Human Research Protection Program

Plan

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Human Research Protection Program Plan

Table of Contents

Scope ........................................................................................................................................... 3
Purpose ........................................................................................................................................ 3
Definitions................................................................................................................................... 3
  Agent ....................................................................................................................................... 3
  Clinical Trial............................................................ 3
  Engaged in Human Research................................. 3
  Human Research: .................................................. 3
  Human Subject as Defined by DHHS ...................... 4
  Human Subject as Defined by FDA ......................... 4
  Investigator ............................................................ 4
  Research as Defined by DHHS ................................. 4
  Research as Defined by FDA .................................. 4
Mission........................................................................................................................................ 5
  Ethical Requirements ................................................... 5
  Legal and Regulatory Requirements ......................... 5
  Other Requirements .................................................. 14
Sponsored Human Research ........................................ 16
Scope of Human Research Protection Program ............ 16
Human Research Protection Program Policies and Procedures .............................................. 16
Human Research Protection Program Components ............................................................ 16
Institutional Official ......................................................... 16
  All Members of the Institution ................................... 17
IRBs ...................................................................................................................................... 18
Designated Faculty Reviewers .................................... 18
Investigators and Research Staff .................................. 19
Legal Counsel ............................................................... 19
Deans/Department Chairs ............................................ 19
Sponsored Programs/Contracts Office ........................ 19
Investigational Drug Services (IDS) Pharmacy ............ 19
Institutional Biosafety Committee (IBC) ....................... 19
Conflict of Interest Committee (COIC) ....................... 20
Cancer Center Scientific Review Committee (CCSRC) ................................................. 20
Radiation Use Committee (RUC) ............................... 20
Stem Cell Research Oversight Committee (SCROC) .................................................. 20
Outreach, Training and Education .............................. 21
Questions and Additional Information for the IRB .......................................................... 22
Reporting and Management of Concerns .................... 22
Monitoring and Auditing .............................................. 22
Disciplinary Actions ..................................................... 23
Approval and Revisions to the Plan ................................ 23
**Scope**

Throughout this document “Institution” refers to University of California Davis.

**Purpose**

This Institution is committed to protecting the rights and welfare of subjects in Human Research. The purpose of this plan is to describe this Institution’s plan to comply with ethical and legal requirements for the conduct and oversight of Human Research.

This Institution’s Human Research Protection Program is a comprehensive system to ensure the protection of the rights and welfare of subjects in Human Research. The Human Research Protection Program is based on all individuals in this Institution along with key individuals and committees fulfilling their roles and responsibilities described in this plan.

**Definitions**

**Agent**

An individual who is an employee is considered an agent of this Institution for purposes of engagement in Human Research when that individual is on-duty in any capacity as an employee of this Institution.

An individual who is not an employee is considered an agent of this Institution for purposes of engagement in Human Research when that individual has been specifically authorized to conduct Human Research on behalf of this Institution.

Legal counsel has the ultimate authority to determine whether someone is acting as an agent of this Institution.

**Clinical Trial**

A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.

**Engaged in Human Research**

In general, this Institution is considered engaged in a particular non-exempt human subjects research project when this Institution’s employees or agents for the purposes of the research project obtain: (1) data about the subjects of the research through intervention or interaction with them; (2) identifiable private information about the subjects of the research; or (3) the informed consent of human subjects for the research. This Institution follows OHRP guidance on “Engagement of Institutions in Research”\(^1\) to apply this definition and exceptions to this definition.

**Human Research:**

Any activity that either:

- Is “Research” as defined by DHHS and involves “Human Subjects” as defined by DHHS (“DHHS Human Research”); or

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\(^1\) [http://www.hhs.gov/ohrp/policy/engage08.html](http://www.hhs.gov/ohrp/policy/engage08.html)
• Is “Research” as defined by FDA and involves “Human Subjects” as defined by FDA (“FDA Human Research”).

Human Subject as Defined by DHHS
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) information that is both Private Information and Identifiable Information. For the purpose of this definition:

• **Intervention** means physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject’s environment that are performed for research purposes.
• **Interaction** means communication or interpersonal contact between investigator and subject.
• **Private Information** means 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).
• **Identifiable Information** means information that is individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information).

Human Subject as Defined by FDA
An individual who is or becomes a subject in research, either as a recipient of the test article or as a control. A subject may be either a healthy human or a patient. A human subject includes an individual on whose specimen (identified or unidentified) a medical device is used.

Investigator
The person responsible for the conduct of the Human Research at one or more sites. If the Human Research is conducted by a team of individuals at a trial site, the investigator is the responsible leader of the team and may be called the principal investigator.

Research as Defined by DHHS
A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.²

Research as Defined by FDA
Any experiment that involves a test article and one or more human subjects, and that meets any one of the following:

• Must meet the requirements for prior submission to the Food and Drug Administration under section 505(i) of the Federal Food, Drug, and Cosmetic Act meaning any use of a drug other than the use of an approved drug in the course of medical practice;

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² For research conducted within the Bureau of Prisons: Implementation of Bureau programmatic or operational initiatives made through pilot projects is not considered to be research.
Must meet the requirements for prior submission to the Food and Drug Administration under section 520(g) of the Federal Food, Drug, and Cosmetic Act meaning any activity that evaluates the safety or effectiveness of a device; OR

Any activity the results of which are intended to be later submitted to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit.

**Mission**

The mission of this Institution’s Human Research Protection Program Plan is to protect the rights and welfare of subjects involved in Human Research that is overseen by this Institution.

**Ethical Requirements**

In the oversight of all Human Research, this Institution (including its investigators, research staff, students involved with the conduct of Human Research, the Institution’s institutional review boards (IRBs), IRB members and chairs, IRB staff, the Institutional official, and employees) follows the ethical principles outlined in the April 18, 1979 report of The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research titled “Ethical Principles and Guidelines for the Protection of Human Subjects of Research,” also known as “The Belmont Report”:

- Respect for Persons
- Beneficence
- Justice

**Legal and Regulatory Requirements**

This Institution commits to apply its ethical standards to all Human Research regardless of funding.

