UCDAVIS
UNIVERSITY OF CALIFORNIA

University of California Davis

Human Research Protection Program

Plan

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Table of Contents

Contents

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 (HRPP) is a comprehensive structure designed to ensure the protection of the rights and welfare of subjects in Human Research. The HRPP is dependent on the participation of 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.

[1] http://www.hhs.gov/ohrp/policy/engage08.html

Human Research:

Any activity that either:

- Is "Research" as defined by DHHS and involves "Human Subjects" as defined by DHHS ("DHHS Human Research"); or
- 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: (1) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (2) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens. For the purpose of this definition:

- **Intervention** means physical procedures by which information or biospecimens are gathered (e.g., 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 that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical record).
- **Identifiable Information** means information for which the identity of the subject is or may be readily ascertained by the investigator or associated with the information (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information).
- **Identifiable Biospecimen:** A biospecimen for which the identity of the subject is or may be readily ascertained by the investigator or associated with the biospecimen.

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. When medical device research involves in vitro diagnostics and unidentified tissue specimens the FDA defines the unidentified tissue specimens as human subjects.

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.

Medical Experiment as Defined by California Health and Safety Code

The severance or penetration or damaging of tissues of a human subject or the use of a drug or device, electromagnetic radiation, heat or cold, or a biological substance or organism, in or upon a human subject in the practice or research of medicine in a manner not reasonably related to maintaining or improving the health of the subject or otherwise directly benefiting the subject.

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;
- 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.

Review of State of California-produced death data files

California law requires IRB approval before conducting research involving State of California-produced death data files containing personal identifying information.

State of California-produced death data files which require IRB approval include:

- All files that can be linked to other death files using the certificate number (e.g., Death Address Files, Multiple Cause of Death Files); and

[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.

- All files that are provided with personal identifiers (e.g., Death Statistical Master Files, Merged Death Files, Fetal Death Statistical Master Files).

Access to State of California-produced death data files that include personal identifying information also requires review by the State of California Committee for the Protection of Human Subjects (CPHS). Researchers apply for CPHS review when ordering the data from the State of California. The State of California requires that researchers have a "valid scientific interest" in order for the IRB to approve such a study.

Mission

The mission of this Institution's HRPP 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, 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

This Institution abides by its ethical principles, regulatory requirements and its policies and procedures for both sponsored and non-sponsored Human Research.

Legal and Regulatory Requirements

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

- All non-exempt Human Research must undergo review by one of the institutionally designated IRBs, or by a designated reviewer.
- Activities that meet the definition of Human Research are reviewed according to the applicable Worksheets and Checklists.[3]

This Institution's IRB approves research according to applicable federal and local law during the review of research. If the applicable law is inconsistent, the IRB will apply the most protective of the applicable laws.

[3] Worksheets and checklists are located on the IRB Administration Website: https://irb.ucdavis.edu/irb-submissions/irb-forms/

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:

- Classified Research

HRPP Policies and Procedures

Policies and procedures for the HRPP are available here on the UC Davis IRB Administration website.

Evaluation of the HRPP

The organization must periodically conduct self-assessments to ensure compliance with the HRPP procedures and other requriements. The HRPP includes a quality improvement plan. The goal of the quality improvement plan is to achieve and maintain compliance and to achieving targeted levels of quality, efficiency, and effectiveness of the HRPP. The HRPP is evaluated monthly and annually for quality improvement. The Institution follows SOPs to complete the evaluation.[4]

HRPP Components

Institutional Official

The Vice Chancellor for Research is designated as the Institutional Official.

Institutional Official Authority:

- Create the HRPP budget.
- Allocate resources within the HRPP 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 HRPP that are binding on the Institution.
- Suspend or terminate research approved by one of the Institution's IRBs.

[4] See SOP: Monthly Evalatuions or the HRPP [HRP-061]) and SOP: Annual Evaluations of the HRPP (HRP-060).

- Disapprove research approved by one of the Institution's IRBs.

Institutional Official Responsibilities

- Oversee the review and conduct of Human Research under the jurisdiction of the HRPP.
- 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 and 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 HRPP 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 HRPP or concerns about the HRPP to the Institutional Official.
- Report allegations or finding of non-compliance with the requirements of the HRPP 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.

Institutional Review Boards (Committees)

Institutional Review Board

Under FDA regulations, an Institutional Review Board (IRB) is a group that has been formally designated to review and monitor biomedical, social and behavioral research involving human subjects. In accordance with FDA regulations, an IRB has the authority to approve, require modifications in (to secure approval), or disapprove research.

For a schedule of meeting dates, click here to access the calendar on the UC Davis IRB Administration Website.

This Institution may rely upon another Institution's IRB.

