

Initial Review	
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1. PURPOSE

- 1.1. Federal regulations require that the IRB have the authority to review, approve, require modifications to secure approval, or disapprove all research activities covered by 45 CFR 46. The IRB shall conduct an initial review of research involving human subjects to assess the risk/benefit analysis, selection of subjects is equitable, and whether informed consent is sought before recommending a course of action.

2. DEFINITIONS

- 2.1. *Research*, as defined in federal regulations by 45 CFR 46.102(d) means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

Systematic investigation, is a study or examination involving a methodical procedure or plan.

Generalizable knowledge, is a conclusion, facts, or principles derived from particulars (individual subjects, medical records, etc.) that are applicable to or affect a whole category (such as members of a class, kind, group, a field of knowledge, etc.) and are intended for dissemination in the public domain, typically through publication.

- 2.2. *Human Subject*, as defined in federal regulations by 45 CFR 46.102(f) means a living individual about whom an investigator (whether professional or student) conducting research obtains

(1) Data through intervention or interaction with the individual, or

(2) Identifiable private information

Intervention includes both physical procedures by which data are gathered (for example venipuncture) and manipulations of the subject or subject's environment that are performed for research purposes.

Interaction includes communication or interpersonal contact between an investigator or subject.

Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects. In general, private information is considered to be individually identifiable when it can be linked to specific individuals by the investigator(s) either directly or indirectly through coding systems, or when characteristics of the information obtained are such that by their nature a reasonably knowledgeable person could ascertain the identities of the individuals.

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2.3. *Coded Private Information or Biological Specimens* means that identifying information (such as name, social security number, medical record number) is replaced with a code comprised of numbers, letters, or a combination thereof; and a key to decipher the code exists, enabling linkage of the individual's identity to specimens or data.

Coded private information or specimens are not considered to be individually identifiable and therefore their use would not fall within the definition of research involving human subjects if the following conditions are **both** met:

- (1) The private information or specimens were not collected specifically for the currently proposed project through an interaction or intervention with living individuals; and
- (2) The investigator(s) cannot readily ascertain the identity of the individual(s) to whom the coded private information or specimens pertain as a result of one of the following circumstances:
 - (a) The key to decipher the code is destroyed before the research begins;
 - (b) The investigators and the holder of the key have entered into an agreement prohibiting the release of the key to the investigators under any circumstances, until the individuals are deceased (Note: DHHS regulations for human subjects research do not require the IRB to review and approve this agreement):
 - (c) There are IRB-approved written policies or procedures for a repository or data management plan or center that prohibit the release of the key to the investigator under any circumstances, until the individuals are deceased; or
 - (d) There are other legal requirements prohibiting the release of the key to the investigators; such as until the individuals are deceased.

Note that some institutions may require documentation of an IRB review determining that the coded information or specimens is not human research or is considered exempt. If this occurs, the IRB staff can be contacted to issue a letter of determination.

3. POLICY and PROCEDURE

3.1. Minimum Criteria for Approval of Human Subjects Research

In order for a research project to be approved under federal regulations set forth by 45 CFR 46.111, the IRB must find that:

A. Risks to subjects are minimized:

- By using procedures that are consistent with sound research design and which do not unnecessarily expose subjects to risk, and
- Whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes
- Points that the IRB may consider include, but are not limited to, the following:
 1. Are research staff qualified?
 2. Are subject numbers adequate/inadequate?