- All Human Research must undergo review by one of the Institutionally designated IRBs.
- Activities that meet the definition of Human Research are reviewed according to the applicable Worksheets and Checklists located on the IRB Administration Website: [http://research.ucdavis.edu/policiescompliance/irb-admin/irb-forms/](http://research.ucdavis.edu/policiescompliance/irb-admin/irb-forms/).

There are four Institutional Review Boards (IRBs) at UC Davis: Biomedical Committee A, Biomedical Committee B, Social and Behavioral Committee C, and Fast Track Committee D. For additional information, including the schedule of meeting dates, please visit [http://research.ucdavis.edu/policiescompliance/irb-admin/researchers/meetings/](http://research.ucdavis.edu/policiescompliance/irb-admin/researchers/meetings/).

Policies and procedures governing activities associated with preparation and conduct of convened IRB meetings are detailed in SOPs HRP-021, 024, 026, 040, 041, 042, 050, 051 and 084, and supplemented by WORKSHEETS HRP-301 and 305.

- Lists of materials provided to IRB members for full committee review of initial and continuing IRB applications are summarized in “WORKSHEET: REVIEW MATERIALS (HRP-301).”
- The IRBs determine that criteria for approval and consent requirements are met according to “WORKSHEET: CRITERIA FOR APPROVAL AND ADDITIONAL CONSIDERATIONS (HRP-314),” and also identified here.
- The IRBs use the required criteria for approval for all reviews of research, including initial review, continuing review, and review of a modification to previously approved research when the modification affects a criterion for approval.
In order to approve research, the IRB determines that the research protocol or plan contains adequate provisions to protect the privacy interests of participants.

In order to approve research, the IRB determines that, when appropriate, the research protocol or plan contains adequate provisions to maintain the confidentiality of data.

In order to approve research the IRB determines that selection of participants is equitable. In making an assessment about whether selection of participants is equitable, the IRB takes into account:

- The purpose of the research.
- The setting in which the research will be conducted.
- Whether prospective participants will be vulnerable to coercion or undue influence.
- The selection (inclusion/exclusion) criteria.
- Participant recruitment and enrollment procedures.
- The influence of payments to participants.

The IRB reviews advertising to ensure that advertisements do not:

- State or imply a certainty of favorable outcome or other benefits beyond what is outlined in the consent document and the protocol.
- Include exculpatory language.
- Emphasize the payment or the amount to be paid, by such means as larger or bold type.
- Promise “free treatment” when the intent is only to say participants will not be charged for taking part in the investigation.

Advertisements are limited to the information prospective participants need to determine their eligibility and interest, such as:

- The name and address of the researcher or research facility.
- The purpose of the research or the condition under study.
- In summary form, the criteria that will be used to determine eligibility for the study.
- A brief list of benefits to participants, if any.
- The time or other commitment required of the participants.
- The location of the research and the person or office to contact for further information.

The IRB reviews:

- The information contained in the advertisement.
- The mode of its communication.
- The final copy of printed advertisements.
- The final audio or video taped advertisements.

The IRB also reviews participant payments listed in the application to determine that:

- The amount of payment and the proposed method and timing of disbursement is neither coercive nor presents undue influence.
- Credit for payment accrues as the study progresses and is not contingent upon the participant completing the entire study.
- Any amount paid as a bonus for completion is reasonable and not so large as to unduly induce participants to stay in the study when they would otherwise have withdrawn.
- All information concerning payment, including the amount and schedule of payments, is set forth in the consent document.
Specific advertising and recruitment requirements pertaining to regulatory agencies are provided in “WORKSHEET: ADVERTISEMENTS (HRP-315),” “WORKSHEET: PAYMENTS (HRP-316),” and “WORKSHEET: ADDITIONAL FEDERAL CRITERIA (HRP-318).”

The IRB considers provisions for monitoring data to ensure the safety of participants to be appropriate when the research is more than minimal risk (INITIAL REVIEW APPLICATION).

In order to approve research in which the IRB considers provisions for monitoring data to ensure the safety of participants to be appropriate, the IRB determines that the research plan makes adequate provisions. The IRB might consider provisions such as:

- What safety information will be collected, including serious adverse events.
- How the safety information will be collected (e.g., with case report forms, at study visits, by telephone calls with participants, etc.).
- The frequency of data collection, including when safety data collection starts.
- The frequency or periodicity of review of cumulative safety data.
- The plan might include establishing a data monitoring committee and a plan for reporting data monitoring and committee findings to the IRB and the sponsor, including the frequency of reporting.
- For studies that do not have or are not required to have a data monitoring committee and are blinded, have multiple sites, enter vulnerable populations, or employ high-risk interventions, the IRB needs to carefully review the data and safety monitoring plan and determine whether a data monitoring committee is needed.
- If not using a data monitoring committee, and if applicable, statistical tests for analyzing the safety data to determine whether harm is occurring.
- Provisions for the oversight of safety data (e.g., by a data monitoring committee).
- Conditions that trigger an immediate suspension of the research, if applicable.

The IRB has the final authority to decide whether any reported financial interest and applicable management plan allow the research to be approved (SOP: FINANCIAL CONFLICTS OF INTEREST [HRP-055]).

The IRB can make the following decisions regarding the research protocol or plan: Approval, Modifications Required to Secure Approval, Tabled, Deferred, or Disapproval (SOP: IRB MEETING CONDUCT [HRP-041]).

The IRB is allowed to require review more often than annually, as per “SOP: IRB MEETING CONDUCT (HRP-041) and WORKSHEET: REVIEW OF INFORMATION ITEMS (HRP-321).”

Approval and expiration dates for all IRB reviews are outlined in “WORKSHEET: CALCULATION OF APPROVAL INTERVALS (HRP-302).”

The policy for expired studies is defined in “SOP: EXPIRATION OF IRB APPROVAL (HRP-063),” whereby if a researcher does not provide continuing review information to the IRB or the IRB has not approved a protocol by the expiration date:

- All research activities must stop.
- Interventions and interactions on current participants must stop, unless the IRB finds an over-riding safety concern or ethical issue involved such that it is in the best interests of individual participants to continue participating.
- New enrollment of participants may not occur.
The IRB reporting requirements for information items post approval are listed in “FORM: REPORTABLE NEW INFORMATION (HRP-214).” Researchers must report information on this form to the IRB Administration within five to ten business days of becoming aware of the information.

