Committee for the Protection of Human Subjects
Application Procedures - Detailed
August 2022

Approval to conduct research with human subjects must be obtained prior to initiation of the research activities involving subjects, including recruitment activities. It is the responsibility of the principal investigator, faculty adviser (for student research), and department IRB chair to assure CPHS review. The Committee does not provide retroactive approval for research with human subjects that has been completed. Literature search and other work not involving human subjects may be initiated prior to CPHS review.

The following information must be submitted via the Kuali IRB electronic system for review:

1. **Abstract:** The abstract should be a one-paragraph summary of the protocol, including potential benefits, potential risks, and risk management procedures.

2. **Protocol:** The protocol describes the objective of the proposed study, methods to obtain the stated objectives, and the investigator's responsibilities toward the human subjects involved in the research. The protocol should contain the following information, as applicable, in the given order.

A. Purpose and Background

This section contains information pertaining to the background of the study and the relation of the proposed research to previous scientific investigations in the field. The amount of background information depends on the nature of the study and the risks involved in participation. For interview and survey procedures, a reference or two to the literature or a brief statement of the problem should be sufficient. For medical research, the section should include relevant laboratory and animal studies and clear justification for the participation of human subjects at this stage of the investigation.

The specific aims and hypotheses of the investigation should be discussed, along with the relevance of the hypotheses to previous work. If specific hypotheses are not being tested, then a brief description should be given of the questions to be answered or the possible information to be gained. Also, if the investigation is a pilot or exploratory one, this section should include a discussion of how the information obtained will be used in future studies.

B. Subjects

This section should include an estimate of the number of subjects involved, as well as a statement describing the population from which they will be drawn, and how they will be recruited. Inclusion and exclusion criteria should be specified. The CPHS will consider sample size effects on risks and risk management.

Justification should be provided for the use of subject groups whose capacities to provide informed consent may be absent or limited. These include children,

incarcerated individuals, residents or clients of institutions for the mentally ill or disabled, senile elderly, pregnant or nursing (breastfeeding) individuals and/or fetuses. A pregnant individual's ability to provide consent is limited insofar as they can participate only in activities for which: 1) The purpose is to meet the health needs of the pregnant individual, and the fetus will be placed at risk only to the minimum extent necessary to meet such needs; or 2) The risk to the fetus is minimal.

C. Methods

This section should provide a detailed description of all procedures involving human subjects for the purposes of research. Recruitment procedures, which ensure voluntary participation, and experimental procedures should be specified. Tests, questionnaires, and interview guides should be identified and described, and a copy of each should be submitted via Kuali as supporting documentation for the protocol. If the final instruments have not yet been developed, drafts or representative samples should be submitted. In cases where information given to subjects about the procedures and purposes of the study would invalidate the objectives, the investigator should report to the Committee reasons for not informing subjects of the procedures. Alternatives to deception should be considered.

Devices or activities that are not customarily encountered by the subjects in their daily living, or unusual application of devices or activities, must be described in detail. Any special procedures involving radioisotopes or investigational new drugs (INDs) must also be described. Approval from appropriate campus and/or federal agencies must be obtained before CPHS approval can be granted. Research involving unusual electrical devices or any source of radiation must be first approved by the Radiation Safety Committee. Use of an investigational new drug must be first approved by the Federal Drug Administration (FDA).

A tentative time schedule for procedures with human subjects should be provided, including frequency and estimated duration of each procedure, as well as intervals between procedures. The precise location for each procedure should be specified.

D. Potential Benefits

Discussion of potential benefits should be an evaluation of the benefits to individual subjects, the population from which they are drawn, and/or society/humanity in general. Benefits are particularly important if participation places subjects at risk. If there are no direct benefits to subjects, please state this explicitly.

E. Potential Risks

Potential risks to human subjects must be identified and discussed. Deleterious effects may be psychological, social, physical, economic, or legal. Some research involves neither risks nor discomfort, but violations of normal expectations. Such violations should be specified. (See Section 3.3.6 of the CPHS Policy and Procedures Handbook for examples of risk.)

F. Management of Risk

Procedures for minimizing potential risks must be described. Risk management procedures range from those applicable to a group (such as the exclusion of pregnant or potentially pregnant individuals from a study involving a new drug) to those applicable to an individual subject.

Special attention should be given to issues of confidentiality. If it is important to collect identifiable information about subjects, the rationale should be provided in the protocol and the mechanism for maintaining confidentiality must be specified, including coding and reporting procedures, storage and access of identifiable data, and the approximate date when identifying data will be destroyed. If confidentiality has been promised and case histories or anecdotes will be reported, explanation should be given about how narratives will avoid identifying subjects through description of unique information about them (such as by assigning each respondent a pseudonym).

Note that management of risk does not change the classification of a study from "at risk" or "minimal risk" to exempt or "less then minimal risk."

G. Subject Compensation

Subjects may be reasonably reimbursed for their participation in an experiment or study. Compensation to subjects should never be such as to constitute coercive inducement. Note that compensation is not a benefit of research.

H. Academic Qualifications

The final section of the protocol should indicate the academic qualifications of faculty, staff, and/or student investigators. For procedures requiring special skills on the part of the investigators, licensure, accreditation, and/or experience qualifying the investigators for the performance of these procedures should be indicated. A complete curriculum vitae/resume is not required.

3. **Consent Form:** Legally effective informed consent must be obtained and documented for the participation of any individual who will be placed at risk. Informed consent means the knowing consent of an individual, or their legally authorized representative, so situated as to be able to exercise free power of choice without undue inducement or any element of force, fraud, deceit, duress, or other form of constraint or coercion.

