legal obligation to report such situations to appropriate authorities. Researchers who are at all likely to uncover reportable situations must be prepared for the possibility. Appropriate consultation should be available if the researcher is not a trained clinician with relevant clinical experience. A strategy for alerting subjects to the need for reporting is essential; depending on the nature of the study and the subject population, this can involve mention of the reporting requirement as part of the informed consent process, or a more ad hoc procedure when the likelihood of reportable situations is small. The IRB should consider the adequacy of the investigator's plans and may want to seek counsel from experts in the field.

CERTIFICATE OF CONFIDENTIALITY

Whether or not a researcher is studying behaviors likely to yield information about reportable situations, subjects' reputations, relationships, employability, or legal status may be threatened by disclosure of identifiable information. The law does not recognize any automatic privilege for social science researchers; data are vulnerable to subpoena or other official inquiry. If identifiers must be retained (for longitudinal studies, or where subjects are videotaped or audiotaped), and if the research deals with very sensitive topics, it may be appropriate to seek a certificate of confidentiality to protect against compelled disclosure—by federal, state, or local authorities—of identifying information. Certificates of confidentiality can be granted by the federal funding agency, upon application, and are also available to investigators without federal funding. These certificates do not prohibit the investigator from disclosing information (and, in some states, confidentiality certificate protections are overridden by mandated reporting requirements), but they do provide a measure of protection for research subjects that would not otherwise be available.

CHAPTER 3-8

RESEARCH WITHOUT INFORMED CONSENT OR DOCUMENTATION

MARIANNE M. ELLIOT AND ROBERT J. AMDUR

Research Without Informed Consent or Documentation Thereof

Requirements to waive the requirement for informed consent:

- The research involves no more than minimal risk to the subjects.
- The waiver or alteration will not adversely affect the rights and welfare of the subjects.
- The research could not practicably be carried out without the waiver or alteration.
- Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

Circumstances when an IRB may waive the requirement for documentation of informed consent:

- The only record linking the subject and the research would be the consent document, and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern.
- 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.

The purpose of this chapter is to explain the situations where federal regulations permit the IRB to approve research and waive the requirement for informed consent or the requirement for documentation of informed consent. A special case of the waiver of consent issue is the situation where research is conducted without consent in the setting of a medical emergency. There is an extensive list of requirements for IRB approval of research in the setting of a medical emergency that are described in federal regulations that were established specifically to deal with this controversial situation. The discussion in this chapter does not apply to the situation where research is conducted without consent in the setting of a medical emergency.

REQUIREMENTS FOR AN IRB TO WAIVE THE REQUIREMENT FOR INFORMED CONSENT (45 CFR 46.116 [D])

An IRB may approve a consent procedure that does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirement to obtain informed consent provided the IRB finds and documents the following:

- The research involves no more than minimal risk to the subjects.
- The waiver or alteration will not adversely affect the rights and welfare of the subjects.
- The research could not practicably be carried out without the waiver or alteration.
- Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

Example 1

The researcher plans to determine how mood and perception of one's body image may be related. Initially subjects complete a series of written questionnaires and scales about their body image. After the subjects are presented with visual images intended to evoke a negative mood, the subjects are asked to complete the same questionnaires and scales. The effect of evoking a negative mood is evaluated.

Although the actual purpose of the research is to determine how mood may be related to body image, subjects are informed that the research is actually two separate research projects: one related to moods and how they may change and the other related to body image. This deception is part of the research design, and the student subjects are not fully informed about the purpose of the research.

In this example, the IRB may find that an alteration of informed consent is appropriate and that the criteria stated above have been met based on the following:

1. **The research involves minimal risk:** The visual images are similar to those that the subjects might see in magazines about health and exercise, or movies. There are no provocative images. The questionnaires and scales are valid and reliable scales that are used in standard psychosocial testing.

2. **The rights and welfare of subjects are not adversely affected:** Subjects are informed about the actual procedures of the research, the lack of anticipated benefits, and the ability to discontinue participation at any time without penalty. Subjects are not informed that the research actually has one purpose and that the data will be evaluated for that intent.