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3. Are procedures that would answer the question being conducted anyway, and if so, can the data from these procedures be used to reduce any likelihood and magnitude of harm?
- B. Risks to subjects are reasonable in relation to anticipate benefits, if any, to subjects, and the importance of the knowledge that may be expected to result.
- When evaluating the risk/benefit ratio, the IRB should consider only those risks and benefits that may result from the research. The IRB should not consider possible long-term 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.
 - Points that the IRB may consider include, but are not limited, to the following:
 1. Is the research likely to achieve its proposed aims?
 2. Is the importance of the aims clear?
 3. Are there any direct potential benefits to the subjects?
 4. Does the benefit (if any) outweigh any real or perceived risk to the subjects?
- C. Selection of subjects is equitable.
- In making this assessment, the IRB should take into account the purposes of the research and the settings 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, people with physical or developmental disabilities, pregnant women, or economically or educationally disadvantaged people.
 - Points that that IRB may consider include, but are not limited to, the following:
 1. Are the burdens of the research distributed fairly?
 2. Are the benefits of the research distributed fairly?
 3. Is a population unfairly targeted?
 4. Is a population unfairly excluded?
- D. Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with and to the extent required by appropriate local, state, and federal regulations.
- One of the following must be met:
 1. Informed consent including the required elements of informed consent will be sought from each prospective participant or the participant's representative.
 2. The informed consent process will be waived or altered and the waiver or alteration must be approved by the IRB during the review process.

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- E. Informed consent will be appropriately documented as required by local, state, and federal regulations.
- One of the following must be met:
 1. Informed consent will be documented.
 2. The requirement for written documentation will be waived and approved by the IRB.
 3. The informed consent process will be waived and approved by the IRB.
- F. Where appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of the subjects.
- Points the IRB may consider include, but are not limited to the following:
 1. Is the research greater than minimal risk?
 2. Is the research likely to result in safety reports to the IRB or sponsor?
 3. What data is being obtained and reviewed?
 4. Who is obtaining the data? How? When?
- G. Where appropriate, there are adequate provisions to protect the privacy of the subjects and to maintain the confidentiality of data.
- *Privacy* refers to persons and their interest in controlling access to themselves.
 - *Confidentiality* refers to agreements with the participant about how their data are to be handled.
 - Points the IRB may consider include, but are not limited to, the following:
 1. What are the participants' expectations of privacy or confidentiality?
 2. Will data release cause risk of harm (such as psychological, physical, autonomy, criminal/civil action, employability, coercion, etc.)?
 3. Are there any legal or ethical requirements?
 4. What measures will be in place, if any, to protect confidentiality? Is a data management plan required?
- H. When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally or physically disabled persons, or economically or educationally disadvantaged persons, additional safeguard will be included in the study to protect the rights and welfare of these subjects. The IRB will review these safeguard and may request additional safeguard to ensure adequate protection of vulnerable populations are met.
- Points the IRB may consider include, but are not limited to, the following:
 1. Who is vulnerable to coercion and/or undue influence?
 2. Is there a power differential and can this be separated or mitigated?
 3. Are there excessive motivating factors?
 4. Are there decisional issues? Do the subjects have the capacity to consent?

3.2. Other Criteria

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- 3.2.1. If the research subjects include pregnant women, fetuses, and/or neonates, children, or prisoners, the project can only be approved if the IRB finds that the applicable criteria for additional protection of these vulnerable populations as set forth in 45 CFR 46 subparts B, C, D are met.
- 3.2.2. The IRB may require verification of information submitted by an investigator. The need to verify any information will be determined by the IRB at convened meeting of Expedited/Exempt review or Full Board Review, or by the IRB staff/chair/member/designee during the review process, such as the pre-review. The purpose of the verification will be to provide necessary protection to subjects when deemed appropriate by the IRB.
- 3.2.3. Projects that need third party verification from sources other than the investigator that no material changes have occurred since a previous IRB review, will have the assessment performed as needed.
- 3.2.4. Additional review criteria pertaining to California state law and/or University policy may be required.
- 3.2.5. This document does not affect any federal, state, local, or foreign law or regulation which may otherwise be applicable and which may provide additional protections for human subjects.

