Social and Behavioral Research

Brief Overview

At UCSF, all research involving contact with human research subjects or identifiable information about people must be reviewed or formally exempted by the IRB. The type of review required is generally determined by the level of risk for the study participants.

Privacy and Confidentiality: The most commonly perceived risks of social and behavior research are the consequences of breaches of confidentiality. Research may gather information about research participants that ? if it became known to others ? could damage the participants? reputation, employability, or insurability or could place them in legal jeopardy. The IRB evaluates how well any such risks are managed in proposed research. Approach prospective participants with sensitivity and respect.

Consent: The IRB expects that most studies will be conducted with the fully informed, individual consent of each participant. Consent often is documented with a signed consent

form, but there are some exceptions, as explained below.

Professional Codes of Ethics: Guidelines for research ethics have been prepared by professional organizations for disciplines like anthropology, psychology and sociology. These professional guidelines provide more detailed guidance than can be included here.

Outside resources

- American Anthropological Association ethics page: [1] Includes links to other professional associations? ethics pages.
- American Psychological Association Ethics Home Page [2]
- American Sociological Association Code of Ethics [3]

Risk Level Determines Level of IRB Review and Type of Application

Federal regulations categorize level of research in relation to "minimal risk." In addition to the information below, see the Levels of Review [4] page for more information on what level of review your research may require and follow the submission instructions on the New Study [5] page.

Minimal risk definition

> **Minimal risk** is the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests (45.CFR.46.102(i)).

More than minimal risk research needs full committee review

The IRB must review any research involving more than minimal risk to subjects needs to be reviewed at a convened IRB meeting [4]. At UCSF, the following factors most often contribute to greater-than-minimal risks in social and behavioral studies:

Sensitive Topics/Questions: If researchers record subjects? identities and if the information gathered in the research could place subjects at criminal or civil liability or damage their financial standing, employability, insurability, reputation, or be stigmatizing, then the research should be submitted for full committee review. Topics that often require full committee review include the following:

- sexual activities and preferences,
- illegal drug use,
- abusive or self-destructive behavior, and
- other illegal activities.

The IRB will review the study to determine whether there are sufficient protections to ensure

that risks to subjects are no greater than minimal.

Sensitive or Vulnerable Subject Populations: In some otherwise harmless research, subjects may be placed at risk because of their vulnerable situations or conditions. Examples include the following groups:

- prisoners or parolees;
- depressed or distressed persons;
- minors;
- abused persons;
- people with chronic illness, very debilitating medical conditions, degenerative diseases, or other physical, mental, or emotional disabilities; and
- the dying.

While some research involving vulnerable groups is eligible for expedited review (especially if identities are not collected), often the subjects? vulnerability raises their risks above the minimal risk standard.

Manipulation of Subjects? Emotions: Research that manipulates subjects? emotions could place them at risk for psychological harm, especially if the subjects are already vulnerable due to personal situations, conditions, or events. For example, studies applying stress to persons already suffering from post-traumatic stress disorder may carry more than minimal risks. Any study involving more than minimal risk should be submitted for full committee review.

Minimal risk research often needs expedited review

Most minimal risk social and behavioral research is submitted for expedited review [4] under the following expedited review category:

- Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

Most participant observation also can receive expedited review. Please review the expedited review categories [4] for a complete list of categories of research that may qualify for expedited review.

Some minimal risk survey research, educational research or observations of public behavior may be exempt

Some types of human research studies are exempted from the requirement for IRB review [4]. However, at UCSF, the IRB must formally certify that a study is exempt. Researchers may not make this determination for their own research. If you believe your study is exempt, submit it to the IRB for review as described on the New Study [5] page.

Categories of Exempt Research: Federal regulations specify what categories of human

research are exempt from regular IRB review. See the Levels of Review [4] page for a detailed explanation of these categories and important exceptions.

Briefly, social and behavioral research that often receives exempt certification at UCSF includes:

- Category 1: Research in established or commonly accepted educational settings, involving normal educational practices
- Category 2: Educational tests, surveys, interviews or observations of public behavior, unless you collect identifiers and info that could place subjects at risk (participants cannot be children, prisoners or inpatients)
- Category 3: Interviews/surveys with elected public officials
- Category 4: Use of existing data, documents, records or specimens, if a) sources are publicly available or b) you record info in a way that subjects cannot be identified

Identification and Recruitment of Prospective Subjects

The IRB has developed detailed recommendations for how to identify and approach individuals about participation in research. See the UCSF Recruitment Methods guidelines [6] for a detailed discussion of allowed recruitment methods.