- The IRB will review FORM HRP-214 to determine if any of the information items meet the definitions of serious noncompliance, continuing noncompliance or an unanticipated problem involving risks to subjects or others (UPIRTSO), as listed in “SOP: DEFINITIONS (HRP-001).”
- Examples of UPIRTSOs include:
  - Internal adverse events that are unexpected, involve new or increased risks, and are related to the research.
  - External adverse events that are unanticipated problems involving risks to participants or others.
  - Changes made to the research without prior IRB approval in order to eliminate apparent immediate harm.
  - Other unanticipated information that is related to the research and when participants or others might be at increased risk of harm.

- Policies and procedures associated with review of unanticipated problems involving risks to subjects or others are addressed in “SOP: NEW INFORMATION (HRP-024),” “SOP: INVESTIGATIONS (HRP-025),” “SOP: IRB MEETING PREPARATION (HRP-040),” “SOP: IRB MEETING CONDUCT (HRP-041),” and “SOP: POST REVIEW (HRP-052).”

Specific requirements pertaining to regulatory agencies for confidentiality are provided in “WORKSHEET: ADDITIONAL FEDERAL CRITERIA (HRP-318).” Specific consent requirements for regulatory agencies are provided in the “INVESTIGATOR MANUAL (HRP-103) and WORKSHEET: ADDITIONAL FEDERAL CRITERIA (HRP-318).”

- The IRB is allowed to waive or alter the consent process by determining that the criteria for waivers or alterations are met.
- The IRB is allowed to waive parental permission by determining that the criteria for waivers or alterations are met.
- The IRB is allowed to waive the requirement for written documentation of the consent process by determining that the criteria for waivers are met.
- The IRB documents its findings justifying the waiver or alteration.

Specific requirements pertaining to regulatory agencies for waiving or altering the consent process or waiving written documentation are provided in “WORKSHEET: CRITERIA FOR APPROVAL AND ADDITIONAL CONSIDERATIONS (HRP-314), CHECKLIST: WAIVER OR ALTERATION OF THE CONSENT PROCESS (HRP-410), and CHECKLIST: WAIVER OF WRITTEN DOCUMENTATION OF CONSENT (HRP-411).”

- The IRB uses “CHECKLIST: WAIVER OF CONSENT FOR EMERGENCY RESEARCH (HRP-419)” or equivalent to ensure compliant review of planned emergency research.

For activities under DOD jurisdiction: An exception from consent in emergency medicine research is prohibited unless a waiver is obtained from the Secretary of Defense.

When following DOD regulations:
- For non-exempt research, the IRB considers the scientific merit of the research.
- The IRB may rely on outside experts to provide an evaluation of the scientific merit.
The IRB uses “WORKSHEET: ADDITIONAL FEDERAL CRITERIA (HRP-318)” and “WORKSHEET: SCIENTIFIC OR SCHOLARLY REVIEW (HRP-320)” to ensure compliance with these requirements. Additional requirements for the Department of Education are provided in “WORKSHEET: FERPA COMPLIANCE (HRP-331) and TEMPLATE: SCHOOL PERMISSION TO CONDUCT RESEARCH (HRP-504).”

The IRBs of the Institution meet the criteria for IRB composition as outlined in “WORKSHEET: IRB COMPOSITION (HRP-304).” IRB SOPs, including HRP-040, 041, 042, 043, 051, and 052 describe policies and procedures that require research protocols or plans to be reviewed by individuals with appropriate scientific or scholarly expertise and other expertise or knowledge as required to review the research protocol or plan. (WORKSHEET: SCIENTIFIC OR SCHOLARLY REVIEW [HRP-320] and FORM: ADMINISTRATIVE APPROVAL [HRP-226])

Alternate IRB members serve the same function as other IRB members with comparable qualifications, except that if both members are present only one member may vote. IRB members and consultants do not participate in any review in which they have a conflict of interest (‘conflicting interest,’ as defined in “SOP: DEFINITIONS [HRP-001]”), except to provide information requested by the IRB. The process to identify and handle IRB members and consultants with a conflict of interest is described in the following SOPs: HRP-040, 041, 042, 050, 051, 052, and CHECKLIST: HRP-402.

Policies and procedures governing post-review activities conducted by IRB staff, including required reporting to institutional officials and federal agencies are detailed in SOPs HRP-043 and 052.

Activities that do not meet the definition of Human Research (e.g., most classroom activities, quality improvement activities, program evaluation, and surveillance activities that do not meet the definition of Human Research) do not require review and approval by one of the Institution’s IRBs and do not need to be submitted to one of the Institution’s IRBs unless there is a question regarding whether the activity is Human Research.

When this Institution is engaged in DHHS Human Research that is conducted, funded, or otherwise subject to regulations by a federal department or agency who is a signatory of the Common Rule, the Institution commits to apply the regulations of that agency relevant to the protection of Human Subjects.

When this Institution is engaged in FDA Human Research, this Institution commits to apply the FDA regulations relevant to the protection of Human Subjects.

The IRB determines that the Investigational New Drug (IND) and Investigational Device Exemption (IDE) requirements are met by following “WORKSHEET: DRUGS (HRP-306) and WORKSHEET: DEVICES (HRP-307)” for information concerning legal and regulatory requirements that apply to the use of investigational test articles.

Research requiring an IND or IDE may not begin until the FDA clears or approves the application (typically 30 days after the FDA receives the application, unless the FDA communicates any objections with the sponsor or sponsor-investigator). The IRB confirms that the IND or IDE number is valid through any of the following evidence:
- Sponsor protocol with the IND#, IDE# or HDE#
- Communication from the sponsor documenting the IND#, IDE# or HDE#
- FDA clearance/approval letter indicating IND#, IDE# or HDE#
When an investigational drug or biologic is involved, the Institution follows 21 CFR Part 312.62 and UC Davis Policy and Procedure Manual (PPM) #240-61 to ensure appropriate storage, distribution and use. The Investigational Drug Services (IDS) Pharmacy, located at the UC Davis Medical Center, handles all investigational drugs and biologics and ensures compliance with the requirements in the IRB-approved study protocol.