3. **The research could not practicably be carried out without the alteration in the informed consent process:** The research evaluates a feature of human behavior that is likely to be affected by the subjects' knowledge of the behavior that is being evaluated.

4. **In this research, it is appropriate to provide subjects with additional pertinent information after participation.** The researcher debriefs the subjects after their participation to explain the actual purpose of the research and why the research design was appropriate. The researcher also offers to be available for any questions subjects may have and provides information about appropriate services if subjects experience distress or anxiety about their participation in the research.

Example 2

The researcher plans to determine whether some specific blood chemistry values change in individuals undergoing clinically indicated abdominal surgery and if there is a correlation of changes with the increased incidence of complications after surgery. The researcher plans to review the medical records of all individuals who have undergone abdominal surgery in the past year and for the next year. From a preliminary estimate, there are about 1,000 abdominal surgeries performed per year at the hospital. The researcher will collect limited data for this for research. The types of data to be collected include such items as the diagnosis before surgery, the type of abdominal surgery, specific blood chemistry values before the surgery, the same specific blood chemistry values after the surgery, a description of problems after surgery, and perhaps the age ranges of the individuals. The researcher will double-code the data so that the link is known only to the researcher and no others, in the unlikely event the data must be verified for accuracy. The results of the research will not affect the clinical care of the individuals, as the information will not be examined until after subjects leave the hospital.

In this example the IRB may find that a waiver of informed consent is appropriate and that the criteria stated above have been met based on the following:

1. **The research involves minimal risk:** The review of medical records is for limited information, the information is not sensitive in nature, and the data are derived from clinically indicated procedures. The precautions taken to limit the record review to specified data and the double coding of the data further minimize the major risk, which is a breach of confidentiality.

2. **The rights and welfare of the individual would not be adversely affected:** The clinically indicated surgical procedure and the associated blood chemistry values were already completed, or would be completed, regardless of the research.
3. **The research could not be practicably carried out without the waiver:** Identifying and contacting the thousands of potential subjects, while not impossible, would not be feasible to get consent to review medical records.
4. **Providing subjects with additional information is not appropriate:** It would not be appropriate to provide these subjects with additional pertinent information about the results of the research as the results would have no effect on the subjects.

REQUIREMENTS FOR AN IRB TO WAIVE THE REQUIREMENT FOR DOCUMENTATION OF INFORMED CONSENT (45 CFR 46.117 [C])

Federal regulations describe two circumstances when an IRB may waive the requirement to obtain a signed consent form:

- The only record linking the subject and the research would be the consent document, and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern.
- 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.

In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

Example 3

A researcher plans to evaluate the effectiveness of a smoking cessation program with women who are receiving prenatal care at the local health clinic. During a prenatal visit, any women who are already participating in the smoking cessation program will be asked to complete a written questionnaire about the program. The one-time written questionnaire includes questions about how well the women are complying with the program and how they feel about their progress. There is no identifying information about subjects on the questionnaire, and whether the subjects complete the questionnaire has no effect on the care they may receive at the clinic.

In this example, the IRB may waive the requirement to obtain a signed consent form because the research presents no more than minimal risk of harm to subjects. The questionnaire has no identifying information about the subject, and the purpose of the research is to evaluate the effectiveness of the program itself. Normally, there is no requirement for written consent for completion of written questionnaires outside the research context. By virtue of completing the questionnaire, subjects have consented to participate in the research. In this case, the IRB may require the researcher to provide subjects with a written summary or an information sheet about the research.

Example 4

A researcher plans face-to-face interviews with university students who belong to a support group on campus for transgendered, gay, lesbian, and bisexual individuals. The purpose of the research is to evaluate the quality of health care services for these individuals. The researcher plans to recruit subjects through flyers and information distributed at support group meetings. Potential subjects will contact the researcher directly. The researcher plans to conduct two face-to-face interviews six months apart. The interviews will be audiotaped, and the researcher will ask subjects to use a pseudonym during the interviews. Also, each subject will be assigned a coded number on the audiotape.