   Legally authorized representative means an individual, judiciary, or other body authorized under applicable law to consent on behalf of the prospective subject to such subject's participation in the research. When the proposed investigation involves a subject who is a minor or legally incompetent to give consent, the consent form must clearly indicate that the procedures are being consented to on behalf of the subject by their legally authorized representative. (See Sample Informed Consent template.)

Basic Elements of Informed Consent Include:

A. A statement that the proposed activity involves research and an explanation of the research purpose, including the larger social purpose, if applicable. When elements of purpose cannot be disclosed without biasing the behavior of subjects in a way that would invalidate the objectives of the study, the investigator may request that modified informed consent be obtained. The investigator's name and affiliation with California State University, Fresno should also be provided.

B. A fair explanation of the procedures, including frequency, duration, site of administration, and identification of any procedures that are experimental. The explanation of the procedures and purposes must be given in terms comprehensible to the intended subject (e.g., 5cc = 1 teaspoon).

C. A description of any reasonably foreseeable risks or discomforts to the subject. It is appropriate to estimate the degree or risk and to be especially candidate about high-risk procedures.

D. A description of any benefits to the subject or to others which may reasonably be expected from the research. A distinction should be made between personal benefits and social benefits.

E. A disclosure of any appropriate alternative procedures that might be advantageous for the subject, including their risks and benefits. Disclosure of alternative procedures is only applicable in certain circumstances, particularly when a new diagnostic or therapeutic procedure is being used. The discussion of the alternative must be fair and should attempt to balance the alternatives against the experimental therapy or procedures. The risks and benefits of the alternatives should, therefore, be discussed.

F. A statement describing the extent to which confidentiality of the subject will be maintained.

G. A statement that participation is voluntary and refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled. If the subject decides to participate, they are free to discontinue participation at any time without penalty.

H. An offer to answer questions, including contact information should a respondent have later questions regarding the research.

I. When applicable, the amount and nature of compensation to be given to the subject and a description of the conditions under which it will be paid.

J. A phone number to call if harm occurred during participation or if subjects have questions about their rights as research participants.

K. When applicable, provision for parental, guardian, or physician consent.

L. When required by the CPHS, the researcher must provide one or more of the following elements of information to the subjects, as applicable: 1) how the subject's name and address or phone number were obtained; 2) the possibility that the particular treatment or procedure may involve risks to the subject (or the embryo or fetus, if the subject is or may become pregnant) that are currently unforeseeable; 3) any additional costs to the subject that may result from participation in the research; 4) circumstances under which the subject's participation may be terminated by the research investigator without regard to the subject's consent; 5) findings developed during the course of the research, which may relate to the subject's willingness to continue participation; and 6) fhe approximate number of subjects involved in the study.

Informed Consent as a Process: Informed consent should not be thought of as a form to be signed, but as an ongoing educational process between the research investigator and the prospective subject. The investigator should attempt to view the activity from the subject's perspective to consider what the subject might want to know before deciding whether or not to participate in the research. Information must be presented to the prospective subject in language they can understand, and a dialog of questions and explanations should be encouraged. The investigator should talk with the subject until they feel confident that the subject understands what is being asked.

If the information is so complex or possibly disturbing that it may require some time to be absorbed and evaluated by the subject, the investigator should consider using a multi-stage consent process. The investigator might present the information and discuss the issues on more than one occasion or allow a period of time to elapse between presenting the information and requesting a signature on the consent form. For procedures that are very stressful or otherwise involve substantial risk, the investigator might also ask for reaffirmation of the subject's consent at various stages of their participation.

Cross-Cultural Considerations:

Informed consent should be obtained in the native language of the subject if English is not readily understood. If the research is done in cultures where signed statements are mistrusted, or where the concept of experimentation is unfamiliar, the protocol should clearly indicate how the project will be explained, how informed consent will be obtained, and who will validate the consent act.

Oral Consent:

If approval for the use of oral consent is sought, the information to be conveyed to the potential subjects must be submitted to the CPHS in the form of an oral consent script. The rationale for the use of the oral consent procedure rather than the written consent procedure should be included.

Exculpatory Clauses:

No consent form may contain exculpatory language through which the subject is made to waive, or appear to waive, any of their legal rights, or to release the institution or its agents from liability for negligence.

4. **Study Instruments:** A copy of each questionnaire, interview guide, or test should be uploaded in the supporting documentation section in Kuali IRB. If the instruments have not yet been developed, drafts or representative sample questions should be submitted. CPHS approval without complete instrumentation will depend on the sensitivity of the research topic and the vulnerability of the subjects, and approval will be conditional upon submission of the final instruments when they are available.

5. **Certification of CITI Human Subjects Assurance Training:** All investigators and student collaborators included as study personnel for the protocol must complete the CITI (Collaborative Institutional Training Initiative) Human Subject Assurance Training. A current and dated copy of the completion certificate for each researcher should be uploaded in the Kuali study personnel section.

6. **Approval from Participating Institutions (If Applicable):** Signed and dated letters of support from participating agencies, institutions, or organizations must be uploaded in Kuali. If approval has not been received at the time of submission, support letters should be uploaded when available, and before initiation of any research activities.

Deadlines for Submission of Protocols: Researchers should submit protocols and supporting documentation through Kuali IRB during regular semester periods. The CPHS reviews only externally funded protocols during winter and summer breaks.

Submission via Kuali IRB: Protocols should be submitted via Kuali IRB, which can be accessed on the CPHS homepage: https://www.fresnostate.edu/academics/humansubjects/

Questions: Questions about these requirements and submission procedures can be submitted to cphs@mail.fresnostate.edu.