In order to approve research where some or all of the participants are likely to be vulnerable, the IRB determines whether additional safeguards have been included in the protocol to protect their rights and welfare.

If research involves adults unable to consent, the IRB considers specific criteria for approval of such research that provides additional safeguards to protect their rights and welfare.

The IRB evaluates whether the research involves participants who have diminished decision-making capacity and, if so, provides additional safeguards to ensure an appropriate consent process.

- When a research study involves populations with diminished decision-making capacity not covered by specific policies and procedures, the IRB uses experienced members and/or expert consultants to evaluate the consent process for these populations.

When research involves pregnant women, fetuses, or neonates, the IRB follows Subpart B of the DHHS regulations (when the activity is DHHS funded) or equivalent laws or regulations to approve an appropriate consent process.

When research involves prisoners as participants, the IRB follows Subpart C of the DHHS regulations (when the activity is DHHS funded) or equivalent laws or regulations to approve an appropriate consent process that includes a determination that:

- The information will be presented in a language that is understandable to prisoners.
- Each prisoner will be informed in advance that participation in the research will have no effect on his or her parole.

If the convened IRB reviews research that involves prisoners, one or more individuals who are prisoners or prisoner representatives have to be present at the meeting.

When research involves children as participants, the IRB follows Subpart D of the DHHS or FDA regulations (when the activity is DHHS funded, or under FDA jurisdiction) or equivalent laws or regulations to approve an appropriate assent process for children and consent process for parents or guardians.

When researchers are likely to approach adults who lack the ability to consent, the IRB evaluates whether:

- The proposed plan for the assessment of the capacity to consent is adequate.
- Assent of the participants is a requirement, and, if so, whether the plan for assent is adequate.

When research involves pregnant women, the IRB determines that the consent of the pregnant women is required if the research holds out:

- The prospect of direct benefit to the pregnant woman.
- The prospect of direct benefit both to the pregnant woman and the fetus.
- No prospect of benefit for the woman or the fetus when risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means.

When research involves pregnant women, the IRB determines that the consent of the pregnant woman and the father is required, except that the father’s consent need not be obtained if he is unable to consent because of unavailability, incompetence, or temporary incapacity or the pregnancy
resulted from rape or incest if the research holds out the prospect of direct benefit solely to the fetus.

The IRB determines and documents whether the approval criteria for consent and permission are met when research involves pregnant women or fetuses.

- The consent of the mother is obtained in accordance with the regulations.
- If the research holds out the prospect of direct benefit solely to the fetus, then the consent of the father is also obtained in accordance with the regulations, except that the father’s consent does not need to be obtained if he is unable to consent because of unavailability, incompetence, or temporary incapacity or the pregnancy resulted from rape or incest.
- Individuals providing consent are fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate.

When the research involves neonates of uncertain viability, the IRB determines that the consent of either parent of the neonate is required or, if neither parent is able to consent because of unavailability, incompetence, or temporary incapacity, the legally effective consent of either parent’s legally authorized representative is required, except that the consent of the father or his legally authorized representative need not be obtained if the pregnancy resulted from rape or incest.

The IRB determines and documents whether the approval criteria for consent and permission are met when research involves neonates of uncertain viability.

- Individuals providing consent are fully informed regarding the reasonably foreseeable impact of the research on the neonate.
- The legally effective consent of either parent of the neonate is obtained in accordance with the regulations.

When the research involves non-viable neonates, the IRB determines that the consent of both parents is required, except:

- If either parent is unable to consent because of unavailability, incompetence, or temporary incapacity, the consent of one parent is required.
- If the pregnancy resulted from rape or incest the consent of the father need not be obtained.

When the research involves non-viable neonates, the IRB is not allowed to approve the consent of a legally authorized representative.

The IRB determines and documents whether the approval criteria for consent and permission are met when research involves non-viable neonates.

- Individuals providing consent are fully informed regarding the reasonably foreseeable impact of the research on the neonate.
- The legally effective consent of both parents of the neonate is obtained in accordance with the regulations.
- The waiver and alteration provisions are not applied.

For research that involves no more than minimal risk or more than minimal risk with the prospect of direct benefit to the individual children, the IRB determines whether:

- The permission of both parents is required unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child, or the permission of one parent is sufficient.
- For research that involves more than minimal risk without the prospect of direct benefit to the individual children, the IRB determines that the permission of both parents is required unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one
parent has legal responsibility for the care and custody of the child.

The IRB determines and documents that assent is a requirement of:

- All children.
- Some children.
- None of the children.

When the IRB determines that assent is not a requirement of some children, the IRB determines and documents which children are not required to assent.

When the IRB determines that assent is not a requirement for some or all children, the IRB determines and documents one or more of the following:

- The children are not capable of providing assent based on the age, maturity, or psychological state.
- The capability of the children is so limited that they cannot reasonably be consulted.
- The intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the child and is available only in the context of the research.
- Assent can be waived using the criteria for waiver of the consent process.

When the IRB determines that assent is a requirement, the IRB determines whether:

- Assent will be documented.
- If so, the process to document assent.

Additional federal regulations regarding appropriate protections for prospective participants who cannot give consent or whose decision-making capacity is in question are addressed in the “INVESTIGATOR MANUAL (HRP-103)” and “WORKSHEET: ADDITIONAL FEDERAL CRITERIA (HRP-318).”


The Institution applies ethical standards to Human Research that it determines to be exempt from the federal regulations by ensuring that:

- The research holds out no more than minimal risk to participants.
- Selection of participants is equitable.
- If there is recording of identifiable information, there are adequate provisions to maintain the confidentiality of the data.
- If there are interactions with participants, the IRB should determine whether there should be a consent process that will disclose such information as:
  - That the activity involves research.
  - A description of the procedures.
  - That participation is voluntary.
  - Name and contact information for the researcher.
  - There are adequate provisions to maintain the privacy interests of participants.
Certain categories of Human Research may be exempt from the regulations but still require IRB review. It is the responsibility of the Institution, not the researcher, to determine whether Human Research is exempt from IRB review. Review “WORKSHEET: EXEMPTION DETERMINATION (HRP-312)” for reference on the categories of research that may be exempt. Submit an “INITIAL REVIEW APPLICATION” for a determination (SOP: NON-COMMITTEE REVIEW PREPARATION [HRP-031]).

