

Instructions

Please follow this numbered outline by specifically addressing 1-9 when preparing the Research Summary. Remember to use layperson terms and if a section does not apply, simply state this. When complete, this Research Summary should be attached to the Request for IRB Review form (Appendix A).

1. Purpose/Significance

Briefly describe the proposed study including its purpose and the research question. Please minimize technical language not readily understood by persons outside your discipline.

Criteria for IRB approval: The proposal is clear as to what the researcher wishes to accomplish. It is clear why the purpose is important enough to warrant participation of human subjects.

2. Methodology

Describe the research design and procedures to be used. It is clear what the participant will encounter: when, where, and how long. The proposal describes the population to be studied (including sample size), how the population is to be approached, and what subjects will experience. Investigatory tools (surveys, questionnaires, etc.) are appended to the proposal.

Criteria for IRB approval: Risks to subjects are minimized by using procedures that are consistent with sound research design and that do not unnecessarily expose subjects to risk, AND, whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

3. Risks/Benefits

- Describe all risks (physical, mental, emotional, and legal) to the subjects. If deception is to be used, describe what the deception will be and why it is necessary. Describe safeguards (e.g., medical consultation, counseling, etc.) that will be taken to reduce risks.
- Describe all benefits to the subjects.
- Describe how the risks are reasonable in relation to anticipated benefits.

Criteria for IRB approval: Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

Examples of research that may potentially involve more than minimal risk (mental or physical) include:

- Surveys or questionnaires that solicit information regarding personal or sensitive aspects of the subjects' behavior, including sexual practices, instances of child or sexual abuse suffered by the subject, criminal activities, drug and alcohol use, or studies of eating disorders.
- Stress testing, drug and alcohol use by the subjects for research purposes, and studies where subjects are asked to do more than moderate physical exercise that could result in injury to the subject.

Examples of Mistakes:

- Risks involved in the procedure are not mentioned in the proposal. For instance, if the following risks are involved in the course of research, they must be explicitly mentioned:
 - sensitive questions which may cause discomfort;
 - expenses incurred by subjects;
 - possible injury to subject;
 - questions about illegal activities;
 - questions/situations which may uncover suspected child abuse which would then be reported;
 - retaliation which may occur when results of study become public.

- Risks are understated or benefits (if any) are overstated, coercive, or excessive. For instance, a researcher describes subjects as greatly benefited by knowing they have contributed generally to scientific knowledge.
- Risks are not reasonable in relation to the expected benefits. For instance, by answering questions, participants risk prosecution by law enforcement officials.
- Steps which could be taken to minimize risks are not taken. For instance, a researcher does not provide referral to a psychologist when very disturbing reactions to questionnaires or interviews may occur.
- Proposal involves risk or benefit which accrues unfairly. For instance, when a proposal offers a treatment (benefit) to participants in the study, the narrowing of the population of the study to exclude some particular group must be justified (such as women or ethnic groups).

4. Subject Recruitment

Describe how subjects will be recruited, selected, and, if part of the design, placed into groups.

Criteria for IRB approval: Selection of subjects is equitable. Equity requires that no group or class of persons should bear more than its fair share of the burdens of participation in research. Similarly, no group should be deprived of its fair share of the benefits of research, short-term or long-term; such benefits include the direct benefits of participation as well as the benefits of new knowledge that the research is designed to yield. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, and economically or educationally disadvantaged persons.

5. Individual Informed Consent

Describe how informed consent will be obtained from each subject or the subject's legally authorized representative.

Criteria for IRB approval: Informed consent will be sought from each prospective subject or the subject's legally authorized representative. Except as provided elsewhere in this policy, no investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agent from liability for negligence.

There are three types of Informed Consent:

- **Written Consent.** A Consent Form signed by each subject is normally required for protocols submitted for either expedited or full reviews. It is also required when subjects include vulnerable populations. Projects qualifying for exempt review normally require only the subject's oral consent to participate unless the researcher intends to audio- or video-tape the subject.
- **Assent.** Projects involving children (up to 17 years, unless emancipated) undergo full review. In addition to written consent forms for parents (see Appendix J), these proposals require written assent forms from children aged 7 to 17 (see Appendix K). "Assent" means a child's affirmative agreement to participate in research. Minors aged 15 to 17 cannot give adult consent but are normally asked to sign an assent form using the same language and information contained in their parents' consent form. Any projects involving minors require a signed consent form from either the child's parents or legal guardians before approaching the child for assent. Certain studies may be exempt from the permission requirement (e.g., if the research is designed for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects (e.g., neglected or abused children; Source 45 CFR 46.408). Proposals of research to be conducted in an educational or other institution must include a letter of approval from the school district, hospital, or other institution.
- **Oral Consent.** A statement of oral consent must include the elements of a Written Consent Form. The IRB should be provided with the oral statement and the rationale for requesting oral consent.