Below are a few issues that commonly appear in social and behavioral research:

Privacy issues

When research is about medical matters or behavior that most people consider private, prospective research participants may be surprised or angry if they learn that unknown researchers have obtained their identity and contact information. Subjects may be particularly upset if researchers have obtained presumably private information about diagnoses like cancer, HIV infections, or mental illness. Carefully consider how best to approach subjects in such situations. For patients, it may be best to have the first mention of the study come from a care provider already known to the prospective participant.

Avoiding revealing subject information to third parties

Researchers should avoid leaving phone messages or sending postcards that may reveal information about a prospective research participant to third parties. Sometimes family members and housemates have not been told details of a prospective subject?s life and diagnoses, and careless phone calls or correspondence may disclose information the subject preferred to keep private. For particularly sensitive topics?for example, the study of abused women or elders?even sealed letters may be opened by others and cause problems for prospective subjects. Researchers have a responsibility to minimize risks from these causes.

Using medical and other health care records

Researchers who do not have a clinical relationship with their prospective subjects often wish

to obtain names of patients with particular conditions from health care providers. In addition to the subjects? concerns about privacy, there are legal restrictions on what information can be shared.

HIPAA Restrictions: Because of the Health Insurance Portability and Accountability Act (HIPAA) health care providers generally are prohibited from providing researchers with identifying information and information about diagnoses and treatments unless (1) patients first authorize the release of the information or (2) a Privacy Board (the IRB at UCSF) approves a waiver of authorization. See the Recruitment Methods guidelines [6] and HIPAA Requirements and Forms for Research [7] pages for additional information.

Information from Multiple Institutions: Researchers seeking access to patients from multiple institutions must meet the HIPAA requirements of each institution that supplies Protected Health Information. Although HIPAA allows an institution to accept authorization forms and even waivers of authorization from any appropriate constituted Privacy Board (like the IRB), many institutions require review by their own Privacy Board and use of their own forms, as there are financial penalties for inappropriate release of information. See HIPAA and Research for more information.

Minors and other vulnerable populations

Researchers considering enrolling minors [8], the cognitively impaired [9], prisoners [10] or other particularly vulnerable populations [11] should be familiar with IRB guidelines regarding these populations. The guideline on minors [8] in particular includes discussions of enrolling minors in educational and health care settings that are frequently used in social and behavioral research.

Intrusive or repetitive contact methods

Social and behavioral researchers sometimes want to send multiple letters or to make repeated phone calls in order to assure participation by a representative sample of their targeted subject population. Because prospective participants have an absolute right to say no to participation in research, the IRB is reluctant to approve recruitment methods that continue to recontact until the person actively and forcefully refuses participation. For example, the IRB has been reluctant to approve some telephone contact approaches that continued calling after a prospective subject gave a ?soft? refusal like saying ?I don?t have time for this.?

Researchers planning to use contact methods that subjects may consider intrusive should explain why the intrusiveness is necessary and should provide scripts to be used in all contact attempts.

Consent

The IRB has extensive guidelines regarding informed consent [12]. A few issues particularly appear in social and behavioral research:

Waiving signed consent

In social and behavioral research, it is sometimes appropriate to forego obtaining a consenting participant?s signature, although it is almost always required that the participant give verbal consent [13]. A waiver of signed consent [13] can only be approved if certain criteria are met. See the Verbal, Electronic or Implied Consent (Waiver of Signed Consent) [13] page for detailed information.

The following special situations appear frequently in IRB applications:

No Need to Record Subject Identities: If subject identities do not need to be recorded for research purposes, and if the main risk to subjects would be from a breach of confidentiality, the IRB can waive obtaining signed consent. Verbal consent [13] should still be obtained and generally subjects should be provided with a copy of the information sheet.

Participant Observation: Consent is not required for observation of behavior in public situations, as long as no identities are recorded. In situations in which participants reasonably expect their behavior and conversation to be private (as in clinics, classrooms, and meetings that are not open to the public), participant observers usually are expected to make their presence as a researcher known, but signed consent is usually waived with the justifications that it is not practicable to obtain signed consent from all involved and that the risks are minimal.

For more formal one-on-one or small group interviews, signed consent may be obtained or verbal consent [13] may be appropriate in some situations.

Telephone or Electronic/Online Consent: The IRB expects that participants in telephone or online surveys will be provided the same types of information that are included in written consent forms. Before any substantive survey questions are asked, prospective participants should be asked explicitly whether they are willing to participate. Include the verbal script or electronic consent [13] with the IRB application.

