Position Description

Under the direction of the Associate Director of IRB Administration, use Institutional Review Board (IRB) knowledge and experience to apply complex federal, state and university regulations, policies and guidelines for human subject protection to conduct non-committee reviews and make determinations for expedited, exempt and not human subjects research (NHSR) studies; serve as an IRB member who, by designation of an IRB chair, conducts non-committee reviews.

Individuals in this position must continuously pursue professional development to advance and maintain current knowledge of human subject projects.

Campus Job Scope:

The IRB Administration unit provides education and training, administrative and record-keeping support, and conducts quality improvement audits for the Institutional Review Board (IRB). The IRB is a campus-wide committee established to protect the rights and welfare of human subjects in research studies conducted under the auspices of the University of California, Davis.

Department Specific Job Scope:

The IRB has the authority to approve, require modifications in, or disapprove all research activities that fall within its jurisdiction. The IRB independently approves or disapproves a research protocol based on whether or not human subjects are adequately protected.

The IRB, which reports to the Vice Chancellor for Research, is comprised of three committees: two clinical and one social and behavioral.

Positions Supervised:

None

Essential Responsibilities:

70% NONCOMMITTEE REVIEWS
-Work across the full range of IRB determinations to best characterize the appropriate level of review for projects submitted to the IRB;
-Independently conduct non-committee reviews by applying complex...
regulations, state law, UC Davis standard operating procedures (SOPs) and ethical standards to projects submitted to the IRB;
-Determine whether the criteria for approval are met by comparing the activities described in a research project to the criteria for approval;
-Provide guidance to investigators and research staff on appropriate revisions to enhance the approvability of submissions;
-Independently determine when a project does not satisfy requirements for non-committee review and prepare the submission for review by a fully convened committee;
-Attend committee meetings and provide review decisions including rationale for higher level review along with an opinion as to whether the project can be approved and/or any revisions are needed for approvability;
-Independently determine whether a project meets the definition of human subject research, meets the requirements for one or more of the exemption categories, or indicates UC Davis is not engaged in human subject research;
-Identify when external departments need to be notified about research activities;
-Identify when external consultations are needed to complete a review as required by regulations and SOPs, identify consultants and request their expertise;
-Document review activities in compliance with federal regulations, state law and institutional policies;
-Communicate determinations as required by regulations and in a manner understandable to individuals who are not familiar with the multifaceted review requirements;
-Collaborate with IRB staff to resolve novel and challenging issues with projects with consistency through active engagement and discussion.

20% INVESTIGATOR GUIDANCE AND ANALYTICAL SUPPORT
-Establish rapport with the research community and provide excellent customer service and guidance;
-Provide guidance to the research community to produce submissions of research that are approvable;
-Handle communication with investigators and research staff with respect for applicable standards and rules and also sensitivity to the impact of non-favorable IRB determinations and actions;
-Relate education and training needs to IRB Education Staff as manifested in review of projects and discussions with the research community;
-Provide support and training to IRB staff members, as applicable.

10% POLICY REVIEW/DEVELOPMENT
-Participate in the review and evaluation of proposed changes in federal regulations and how they impact local policies and SOPs;
-Review and revise SOPs to ensure they provide adequate human subject protections in a highly transactional, multi-step and branched decision-making environment, while maximizing efficiency;
-Assist with the development and implementation of mechanisms to ensure that University policy is consistent with federal regulations regarding the reporting of adverse events, possible violations of human subject protection procedures and the use of investigational products.
-Provide administrative and analytical support for the Director and Associate Director, including special projects.

Physical Demands:
-Work at a computer video display for extended periods of time;
-Lift and carry stacks of files/documents weighing up to 25 lbs.
-Filing requires bending and lifting files.

Work Environment:
- Restricted vacation during peak periods.
-Work flexible schedule, occasional varied lunch hour evenings/night, weekends and holidays, usually on short notice to meet operational needs.
- Must be able to travel to various UCD offices located on campus, at times
on short notice.
- Travel to/from Davis campus to attend meetings.
- Certification for IRB Professional or within one year of hire obtain Certification for IRB Professional (CIP) from the Council for Certification of IRB Professionals.
- UC Davis is a smoke and tobacco free campus effective January 1, 2014. Smoking, the use of smokeless tobacco products, and the use of unregulated nicotine products (e-cigarettes) will be strictly prohibited on any UC Davis owned or leased property, indoors and outdoors, including parking lots and residential space. Additional information and specifics regarding the policy are available at http://breathefree.ucdavis.edu/index.html.

Background Check: Yes

QUALIFICATIONS

Minimum Qualifications:

- Experience in human subject research protections, specifically biomedical research;
- Knowledge of NIH and other funding agency regulations for protections of human subjects as well as FDA regulations for use of investigational drugs, devices and biologics in clinical investigations;
- Ability to identify applicable law and policy and compare requirements thereof to proposed research in order to determine whether a project is approvable.
- Ability to identify revisions that could be made to a proposed project to enhance its approvability.
- Knowledge of the ethical principles related to human subject research and the ability to apply the principles to research proposals to determine whether the project is approvable;
- Demonstrated interpersonal skills to work effectively and diplomatically with a broad range of diverse individuals in a professional manner.
- Excellent written and oral communication skills to compose detailed, grammatically correct technical and comprehensive letters, memos and reports to investigators.
- Experience with word processing, spreadsheet, email, database, and presentation software programs.
- Time management and organizational skills to successfully prioritize and complete workload and activities that have immediate and sometimes conflicting deadlines.
- Familiarity with campus issues, policies, procedures, and practices in the area of human subjects.
- Extensive knowledge of Phases I-IV drug development processes, research with investigational devices and study design.
- Knowledge of anatomy and physiology and disease processes.
- Expertise in the area of the FDA approval process of investigational drugs and devices.
- Extensive knowledge of medical/research terminology.
- Skills to organize effective record keeping and information retrieval systems.

Preferred Qualifications for Selection:

SIGNATURES

______________________________________________  ______________________
Employee                                            Date
I have read this position description and understand its contents.

______________________________________________  ______________________
Supervisor                                          Date
This position description accurately describes the essential responsibilities assigned to this position.

______________________________________________

Department Head
This position description accurately describes the essential responsibilities assigned to this position.

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Date