3.3. **Types of Review**

The federal regulations permit different types of review. The standard type of review is by a quorum of IRB members at a convened meeting (full board review). However in circumstances where certain criteria are met, an initial protocol, a continuing review, or a modification may be reviewed by the IRB Chair/Designee, IRB staff member who also serves as a voting member, and/or member at a sub-committee meeting (expedited review). Expedited review will also consist of reviewing protocols that qualify for exemption under 45 CFR 46.101(b).

3.4. **Approval Period**

Research under federal oversight will generally be reviewed at intervals of once year. Research that is not under federal oversight will be generally reviewed at intervals of once year. The IRB may shorten approval periods depending upon the degree of risk to which subjects are exposed due to participation in the research, or new knowledge of concern (such as investigator non-compliance, adverse events or unanticipated problems).

3.5. **Documentation**

See HSC SOP 003.02

3.6. **Reliance on Other IRBs for Review and Approval of Research Conducted at the University of California, Santa Barbara.**

Under the authority granted by the Board of Regents of the University of California, the Institutional Official may enter into joint review agreements on behalf of the institution, to rely upon the review of another qualified IRB or to serve as the IRB

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of record for another institution, or to make similar arrangements to avoid duplication of effect.

- 3.6.1. When agreeing to rely, the IRB may require copies of the approval notice, approved protocol, approved consent form, recruitment materials, verification of training completion, and any other pertinent documents.
- 3.6.2. When agreeing to rely, the IRB may require the Reviewing IRB enter into an Institutional Authorization Agreement signed by the Institutional Official.
- 3.6.3. When agreeing to be the IRB of record, the IRB may require the Relying IRB enter into an Institutional Authorization Agreement signed by the Institutional Official.

4. SCOPE

The procedures apply to all IRB staff and members and to the research that involves human subjects.

5. RESPONSIBILITY

The IRB staff are responsible for facilitating the review process, pre-reviewing submissions, and ensuring that IRB members have all the tools and resources necessary to complete their research reviews. When the IRB requires modifications to secure approval, it may designate a staff member who also serves as a voting member to verify that the modifications for approval have been satisfied.

The IRB reviewers are responsible for conducting a thorough review and recommending any criteria for approval (if applicable).

6. PROCESS OVERVIEW

IRB staff will initially determine whether an application meets the definition of research involving human subjects. For all research involving human subjects, the IRB staff will then determine (in consultation with the IRB Chair/designee, as necessary) if the application is eligible for exemption or expedited review. If the application does not meet the criteria for exemption or expedited review, then the protocol will be reviewed by the full committee at a convened meeting (full board review) as described below.

In general, the application will be added to the agenda for the next regularly scheduled convened meeting. An IRB staff member will conduct an administrative pre-review and may require corrections, clarifications, or additions to the protocol before setting it for review. After the revisions have been received, the IRB staff member will set-up the protocol for review and inform the Committee. The IRB staff member will assign a primary reviewer to present the protocol for review and discussion at the convened meeting. If the protocol requires special expertise, the IRB staff member or Chair may arrange for a consultant's participation and discussion of the project.

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6.1. At the IRB meeting, the primary reviewer presents the study to the full board, and opens the protocol up for discussion.

6.1.1. The convened IRB may through a quorum of its members:

- Approve the protocol;
- Disapprove the protocol;
- Table the protocol for review at a future meeting if sufficient information is lacking to conduct a thorough protocol review and risk assessment; or
- Require modifications to secure approval

6.1.2. The investigator will be notified in writing of the review outcome.

6.1.3. If modifications are requested in order to secure approval, the modifications may be reviewed by IRB staff and/or an IRB member in order to verify that the conditions for approval have been satisfactorily addressed. The reviewing IRB staff member also serves as a voting member of the IRB.

6.1.4. Following approval, the approval notice, approved protocol, approved consent form(s), and approved pertinent documents will be made available to the investigator.

References:

45 CFR 46 Regulations

UC Berkeley Policies and Procedures

OHRP Guidance on Research Involving Coded Private Information on Biological Specimens

The Belmont Report