The IRB may approve waiver of the requirement of a signed consent form, if it finds either:

- The only record that links the subject to the research is the signed consent form, and the principal risk to the subject would be a breach of confidentiality. In this case, subjects must be asked if they want to sign a consent form that links them to the research.
- The research presents no more than minimal risk of harm to the subjects – that is, risk that is no more likely and not greater than that attached to routine medical or psychological examination – and if the research involves no procedures for which written consent would be required outside of the research context. Such low-risk research may include completion of a questionnaire that does not contain sensitive material, or removal of a small volume of blood by venipuncture on a single occasion. If the research involves more than “minimal risk,” then no waiver or alteration of informed consent is allowed.

In these cases, the IRB may require the investigator to provide subjects with information sheets to retain (e.g., an information letter that contains the information normally included in a consent form, but with no signature line).

Cultural Considerations. In some cultures an investigator may enter a community to conduct research or approach prospective subjects for their individual consent only after obtaining permission from a community leader, a council of elders, or another designated authority. Such customs must be respected. In no case, however, may the permission of a community leader or other authority substitute for individual informed consent.

In some populations the use of a number of local languages may complicate the communication of information to potential subjects and the ability of an investigator to ensure that they truly understand it. Many people in all cultures are unfamiliar with, or do not readily understand, scientific concepts such as those of placebo or randomization. Investigators should develop culturally appropriate ways to communicate information that is necessary for adherence to the standard required in the informed consent process. Also, they should describe and justify in the research protocol the procedure they plan to use in communicating information to subjects. When consent forms need to be translated into different languages, the IRB will need to see copies of those translated forms, along with evidence (through back translation) that the pertinent information has been included.

6. Informed Consent Document

Attach an informed consent document that contains the following items:

A. General Elements of Informed Consent:

1. Identification of investigator’s name, department, institution, status, mailing address, telephone. If the researcher is a student, the name, address, and telephone number of the faculty advisor must be included.
2. A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject’s participation, a description of the procedures to be followed, and identification of any procedures that are experimental. The informed consent form should tell the potential participant all s/he will encounter, how long it will take, where it will take place, etc. It should be written at a reading level appropriate for the particular subjects. Consent forms should provide a description of the types of questions to be asked (e.g., “In this study we are exploring whether some people are ‘at their best’ at different times of the day. We will be asking you questions about your daily activities, your personality, and some basic demographic characteristics, such as your age, gender, and race.”)
3. A description of any reasonably foreseeable risks or discomforts to the subject. The following risks, if foreseeable, must be thoroughly explained:
 - When sensitive questions are to be asked, either examples of the most sensitive questions or an explicit description of these questions should be given (e.g., We will be asking you questions, the most sensitive of which might be: Have you ever considered committing suicide? Have you ever made yourself throw up after a meal? Do you enjoy looking at people of the same sex?)When research gathers information about a subject’s involvement in illegal activities and no Certificate of Confidentiality is held by the researcher (see Question 8), the researcher must provide a statement that questions regarding illegal activities will be asked as part of the research study. Also, the researcher must state in the consent form that the possibility exists, although it is not probable, that the researcher’s data could be subpoenaed and used against the subject.