A single designated reviewer or trained IRB staff member may make this determination. Designated reviewers are trained by the IRB and include the IRB chairpersons or experienced IRB members designated by the IRB chairpersons to conduct non-committee reviews (SOP: DESIGNATED REVIEWERS [HRP-030]). An IRB member is considered experienced if the IRB chair considers the IRB member to have sufficient experience in and knowledge of conducting IRB reviews (SOP: DEFINITIONS [HRP-001]). In addition, designated faculty reviewers are trained and authorized by the IRB to determine exempt human subjects research and to determine not human subjects research (SOP: DESIGNATED FACULTY REVIEWERS [HRP-033]).

The designated reviewers and designated faculty reviewers use “CHECKLIST: PRE-REVIEW (HRP-401)” or equivalent and “CHECKLIST: NON-COMMITTEE REVIEW (HRP-402)” or equivalent to document their determination (SOP: NON-COMMITTEE REVIEW CONDUCT [HRP-032] and SOP: DESIGNATED FACULTY REVIEW CONDUCT [HRP-034]). Use of “WORKSHEET: EXEMPTION DETERMINATION (HRP-312)” or confirms that the criteria for exemptions are consistent with:

- Subpart A of the DHHS regulations.
- Subpart B of the DHHS regulations.
- Subpart D of the DHHS regulations.
- FDA regulations.

The IRB will provide researchers with a determination letter indicating the exempt category(ies) or a determination letter indicating that the research is not human subjects research.

Any questions about whether an activity meets the regulatory definitions of Human Research should be referred to the IRB Administration who will provide a determination (WORKSHEET: HUMAN RESEARCH DETERMINATION [HRP-310]).

Certain categories of Human Research may be eligible for review using the expedited procedure (WORKSHEET: ELIGIBILITY FOR REVIEW USING THE EXPEDITED PROCEDURE [HRP-313]). The HRP-313 worksheet covers the eligible categories for initial reviews, continuing reviews, and reviews of minor modifications. Submit “INITIAL REVIEW APPLICATION,” including the required attachments, for review and approval (SOP: NON-COMMITTEE REVIEW PREPARATION [HRP-031], SOP: NON-COMMITTEE REVIEW CONDUCT [HRP-032], and SOP: POST-REVIEW [HRP-052]).

A single designated reviewer may review research eligible for the expedited procedure. Designated reviewers are trained by the IRB and include the IRB chairpersons or experienced IRB members designated by the IRB chairpersons to conduct non-committee reviews (SOP: DESIGNATED REVIEWERS [HRP-030]). An IRB member is considered experienced if the IRB chair considers the IRB member to have sufficient experience in and knowledge of conducting IRB reviews (SOP: DEFINITIONS [HRP-001]).

The designated reviewers receive and review the same materials as the convened IRB (WORKSHEET: REVIEW MATERIALS [HRP-301]), apply the same regulatory criteria for
approval as the convened IRB (WORKSHEET: CRITERIA FOR APPROVAL AND ADDITIONAL CONSIDERATIONS [HRP-314]), and use “CHECKLIST: PRE-REVIEW (HRP-401)” or equivalent and “CHECKLIST: NON-COMMITTEE REVIEW (HRP-402)” or equivalent to document their approval (SOP: NON-COMMITTEE REVIEW CONDUCT [HRP-032]). The IRB will provide researchers with an approval letter indicating the expedited category(ies).

For continuing review of research, the IRB members determine whether:

- The protocol needs verification from sources other than the researchers that no material changes had occurred since previous IRB review.
- The current consent document is still accurate and complete.
- Any significant new findings that arise from the review process and that might relate to participants’ willingness to continue participation will be provided to participants.

The designated reviewers using the expedited procedure may not disapprove research.

Other Requirements

When reviewing research that involves community-based research, the IRB reviews required information in the “INITIAL REVIEW APPLICATION” and ensures the inclusion of members or consultants with expertise in this type of research (FORM: HRP-333 RESEARCH INVOLVING COMMUNITIES). If members or consultants with this expertise are not available, the IRB obtains consultation or training on:

- Use of community-based participatory research design.
- Use of community advisory boards.
- Use of participant advocates.
- Partnerships with community-based Institutions.

When the researcher is the lead researcher of a multi-site study, IRB applications include information about the management of information that is relevant to the protection of participants, such as:

- Unanticipated problems involving risks to participants or others (UPIRTSOs).
- Interim results.
- Protocol modifications.

When the researcher is the lead researcher of a multi-site study, the IRB evaluates whether the management of information that is relevant to the protection of participants is adequate.

All policies and procedures are applied identically to all research regardless of whether the research is conducted domestically or in another country, including:

- Confirming the qualifications of investigators and the research team for conducting the research (INITIAL REVIEW APPLICATION and FORM: ADMINISTRATIVE APPROVAL [HRP-226])
- Using “WORKSHEET: EVALUATION OF QUORUM AND EXPERTISE (HRP-305) and “WORKSHEET: HRP-332 REVIEW OF LOCAL RESEARCH CONTEXT” to ensure:
  - The appropriate expertise and knowledge of the country(ies) through IRB members, government agencies and/or consultants.
  - Knowledge of local laws.
  - Knowledge of cultural context.
- Conducting initial review, continuing review, and review of modifications to previously approved research.
- Post-approval monitoring.
• Handling of complaints, non-compliance, and unanticipated problems involving risks to subjects or others.
• Consent process and other language issues.
• Ensuring all necessary approvals are met.
• Coordination and communication with local IRBs and/or government agencies.

Researchers provide this information to the IRB using “INITIAL REVIEW APPLICATION” The IRBs use “WORKSHEET: EVALUATION OF QUORUM AND EXPERTISE (HRP-305)” to ensure appropriate expertise for the review. The IRBs also use OHRP’s International Compilation of Human Research Standards as a resource: http://www.hhs.gov/ohrp/international/. If the IRB expertise is not available, the IRB uses consultants, government agencies and/or local ethics committees to provide the context.