Reliance on an external IRB requires an Institutional Agreement for IRB review and a local administrative and context review for compliance with applicable law, regulatory requirements, and policies of the Institution.

IRB Authority:

- Approve, require modifications to secure approval, and disapprove all Human Research overseen and conducted by the Institution. Officials of reviewing Institution may not approve Human Research that has not been approved by one of the Institution's IRBs.[5]
- 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.
- Make determinations of Serious and Continuing Non-compliance and Unanticipated Problems Involving Risks to Subjects or Others.
- 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 applicable Institutional HRPP policies and procedures.

Designated Reviewers

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 and

[5] For program specifics, see SOP: IRB Meeting Conduct (HRP-041)

ensure compliance with SOPs and applicable regulations.[6] 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.[7] Designated Reviewers may be IRB Administration staff members or trained faculty reviewers.[8]

The designated reviewers receive and review the same materials and apply the same regulatory criteria for approval as the convened IRB and use applicable worksheets and checklists to complete the review.[9] Upon completion of the review, the IRB will provide researchers with an approval letter indicating the expedited category(ies) applied or a determination letter indicating that the proposed activity is exempt or not Human Research.[10]

Designated Reviewer Authority

Designated reviewers have the authority to review and make the following determinations:

- Whether an activity is Human Research.
- Whether the Institution is engaged in Human Research.
- Whether a proposed activity is exempt from the requirements for IRB review and approval.
- Approval of a proposed research activity.
- 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 Human Research involving only minimal risk to be approved.

Designated reviewers may not disapprove a proposed research activity and must refer such activities to a convened IRB for a determination. Designated reviewers are responsible to review the Human Research in accordance with this Institution's policies and procedures.

Investigator and Research Staff Responsibilities

Investigators and research staff have the responsibility to:

- Follow the HRPP requirements described in the Investigator Manual (HRP-103).
- Follow the HRPP policies and procedures that apply to IRB members and staff.

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[6] For program specifics, see SOP: Designated Reviewers (HRP 030)
[7] See SOP: Definitions (HRP-001)
[8] For specifics, see SOP: Designated Faculty Reviewers (HRP-033)
[9] Applicable worksheets and checklists are located on the IRB Administration Website.
[10] For program specifics, see CHECKLIST: Pre-Review (HRP-401), CHECKLIST: IRB Review (HRP 402), SOP: Non-Committee Review Conduct (HRP-032), SOP: Designated Faculty Review Conduct (HRP-034), WORKSHEET: Human Research Determination (HRP-310), WORKSHEET: Engagement Determination (HRP-311), WORKSHEET: Exemption Determination (HRP 312), and WORKSHEET: Eligibility for Review Using the Expedited Procedure (HRP-313)

- 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.
- Determine the scientific validity, investigator qualifications and available resources for proposed research and provide administrative approval of submissions for initial review.
- Forward complaints and allegations regarding the HRPP 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 UC Davis Health Office have the responsibility to review contracts and funding agreements for compliance with HRPP policies and procedures.[11] 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 the research involves an investigational drug or biologic, 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 (1) reviews research using biological agents and recombinant DNA for compliance and conformance with NIH Guidelines; (2) recommends level of medical surveillance of

[11] For program specifics, see WORKSHEET: Contract Items Related to Human Subject Protections (HRP-324)

personnel associated with the research project after review by the campus Occupational Health Physician; and (3) 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 COIC. Principal Investigators are required to report financial relationships with research to the COIC and the IRB at initial review and during the conduct of the research. The COIC will inform the IRB when investigators conducting human research have significant financial interests that constitute a financial conflict of interest and provide the COIC management plan. 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 COIC's determinations.[12] 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

[12] For program specifics, see SOP: Financial Conflicts of Interest (HRP-055).

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.

Human Subject Research Training Requirements

Individuals conducting research involving humans as subjects must read the UC Davis Investigator Manual. Specific information on Institutional training requirements can found in the manual.

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. 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.

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.

Completion of training requirements is monitored in the following ways:

- On the Initial Review Application, principal investigators attest that research personnel have completed required training.
- IRB staff review training history of principal investigators and co-principal investigators whenever a submission for initial review or continuing review is received by the IRB.
- The Research Compliance and Integrity Office conducts audits of research records during which training records are reviewed.
- IRB staff training is evaluated during the annual employee evaluation process.
- IRB member training is evaluated during the IRB member evaluation process.

Community Outreach

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 (UCDH) at hospital-based clinics, Primary Care Network-based clinics, and medical student-run clinics in the community. UCDH 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 Initial Review Application.