- Suspected child abuse/neglect: When applicable, a statement should be included in the consent form that the researcher may report to appropriate legal authorities known or suspected child abuse or neglect, and circumstances or conditions which might reasonably result in abuse or neglect, that become apparent as a result of a parent's participation or their child's participation in a research study.
 - If the subject incurs or may incur expenses as a result of participating in the project (e.g., medical or transportation expenses), the researcher must clearly state whether the subject will be reimbursed for those expenses or if there will be no reimbursement for participating in the research.
 - In a situation where a subject could be injured while participating in a project, the researcher must clearly explain any limitations of liability on the part of the researcher.
4. A description of any benefits to the subject or to others that may reasonably be expected from the research. The following benefits, if mentioned, must be accurately described:
 - a. Possible benefits to society: Societal benefits should not be overstated. There may be no direct benefit to the participant, other than a sense of helping the public at large.
 - b. Payment of subjects: Only include information on payment if payment is available. Then any conditions for receiving the payment must be included in the consent form (e.g., if only partial payment will be made to a subject who withdraws from the study, the researcher must clearly explain the formula for partial payment). If payment is given to defray the incurred expense of participation, it must not be coercive in amount or method of distribution.
 5. A disclosure of appropriate alternative procedures or courses of treatment, if any, which might be advantageous to the subject. For example, in drug studies the medication(s) may be available through their family doctor or clinic without the need to volunteer for the research activity.
 6. A statement describing the extent to which confidentiality of records identifying the subject will be maintained. Federal Regulations stipulate that, where appropriate, proposals should include adequate provisions to protect the privacy of subjects and to maintaining the confidentiality of data. When a proposal does not explain if and how privacy will be maintained, subjects cannot know the future status of their contributions to the study and so they cannot provide truly informed consent. The section on privacy and confidentiality should include the following statements:
 - a. Explaining how the subject's participation will either be known, kept confidential, or anonymous. Anonymity means that there is no way to identify individual subjects' responses. Confidentiality implies subjects' identities are known, but will be protected by the investigator (to the best of his/her ability). For example, if subjects sign a consent form and their names are tied to their responses through a master list of names and code numbers, and in addition the coded responses are kept in a secure location, the subject's responses may be considered confidential, but are not anonymous.
 - b. How individual privacy will be maintained in publications or presentations.
 - c. Explaining what the disposition of audio- or video-tapes will be at the conclusion of the study (e.g., destroyed, erased, given to subjects, used for other purposes such as advertising a product or procedure).
 - d. Explaining what the disposition of master lists (linking participants' names with data) will be at the conclusion of the study.
 - e. If Protected Health Information is to be collected or transferred, include all required elements for an authorization (see IRB Policy for HIPAA Compliance)
 7. For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained. Note that the federal regulations (see CFR 46.102[g]) do not limit injury to "physical injury."
 8. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled, and that the subject has the right to refuse to answer questions.
 9. An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject. The name and telephone number of the IRB Chairperson should be included should the potential participant wish to contact the IRB, should s/he have questions or concerns.

- B. Additional elements of informed consent. When appropriate, one or more of the following elements of information shall also be provided to each subject:
1. a statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;
 2. anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;
 3. any additional costs to the subject that may result from participation in the research;
 4. the consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
 5. a statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation, will be provided to the subject; and
 6. the approximate number of subjects involved in the study.
 7. All studies funded by federal agencies which require demographic information about gender and race/ethnicity must include the following statement: "This study is being funded by a federal agency which requires that data be collected in a form that may be analyzed for differences between men and women and races or ethnic groups."

Criteria for IRB approval: Each required item is present, or an explanation is provided for any elements that have been omitted or modified. The IRB may waive or modify this requirement under certain circumstances. For projects where no written consent is obtained, provide a written assurance that the subjects will be informed of their rights (i.e., the right not to participate, the right to omit answers to any questions, and the right to withdraw from the study at any time).

7. Data Monitoring

Describe how the data will be monitored to ensure the safety of the subjects.

Criteria for IRB approval: When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

8. Privacy and Confidentiality

Describe how the privacy of research subjects and the confidentiality of the data will be maintained. If Protected Health Information is to be collected or transferred, researchers must comply with the Privacy Rule associated with HIPAA.

Some studies require disclosure of information to other parties; describe any limits to confidentiality. If research is contemplated on a topic which is likely to be subject to legal proceedings, the federal government can issue a "Certificate of Confidentiality" which shields the data from required disclosure by the researcher. Information on certificates of confidentiality is available at <http://ohrp.osophs.dhhs.gov/humansubjects/guidance/certconpriv.htm> and <http://grants.hin.gov/grants/policy/coc/index.htm>.

9. Protection of Subjects' Rights

If the research involves any subjects likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, and economically or educationally disadvantaged persons, describe the additional safeguards that have been included in the study to protect the rights and welfare of these subjects.

Criteria for IRB approval: When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, and economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.