• For research that is greater than minimal risk, the IRB requires a copy of the local ethics committee approval (or equivalent) before approving the research.

• For research that is no more than minimal risk, the IRB adds an administrative requirement to the approval letter stating that the researcher may not begin the research until the local ethics committee (or equivalent) approves the research.

• If there is no collaboration and/or ethics review in the foreign country, the IRB uses local ‘officials’ and/or representatives to provide the local approval.

For clinical trials, this Institution commits to apply the “International Council on Harmonization – Good Clinical Practice E6.” (ICH-GCP)

This Institution prohibits payments to professionals in exchange for referrals of potential subjects (“finder’s fees”) and payments designed to accelerate recruitment that were tied to the rate or timing of enrollment (“bonus payments.”)

When Human Research is conducted or funded by the Department of Justice (DOJ), this Institution commits to apply 28 CFR §22. When Human Research is conducted with the federal Bureau of Prisons (DOJ), the Institution commits to comply with 28 CFR §512.

When Human Research is conducted or funded by the Department of Defense (DOD), this Institution commits to apply the Department of Defense (DOD) Directive 3216.02, which includes the requirement to apply 45 CFR §46 Subparts B, C, and D³. This Institution will comply with the terms of the DFARS clause or comparable language used in the agreement with the Department of Defense (DOD) Component supporting the research involving human subjects. The training requirements listed in the ‘Education and Training’ section of this Plan apply to all personnel who conduct, review, approve, oversee, support, or manage human subjects research. Depending on the project, there may be additional, specific educational requirements or certification required. Any additional requirements will be directed by the funding agency, Sponsored Programs, Legal Affairs, Compliance, Contracts, your department, and/or the IRB Administration.

³ Quick applicability table for DHHS Subparts:

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When Human Research is conducted or funded by the Department of Education (ED), this Institution commits to applying 34 CFR §97 Subpart D (equivalent to 45 CFR §46 Subpart D), 34 CFR §98.3, 34 CFR §98.4, 34 CFR §356.3, and 34 CFR §99. Per the ED regulations, when reviewing research funded by the National Institute on Disability and Rehabilitation Research that purposefully requires inclusion of children with disabilities or individuals with mental disabilities as research participants, the IRB will include at least one person primarily concerned with the welfare of these research participants.

When Human Research is conducted or funded by the Department of Energy (DOE), this Institution commits to applying the Department of Energy (DOE) O 443.1A and to use “Checklist for IRBs to Use in Verifying That HS Research Protocols Are in Compliance with the Department of Energy (DOE) Requirements.”

When Human Research is conducted or funded by, or when the results of research are intended to be submitted to or held for inspection by the Environmental Protection Agency (EPA), this Institution commits to applying 40 CFR §26, which includes the requirement to apply 45 CFR §46 Subparts B and D.

Sponsored Human Research
For both sponsored and non-sponsored Human Research this Institution abides by its ethical principles, regulatory requirements and its policies and procedures.

Scope of Human Research Protection Program
The categories of Human Research overseen include:
- All forms of human research except those listed below.

The categories of Human Research not overseen include:
- Research conducted or funded by the Veteran Administration (VA)

Human Research Protection Program Policies and Procedures
Policies and procedures for the Human Research Protection Program are available on the following Web site: http://www.research.ucdavis.edu/policiescompliance/irb-admin/

The Human Research Protection Program is evaluated monthly and annually for quality improvement (see SOP: MONTHLY EVALUATIONS OF THE HRPP [HRP-061]), and the IRB chairs, members, staff and resources are evaluated annually as per “SOP: ANNUAL EVALUATIONS OF THE HRPP (HRP-060).”

Human Research Protection Program Components

Institutional Official
The Vice Chancellor for Research is designated as the Institutional Official.
The Institutional Official has the authority to take the following actions or delegate these authorities to a designee:
- Create the Human Research Protection Program budget.
- Allocate resources within the Human Research Protection Program budget.
- Appoint and remove IRB members, alternate members and IRB chairs.
- Hire and fire research review staff.
• Determine what IRBs the Institution will rely upon.
• Approve and rescind authorization agreements for IRBs.
• Place limitations or conditions on an investigator’s or research staff’s privilege to conduct Human Research.
• Create policies and procedures related to the Human Research Protection Program that are binding on the Institution.
• Suspend or terminate research approved by one of the Institution’s IRBs.
• Disapprove research approved by one of the Institution’s IRBs.

The Institutional Official has the responsibility to:
• Oversee the review and conduct of Human Research under the jurisdiction of the Human Research Protection Program.
• Periodically review this plan to assess whether it is providing the desired results and recommend amendments as needed.
• Establish policies and procedures designed to increase the likelihood that Human Research will be conducted in accordance with ethical and legal requirement.
• Institute regular, effective, educational and training programs for all individuals involved with the Human Research Protection Program.
• Ensure that the research review process is independent and free of coercion or undue influence, and ensure that officials of the Institution cannot approve research that has not been approved by one of the IRBs designated by the Institution.
• Implement a process to receive and act on complaints and allegations regarding the Human Research Protection Program.
• Implement an auditing program to monitor compliance and improve compliance in identified problem areas.
• Investigate and remediate identified systemic problem areas, and where necessary removal of individuals from involvement in the Human Research protection program.
• Ensure that the Human Research Protection Program has sufficient resources, including IRBs appropriate for the volume and types of Human Research to be reviewed, so that reviews are accomplished in a thorough and timely manner.
• Review and sign federal assurances (FWA) and addenda.
• Fulfill educational requirements mandated by OHRP.

All Members of the Institution
All individuals within the Institution have the responsibility to:
• Be aware of the definition of Human Research.
• Consult the IRB when there is uncertainty about whether an activity is Human Research.
• Not conduct Human Research or allow Human Research to be conducted without review and approval by an IRB designated by the Institutional Official.
• Report allegations of undue influence regarding the oversight of the Human Research Protection Program or concerns about the Human Research Protection Program to the Institutional Official.
• Report allegations or finding of non-compliance with the requirements of the Human Research Protection Program to the IRB.
Individuals who are responsible for business development are prohibited from carrying out day-to-day operations of the review process, and are prohibited from serving as members or *ex officio* members on the IRB.