IRB Review Process

In order to approve human subject research, the Committees and Designated Reviewers must determine that the criteria for approval[13] are satisfied. The IRB uses the 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. The IRBs of the Institution meet to ensure the regulatory requirements for IRB composition are satisfied.[14]

IRB SOPs 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.[15]

Policies and procedures governing activities associated with preparation and conduct of convened IRB meetings are detailed in SOPs.[16]

For non-exempt research, the IRB considers the scientific merit of the research.[17] The IRB may rely on outside experts to provide an evaluation of the scientific merit.

The Institution follows policies and procedures for required reporting to institutional officials and federal agencies.[18]

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,[19] except to provide information requested by the IRB.

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.")

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[13] See federal regulation 21 CFR 56.111 and 45 CFR 46.111
[14] See WORKSHEET: IRB Composition (HRP-304)
[15] See SOP: Non-Committee Review Preparation (HRP-031), SOP: IRB Meeting Preparation (HRP-040), SOP: IRB Meeting Conduct (HRP-041), SOP: IRB Meeting Attendance Monitoring (HRP-042), SOP: IRB Meeting Minutes (HRP-043), SOP: Consultation to the IRB (HRP-051), and SOP: Post-Review (HRP-052)
[16] See SOP: Pre-Review (HRP-021), SOP: New Information (HRP-024), SOP: Suspension or Termination of IRB Approval (HRP-026), SOP: IRB Meeting Preparation (HRP-040), SOP: IRB Meeting Conduct (HRP-041), SOP: IRB Meeting Attendance Monitoring (HRP-042), SOP: IRB Meeting Minutes (HRP-043), SOP: Consultation to the IRB (HRP-051), SOP: Post-Review (HRP-052), and SOP: IRB Meeting Scheduling and Notification (HRP-084)
[17] See WORKSHEET, Scientific or Scholarly Review (HRP-320)
[18] For program specifics, see SOP: IRB Meeting Minutes (HRP-043) and SOP: Post-Review (HRP-052)
[19] For program specifics, see SOP: Definitions (HRP-001) SOP: IRB Meeting Preparation (HRP-040), SOP: IRB Meeting Conduct (HRP-041), SOP: IRB Meeting Attendance Monitoring (HRP-042), SOP: Conflicting Interests of IRB Members (HRP-050), SOP: Consultation to the IRB (HRP-051), and CHECKLIST: (HRP-402)

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.

Certain categories of Human Research may be exempt from the regulations. It is the responsibility of the Institution, not the researcher, to determine whether Human Research is exempt from IRB review.[20] A single designated reviewer or trained IRB staff member may make this determination.

IRB Members and Designated Reviewers are provided with adequate materials to complete their review.[21] The Committees use worksheets and checklists to determine whether the criteria for approval and are required determinations are satisfied.[22]

IRB Determinations

In order to approve research, the IRB determines that:

- Risks are minimized.
- Risks are acceptable in relation to anticipated benefit.
- 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 research protocol or plan contains adequate provisions to protect the privacy interests of participants.
- When appropriate, the research protocol or plan contains adequate provisions to maintain the confidentiality of data.[23]
- 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.

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[20] For program specifics, see WORKSHEET: Exemption Determination (HRP-312)

[21] For program specifics, see WORKSHEET: Review Materials (HRP-301)

[22] Children (HRP-416) and Waiver or Alteration of the Consent Process (HRP-410). Additional worksheets and checklists are found at https://irb.ucdavis.edu/irb-submissions/irb-forms/#For%20IRB%20Administration.

[23] Specific requirements pertaining to regulatory agencies for confidentiality are provided in Worksheet: Additional Federal Criteria (HRP-318)

  - 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 reviews the consent process and document and ensures the process and document are compliant with SOP: Informed Consent Process for Research (HRP-090) and Written Documentation of Consent (HRP-091) is allowed to waive or alter the consent process, waive the requirements for parental permission and waive the requirement for written documentation of the consent by determining that the criteria for waivers or alterations are met. The IRB documents its findings justifying the waiver or alteration [24] The IRB determines when proposed research meets the requirements for the exception to the requirement for informed consent for planned emergency research.[25] For human subject research activities under DOD jurisdiction: An exception from consent in emergency medicine research is prohibited unless a waiver is obtained from the Secretary of Defense.
- The Committees determines whether advertisements and recruitment activities are consistent with Institutional policy.[26]

Continuing Review

The IRB approves non-exempt human subject research for periods consistent with federal regulations and institutional policy.[27] Dates of approval and expiration can be found in the IRB system of record and IRB determination letters. Investigators are required to submit

[24] For program specifics, see "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)

[25] For program specifics, see CHECKLIST: Waiver of Consent for Emergency Research (HRP 419)

[26] For program specifics, see Worksheet: Advertisements (HRP-315); "Worksheet: Payments (HRP-316) and Worksheet: Additional Federal Criteria (HRP-318)

[27] For program specifics, see Worksheet: Calculation of Approval Intervals (HRP 302)

information needed for continuing review. 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 on and interactions with 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.[28]

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 the 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.