Implied Consent: When a questionnaire has been mailed to prospective participants or is made available in an office or clinic, it may be appropriate to tell subjects that by returning a completed questionnaire they are consenting to be included in the research. Use of such implied consent is particularly appropriate where subjects? identities are not otherwise recorded. See the Verbal, Electronic or Implied Consent (Waiver of Signed Consent) [13] page for details.

The IRB usually will ask that the questionnaire include an introduction or be accompanied by a separate information sheet or cover letter that contains all the information that would be included in a standard consent form.

Deception and withholding information

The IRB may approve a consent process and a written consent form that withhold some key information about a study or even actively mislead prospective subjects. For example, it may

be necessary that subjects not be told the true purpose of a study, because knowing the purpose might change their reactions.

Criteria for Approval: The IRB can approve the deception only if the study meets specific criteria laid out in 45 CFR 46.116.d. These are the same criteria as for waiving all consent; see Consent Guidelines for more information. The key criteria are that it must be impracticable to carry out the study without the deception, and the deception must involve minimal risks to participants.

Debriefing: The IRB generally requires that participants be debriefed after their participation and be given a full explanation of the reasons for the deception.

Prior Disclosure: In some studies it may be possible to explain during the original consent process that some information is being withheld. However, researchers have successfully argued that in many studies even vague references to hidden purposes will affect subjects? behavior and make the study impracticable.

Sample consent forms

Generally, use the Social or Behavioral consent form template or One-time Survey consent form (if applicable) template when preparing a written consent form. These and additional templates are available on the Consent and Assent Form Templates [14] page. If your study qualifies for exempt certification [4], review the Exempt Consent Templates and Guidance [15] page.

Risks to Subjects

Less experienced researchers may fail to consider all the risks that can arise in social and behavioral research. As discussed above, if the risks are more than minimal, the study must be reviewed by the full IRB, while studies with minimal risks are usually eligible for expedited review.

The following risks frequently are found in research reviewed by the IRB. In the IRB Application, explain how any such risks will be managed and minimized. Also describe these risks in the consent documents.

Loss of confidentiality

Researchers frequently gather information that, if it became known outside of the study context, could harm participants by damaging their reputations, employability, or insurability. Other information could put subjects in legal jeopardy. Researchers should minimize such risks by asking for the minimal amount of information needed for study purposes and by protecting the information that is gathered.

Legal risks

Mandatory Reporting: Many professionals are subject to legal requirements to report

situations like the intent to harm oneself or others. The IRB generally expects that professionals conducting research will comply with their professional reporting requirements; the legal requirements to do so when acting as a researcher may not always be clear, but the IRB usually still sees an ethical obligation.

Similarly, if a social or behavioral study includes testing for reportable medical conditions, such as certain sexually transmitted diseases, the medical reporting requirements remain in effect.

Consent forms should warn subjects of reporting obligations in any study in which reportable information is likely to be evoked. There is no need to warn subjects about reporting requirements if the study design is not likely to evoke reportable information.

Subpoenas of Research Information: Unlike medical records, research records have no automatic protection against many legal subpoenas. This means that without additional protection, anything a research participant says or otherwise reveals in the course of study participation could potentially be used against the participant in a criminal or civil legal action.

Consent forms should warn subjects of the risk of subpoenas in any study which is designed to evoke information that has likely use in legal actions, such as admissions of illegal activities. Researchers receiving a subpoena should consult with legal counsel.

Certificates of Confidentiality: For studies which gather information that might be used against participants in legal actions, the federal government can issue a Certificate of Confidentiality [16]that protects researchers from being compelled by a subpoena to reveal research-related information. The Certificates can be granted regardless of the source of funding for the research.

Psychological harms

IRB reviewers frequently express concerns that research participants who are asked about emotional situations or who are deliberately subjected to stress will be harmed emotionally to the extent that they become less functional, need to seek professional help, and even become suicidal. Applications should include plans to handle any such problems that may arise.

Physical harms

Although physical harm seems unlikely in social and behavioral research, the IRB has seen studies with physical risks:

Domestic Violence and Abuse: Participants in studies may be at risk if an abuser learns about their participation. Abusers may feel threatened and increase abuse if they believe study participation involves revealing or discussing abuse. Even contacting a prospective participant by phone, letter, or in person if the abuser is present may raise an abuser?s suspicions.

Clinical Procedures: Social and behavioral research sometimes includes medical aspects, such as blood draws, administration of medications, or physical exercise or stress. The level of review required and the type of application to be submitted should be determined by the

most risky procedure being performed.

Social pressure

Various kinds of social pressure can be placed on people who participate or fail to participate in a study. For example, in some communities or classrooms, people who talk to researchers might be considered untrustworthy informers, while in other situations non-participants might be seen as failing to contribute to a potential good for the group.