**IRBs**

The list of IRBs designated by the Institution Official to be the IRBs relied upon by the Human Research Protection Program and the scope of review of these IRBs is listed in the IRB rosters available from the IRB Administration.

This Institution may rely upon IRBs of another Institution provided one of the following is true:

- The IRBs are part of an AAHRPP accredited Institution (exceptions may be granted by the IO or designee).
- This Institution’s investigator is a collaborator on Human Research that is primarily conducted at another Institution and the investigator’s role does not include interaction or intervention with subjects.
- The Institution is engaged in the Human Research solely because it is receiving federal funds. (Employees and agents of the institution do not interact or intervene with subjects, gather or possess private identifiable information about subjects, nor obtain the consent of subjects.)

Reliance on an external IRB requires an Institutional Agreement for IRB review (IAIR) and a local review for compliance with local policies of the Institution.

The IRBs relied upon by this Institution have the authority to:

- Approve, require modifications to secure approval, and disapprove all Human Research overseen and conducted by the Institution. All Human Research must be approved by one of the IRBs designated by the Institutional Official. Officials of this Institution may not approve Human Research that has not been approved by one of the Institution’s IRBs.
- Suspend or terminate approval of Human Research not being conducted in accordance with an IRBs’ requirements or that has been associated with unexpected serious harm to subjects.
- Observe, or have a third party observe, the consent process and the conduct of the Human Research.
- Determine whether an activity is Human Research.
- Evaluate financial interests of investigators and research staff and have the final authority to decide whether the financial interest and management plan, if any, allow the Human Research to be approved.

IRB members and IRB staff have the responsibility to follow Human Research Protection Program policies and procedures that apply to IRB members and staff.

**Designated Faculty Reviewers**

IRB-Designated Faculty has the authority to review and make exempt determinations of Human Research conducted within their department, division or school.

Designated Faculty members are responsible to review the Human Research in accordance with this Institution’s policies and procedures.

For program specifics please review DESIGNATED FACULTY REVIEWERS (HRP-033) and DESIGNATED FACULTY REVIEW CONDUCT (HRP-034).
Investigators and Research Staff

Investigators and research staff have the responsibility to:

- Follow the Human Research Protection Program requirements described in the INVESTIGATOR MANUAL (HRP-103).
- Follow the Human Research Protection Program policies and procedures that apply to IRB members and staff.
- Comply with all determinations and additional requirements of the IRB, the IRB chair, and the Institutional Official.

Legal Counsel

Legal Counsel has the responsibility to:

- Provide advice upon request to the Institutional Official, IRB, and other individuals involved with the Human Research Protection Program.
- Determine whether someone is acting as an agent of the Institution.
- Determine who meets the definition of “legally authorized representative” and “children” when Human Research is conducted in jurisdictions not covered by policies and procedures.
- Resolve conflicts among applicable laws.

Deans/Department Chairs

Deans and Department Chairs have the responsibility to:

- Oversee the review and conduct of Human Research in their department or school.
- Forward complaints and allegations regarding the Human Research Protection Program to the Institutional Official.
- Ensure that each Human Research study conducted in their department or school has adequate resources.

Sponsored Programs/Contracts Office

The Sponsored Programs Office and the Health System Contracts Office have the responsibility to review contracts and funding agreements for compliance with Human Research Protection Program policies and procedures, using the criteria in “WORKSHEET: CONTRACT ITEMS RELATED TO HUMAN SUBJECT PROTECTIONS (HRP-324).” If a sponsor requests changes to template language in the IRB consent document or the contract, the IRB Administration, Sponsored Programs Office, and/or the Contracts Office communicate via e-mail, teleconferences and meetings to ensure consistency between the documents and contracts or funding agreements.

Investigational Drug Services (IDS) Pharmacy

When an investigational drug or biologic is involved in the research, the Principal Investigator is required to defer responsibility for accounting, storage, dispensing, etc. to the Investigational Drug Services (IDS) Pharmacy, located at the UC Davis Medical Center.

Institutional Biosafety Committee (IBC)

The IBC reviews research using biological agents, recombinant DNA research for compliance and conformance with NIH Guidelines, recommends level of medical surveillance of personnel associated with the research project after review by the campus Occupational Health Physician, and recommends
modifications, curtailment, or termination of any projects when it is in the best interest of the health and safety of the campus community. If the IRB identifies studies not approved by the IBC, the IRB review process will be postponed pending review and approval by the IBC. Investigators may also contact the Committee directly for review requirements. The IRB will not approve a study requiring IBC review without that Committee’s approval.

**Conflict of Interest Committee (COIC)**

Any actual or perceived conflict of interest as defined by institutional policy, consistent with applicable federal and state regulations is required to be reported to and reviewed by the Conflict of Interest Committee (COIC). The COIC will inform the IRB when investigators conducting human research have significant financial interests that constitute a financial conflict of interest. The IRB has the final authority and may grant final approval of research studies with a disclosed conflict of interest, provided that the IRB has taken appropriate steps to eliminate or manage the conflict, consistent with the Conflict of Interest Committee determination (see SOP: FINANCIAL CONFLICTS OF INTEREST [HRP-055]). Should the IRB or the Conflict of Interest Committee require changes in the research study to mitigate a conflict, the Principal Investigator will be required to submit the revised documents for IRB review and approval.

**Cancer Center Scientific Review Committee (CCSRC)**

The CCSRC is charged with the review and monitoring of protocols involving cancer patients and/or their data. The Committee provides a centralized mechanism for prospective evaluation of scientific merit, resource allocation, and clinical cancer research monitoring. The application requires that Principal Investigators contact the Cancer Center Scientific Review Committee for the review and approval of their research study, prior to submission of the protocol for IRB review and approval. The IRB will not approve a protocol involving cancer patients and/or their data without the approval of the CCSRC.

**Radiation Use Committee (RUC)**

The RUC is responsible for the surveillance of all uses of radioactive materials and ionizing radiation (including diagnostic x-rays/fluoroscopy/DEXA) in research involving human participants. Principal Investigators are required to identify, on “INITIAL REVIEW APPLICATION,” all proposed radiation use. The application requires that Principal Investigators contact the Radiation Use Committee for the review and approval of their study, prior to IRB review and approval. The RUC may require amendments to the design of the study, restrictions, or specific wording in the informed consent document, to ensure conformance with the University’s Radioactive Material License and state and federal regulations. The IRB will not approve a research study involving radiation without the prior approval/exemption of the Radiation Use Committee.