In this example, the IRB determines that the only record linking the subject and the research would be the consent document. The principal risk would be potential harm resulting from a breach of confidentiality if the consent documents were disclosed, purposefully or inadvertently. To minimize the potential harm to subjects, the IRB may permit the informed consent process to be conducted verbally and have the researcher document, perhaps in a research note, the circumstances of the consent process. The IRB may then request that the researcher ask subjects whether they want documentation linking them with the research, and each subject's wishes will be honored. The IRB may also require the researcher to provide each subject with a written summary or information sheet about the research. However, in this example, even having an information sheet about the research could be potentially harmful to subjects who may already suffer from social stigma, embarrassment, or ostracism. The IRB may suggest providing subjects with a card with only the name and phone number of the researcher in the event they have any questions or concerns.

It may be useful for the IRB to require that the investigator inform each subject about the temporal aspects of the risks associated with a signed consent document as the only link between the subject and the research. Subjects, as students or activists, might feel that the immediate potential harm from having a document with their signature confirming their participation in the research is minimal and a potential breach of confidentiality is not relevant. In contrast, the same subjects may find that the harm caused by an inadvertent breach of confidentiality perhaps five to ten years later during a job interview to be greater.

CHAPTER 3-9

PASSIVE CONSENT (NOT SAYING NO)

LINDA J. KOBOKOVICH, ROBERT J. AMDUR, AND ELIZABETH A. BANKERT

Research That Uses a Passive Consent Process

To approve the use of passive consent an IRB must determine that the research meets either the regulatory criteria for waiver of the requirement for informed consent or documentation thereof.

Requirements for an IRB to waive the requirement for informed consent:

- The research involves no more than minimal risk to the subjects.
- The waiver or alteration will not adversely affect the rights and welfare of the subjects.
- The research could not practicably be carried out without the waiver or alteration.
- Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

Circumstances when an IRB may waive the requirement for documentation of informed consent:

- The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern.
- 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.

In organizations that conduct research involving survey interviews, the collection of information from the medical record, or the study of children at school, the IRB may encounter the situation where the investigator requests that the study be conducted based on the use of passive consent. For the purposes of this discussion, *passive consent* is defined as a situation where the lack of an objection to research participation is considered to be an affirmative declaration of informed consent. This is a complicated way of saying that passive consent means that if you do not say "no," it means that you say "yes."

Example 1

A research study involves a survey that evaluates alcoholic beverage consumption in junior high school students. The survey will be administered in the school cafeteria during the student lunch break. The researchers will explain the essential elements of informed consent to potential subjects, and their assent is a requirement for study participation. The researchers have permission to conduct the study from the school principal. The researchers plan to inform parents of the study by sending them a letter at home that explains the study in detail. The letter explains that students will not be approached about the study if parents send in a "refusal to participate" card; the stamped, self-addressed card is included with the letter. The letter explains that if parents do not register an objection to the study, it will be assumed that they are giving the researchers permission to ask their child to participate.

In this example the researchers are asking the IRB to approve the study with the understanding that parental permission will be obtained using a passive procedure. To evaluate this issue, it is important that the IRB understand that to approve the use of a passive consent procedure, an IRB that operates in compliance with federal regulations must determine that the study meets either the criteria to waive the requirement for informed consent or the criteria to waive the requirement for documentation of informed consent.

The following requirements must be met for an IRB to waive the requirement for informed consent (45 CFR 46.116 [d]):

- The research involves no more than minimal risk to the subjects.
- The waiver or alteration will not adversely affect the rights and welfare of the subjects.
- The research could not practicably be carried out without the waiver or alteration.
- Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

There are two circumstances when an IRB may waive the requirement for documentation of informed consent (45 CFR 46.117 [c]):

- The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern.
- 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.

In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.