Research Methods and Situations

The research methods and situations listed below appear repeatedly in IRB applications. The IRB has developed expectations for how research will be conducted in these situations, and researchers sometimes omit information the IRB needs. The expectations are not rigid requirements, but researchers who need to go against the expectations should take care to explain their reasons.

Questionnaires/surveys

Include with Application: All questionnaires, surveys, lists of topics to be discussed and similar documents should be included in the IRB application, unless they are standard instruments commonly known in the researchers? field, in which case the instruments need only be identified in the application.

If the questionnaires/surveys are not ready when the IRB application is prepared, the investigator should provide the best draft or outline available and should assure the IRB that the final version will be submitted for approval before it is used.

Submit Changes for IRB Approval Before Implementing: Do not implement any revised document until the revision has been submitted to and approved by the IRB. For more information, review the Modification [17] instructions.

Consent: See the guidance above regarding verbal, electronic or implied consent.

Audio and video recording

Any recording that will be done should be described in the consent form as one of the study procedures. The consent form should also say how the recordings will be used and how long they will be kept before they are erased or destroyed. It is acceptable to say that the recordings will be kept indefinitely. If research recordings may also be used in teaching, presentations or for other purposes, consult the UCSF News Office [18] about obtaining releases for non-research use.

Focus groups

It is common practice to ask participants in focus groups to use only their first names and to not discuss what was said in the group with other people outside the group. Because these requests cannot guarantee that participants will behave as asked, wording like the following should be included in the consent form?s discussion of confidentiality:

The researchers will ask you and the other people in the group to use only first names during the group session. They will also ask you not to tell anyone outside the group what any particular person said in the group. However, the researchers cannot guarantee that everyone will keep the discussions private.

Participant observation

Terminology: Not all IRB members are not experts in the social sciences and therefore will not be familiar with terminology (like ?grounded theory?) that is common in the field. Please explain theory, design and consent issues in a vocabulary that is accessible to non-experts.

Consent: See guidance above. Less experienced researchers should consult, and may want to cite in their application, the research ethics guidance provided by the professional organizations in their field.

Internet research

Ethical guidelines for internet research are still being debated. Researchers should carefully consider ethical issues and explain their thinking in their IRB applications. A few general suggestions have emerged.

Protecting Information: Be aware of potential security breaches, provide increased security as they gather increasingly sensitive information and use a consent process that frankly warns potential research subjects of the security risks. See the Electronic Data Security [19] page for more information and strategies you may employ to protect participants.

Submit Online Materials: With your IRB Application, include copies of any web pages (or a detailed description of the webpage content) and documents that will be used in a research study, including pages or messages used to announce a study and obtain consent. Also include the text from any online questionnaires.

Revealing the Researcher?s Presence: Just as researchers who observe public behavior are not necessarily expected to announce their presence and obtain informed consent as long as the researchers do not record identities of the persons observed, it *may* be acceptable for researchers who are merely observing interactions on public websites to refrain from identifying themselves.

However, researchers who interact with others on a website, or who observe in situations that might not be considered fully public ? such as a chat room that requires registration, has membership criteria or has rules about research ? probably have an obligation to announce their presence, to withdraw from situations in which they are not welcome and to obtain informed consent from anyone with whom they will have extended interaction.

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Links
[1] http://www.aaanet.org/committees/ethics/ethics.htm
[2] http://www.apa.org/ethics/index.aspx
[3] http://www.asanet.org/about/ethics.cfm
[4] http://irb.ucsf.edu/levels-review
[5] http://irb.ucsf.edu/new-study
[6] http://irb.ucsf.edu/recruitment
[7] http://irb.ucsf.edu/hipaa
[8] http://irb.ucsf.edu/children-and-minors-research
[9] http://irb.ucsf.edu/enrolling-individuals-cognitive-impairments-and-assessing-decisional-capacity
[10] http://irb.ucsf.edu/research-involving-prisoners
[11] http://irb.ucsf.edu/special-consent-requirements-vulnerable-populations
[12] http://irb.ucsf.edu/recruitment-consent-and-hipaa
[13] http://irb.ucsf.edu/verbal-electronic-or-implied-consent-waiver-signed-consent
[14] http://irb.ucsf.edu/consent-and-assent-form-templates
[15] http://irb.ucsf.edu/exempt-consent-templates-and-guidance
[16] http://irb.ucsf.edu/certificate-confidentiality-nih
[17] http://irb.ucsf.edu/modification
[18] https://www.ucsf.edu/news/news-media-services-old
[19] http://irb.ucsf.edu/electronic-data-security