Researchers must report information to the IRB Administration within five to ten business days of becoming aware of the information. A trained IRB staff member or an IRB reviewer will review the report 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.[29],[30]

Compliance with Federal Funding Requirements

- 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.[31] 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#

28 For program specifics, see SOP: Expiration of IRB Approval (HRP-063).
[29] See SOP: Definitions (HRP-001)
[30] 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).
[31] See Worksheet: Drugs (HRP-306) and Worksheet: Devices (HRP-307)

- When this Institution is engaged in Human Research funded or supported by an agency of the Department of Health and Human Services (DHHS), this Institution commits to comply with 45 CFR 46, Subparts A, B, C and D.
- When this institution is engaged in Human Research funded or supported by a federal department or agency that is a signatory of the Common Rule, the Institution commits to comply with the regulations of that agency relevant to the protection of Human Subjects.[32]
- This Institution commits to comply with 34 CFR § 97, including Subpart D, 34 CFR § 98.3-4, 34 CFR §356.3, and 34 CFR §99 when engaging in Human Research that is funded or supported by the Department of Education (ED).[33] 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.
- This Institution commits to comply with 28 CFR §22 when engaging in Human Research that is funded or supported by the Department of Justice (DOJ).
- When Human Research is conducted with the federal Bureau of Prisons (DOJ), the Institution commits to comply with 28 CFR §512.
- This Institution commits to comply with the Department of Defense (DOD) Directive 3216.02, which includes the requirement to comply with 45 CFR §46 Subparts B, C, and D[34].when this institution engages in Human Research conducted or funded by the Department of Defense (DOD). 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 and the UC Davis Investigator Manual apply to all personnel who conduct, review, approve, oversee, support, or manage human subjects research.
- When Human Research is conducted or funded by the Department of Energy (DOE), this Institution commits to comply with the Department of Energy (DOE) O 443.1A.
- 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

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32 For specifics, see WORKSHEET: Additional Federal Criteria (HRP-318).

33 For program specifics, see "WORKSHEET: FERPA Compliance (HRP-331), and WORKSHEET: Evaluation of Quorum and Expertise (HRP-305).

34 Quick applicability table for DHHS Subparts:

	DHHS	DOD	ED	EPA
Subpart B	X	X		X
Subpart C	X	X		
Subpart D	X	X	X	X

Agency (EPA), this Institution commits to comply with 40 CFR §26, which includes the requirement to comply with 45 CFR §46 Subparts B and D.

Community Based Participatory Research

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.[35] 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.

Multi-Site Human Research

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 subjects or others (UPIRTSOs).
- Interim results.
- Non-administrative 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 by the Institution or a relying Institution or Independent Investigator and whether the research is conducted domestically or in another country, including:

- Confirming the qualifications of investigators and the research team for conducting the research
- Ensuring quorum and expertise during the conduct of the review[36]
- Ensuring knowledge of local research context,[37] including
    - 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 non-administrative modifications to previously approved research.
- Post-approval monitoring.

[35] See FORM: Research Involving Communities (HRP 333)
[36] See Worksheet: Evaluation of Quorum and Expertise (HRP-305)
[37] See Worksheet Review of Local Research Context (HRP-332)

- 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 the Initial Review Application. The IRBs also use OHRP's International Compilation of Human Research Standards as a resource. 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.
- 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.

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. The goal of the program is to monitor compliance and continuously increase compliance with the HRPP throughout the Institution. Audits of IRB minutes, investigator records and the HRPP program will be conducted using an applicable checklist.[38]

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.

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:

38 For program specifics, see CHECKLIST: Investigator Quality Improvement Assessment (HRP-430); CHECKLIST: Minutes Quality Improvement (HRP 431); and SOP: Monthly Evaluations of HRPP (HRP-061)

John D. Tupin, J.D.
Director, IRB Administration
Office of Research
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Davis, CA 95618-6153
Email: jdtupin@ucdavis.edu
Phone: (530) 304-1226

Reporting and Management of Concerns

Questions, concerns, complaints, allegations of undue influence, allegations or findings of non-compliance, or input regarding the HRPP 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. This Institution follows policies and procedures when suspending or terminating IRB approval of Human Research.[39] 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:

Simon Atkinson, Ph.D.
Vice Chancellor for Research and Institutional Official
Office of Research
One Shields Avenue Davis, CA 95616
Email: sjatkinson@ucdavis.edu

Approval and Revisions to the Plan

This HRPP has been approved by Vice Chancellor for Research and Institutional Official, Simon Atkinson. 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. 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.

[39] For program specifics, see SOP: Suspension or Termination of IRB Approval (HRP-026)