**Stem Cell Research Oversight Committee (SCROC)**

The SCROC 1) provides oversight of all issues related to derivation and use of human adult and embryonic stem cell lines; 2) reviews and approves the scientific merit of research protocols; 3) reviews compliance of all human adult and embryonic stem cell research with all relevant regulations and guidelines; and 4) facilitates education of investigators involved in human adult and embryonic stem cell research. Principal Investigators are required to identify, on “INITIAL REVIEW APPLICATION,” all human adult and embryonic stem cell studies. The application requires that
Principal Investigators contact the Stem Cell Research Oversight Committee for the review and approval of their research study.

**Outreach, Training and Education**

All new employees are to review this plan as part of initial orientation. The Office of Research Human Resources Department is to conduct refresher training on current employees as needed to maintain awareness of this policy.

IRB members, IRB staff, and others involved in the review of Human Research must complete the online Collaborative Institutional Training Initiative (CITI) human subjects online training program. See the IRB Web site for a link to this training. This training is valid for a three-year period, after which time a refresher CITI course or additional training must be completed. IRB staff also train IRB members on the SOPs, checklists, and worksheets applicable to IRB members including regulatory and guidance requirements noted in the section “Other Requirements.”

Investigators and research staff must complete one of the training programs specified in the INVESTIGATOR MANUAL (HRP-103). This training is valid for a three-year period, after which time a refresher course or additional training as specified in the INVESTIGATOR MANUAL (HRP-103) must be completed.

The institution has multiple internal and external resources for outreach to the community. Research brochures (e.g., SHOULD I TAKE PART IN RESEARCH [HRP-104]) are available to all patients of the UC Davis Health System at hospital-based clinics, Primary Care Network-based clinics, and medical student-run clinics in the community. The Health System also hosts a clinical trials search page, to allow potential participants to search for active clinical trials at UC Davis and contact researchers and research teams for additional information.

In addition, the IRB Administration is housed within the NIH-funded Clinical and Translational Science Center (CTSC). The Center, through the Community Engagement Program, places particular emphasis on ensuring active participation of the community to help reduce health disparities in clinical research. A major component of the Community Engagement Program is the Research and Education Community Advisory Board (RECAB), which reviews active research studies and advertisements and provides community input for future studies. This allows community representatives to be involved in the research design and provide feedback from the community. The 15-person Board consists of a diverse membership, including community activists, elected officials, and community business leaders. Members are drawn from throughout the region to reflect the needs and concerns of various ethnic, economic and cultural groups within the greater Sacramento area.

The IRB Administration works closely with the CTSC’s Community Engagement Program and RECAB whenever consultation or advice is needed on research impacting the community. The following is a list of services available:

- Community Engagement Seminar Series – highlights the latest issues in bioethics, health disparities, community-based participatory research, and other topics the community provides.
- CTSC Community Engagement Consultation Service – UCD researchers and community members can explore together opportunities for dialogue and action around health research ideas.
- Community-engaged Research Training Program – creates occasions for building skills, pursuing partnerships, and ensuring that scientific breakthroughs ultimately improve the health of all.
• The Health Disparities Resource List – provides researchers and community members with the demographic and statistical information needed to develop projects and proposals aimed at reducing health disparities.

Researchers are required to submit a description of community involvement in the design and conduct of community-based research with their IRB application (INITIAL REVIEW APPLICATION).

Questions and Additional Information for the IRB

The IRB Administration wants your questions, information, and feedback.

Contact and location information for the IRB Administration is:

Cynthia M. Gates, J.D., R.N., C.I.P.
Director, IRB Administration
2921 Stockton Blvd
Suite 1400, Room 1429
Sacramento, CA 95817
Email: cmgates@ucdavis.edu
Phone: (916) 703-9154
Fax: (916) 703-9160

Reporting and Management of Concerns

Questions, concerns, complaints, allegations of undue influence, allegations or findings of non-compliance, or input regarding the Human Research Protection Program may be reported orally or in writing. Employees are permitted to report concerns on an anonymous basis. Concerns may be reported to the IRB Chair, IRB Administration, Institutional Official, Legal Counsel, Deans, or Department Chairs.

The IRB has the responsibility to investigate allegations and findings of non-compliance and take corrective actions as needed. Policies and procedures associated with suspensions and terminations of IRB approval are addressed in “SOP: SUSPENSION OR TERMINATION OF IRB APPROVAL (HRP-026)” The Institutional Official has the responsibility to investigate all other reports and take corrective actions as needed.

Employees who report in good faith possible compliance issues should not be subjected to retaliation or harassment as a result of the reporting. Concerns about possible retaliation should be immediately reported to the Institutional Official or designee.

To make such reports, contact:

Harris Lewin
Vice Chancellor for Research and IO
Office of Research
One Shields Avenue Davis, CA 95616
Email: lewin@ucdavis.edu

Monitoring and Auditing

In order to monitor and ensure compliance, internal or external auditors who have expertise in federal and state statutes, regulations and Institutional requirements will conduct periodic audits. Audits will
focus on areas of concern that have been identified by any entity, i.e., federal, state or institutional. Random audits may also be conducted.

**Disciplinary Actions**

The Institutional Official may place limitations or conditions on an investigator’s or research staff’s privilege to conduct Human Research whenever in the opinion of the Institutional Official such actions are required to maintain the Human Research Protection Program.

**Approval and Revisions to the Plan**

This Human Research Protection Program Plan has been approved by Executive Associate Vice Chancellor for Research Administration, Cindy Kiel. This plan is intended to be flexible and readily adaptable to changes in regulatory requirements. The Institutional Official has the responsibility to review this plan to assess whether it is providing the desired results. At the request of the Institutional Official, the Executive Associate Vice Chancellor for Research Administration has the authority to amend this plan as deemed necessary. Any changes to policies or procedures are communicated to the research community via listserv announcements, updates to the Office of Research Website, and/or updates to the IRB Administration Website.