Position Description

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Position Number: 02022597
UC Path Position #: 40223526
Dept: IRB ADMINISTRATION - 061811
Position: IRB RELIANCE ANALYST
Approved Payroll Title Code: 6230
Approved Payroll Title: RSCH CMPLNC ANL 3
Approved MSP Salary Grade:
Approved PSS Salary Grade: PSS22

POSITION DETAILS

Job Summary: Under general supervision of the Director of IRB Administration, work with a Non-Committee Reviewer to coordinate activities related to IRB reliances where external researchers or institutions rely on UC Davis IRB and where UC Davis relies on an external IRB for review of human subject research.

Campus Job Scope: The UC Davis IRB Administration unit administers and provides ethical and regulatory review of research involving human subjects conducted by UC Davis employees, students, faculty and agents and external researchers who rely on UC Davis for IRB services.

The UC Davis 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: Each IRB Committee 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.

Each designated reviewer has the authority to approve, require modifications in all research activities that fall within the UC Davis criteria for expedited review. Designated reviewers do not have the authority to disapprove human subject research activities.

Each IRB Member and Committee receive regulatory guidance and input from the IRB Director and reports to the Vice Chancellor for Research. There are four Committees: two biomedical (clinical), one social and behavioral, and one fast track.

Positions Supervised:
Essential Responsibilities:

50% COORDINATION OF RELIANCES & MULTI CENTER TRIALS work with non-committee reviewers to:
- Review complex agreements to determine compliance with federal regulations and UCOP policy;
- Independently identify when a signed agreement is required;
- Work with investigators, coordinators & sponsors to obtain signed agreements;
- For proposed external agreements, complete HRP 334 WORKSHEET Reliance Agreement to determine compliance with UCD requirements, & refer non-compliant agreements to Director;
- Maintain database of active reliance agreements in a manner such that the existence of the agreement, expiration dates & affected studies are easily accessible by IRB staff.

20% NONCOMMITTEE REVIEW OF RELIANCE SUBMISSIONS - 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, UCD standard operating procedures (SOPs) & 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 & research staff on appropriate revisions to enhance the approvability of submissions;
- Independently determine when a project does not satisfy requirements for non-committee review & prepare the submission for review by a fully convened committee;
- Attend committee meetings & provide review decisions including rationale for higher level review with an opinion as to whether the project can be approved & 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 & SOPs, identify consultants & request their expertise;
- Document review activities in compliance with federal regulations, state law and institutional policies;
- Communicate determinations as required by regulations & in a manner understandable to individuals who are not familiar with the multifaceted review requirements;
- Collaborate with IRB staff to resolve novel & challenging issues with projects with consistency through active engagement and discussion.

20% INVESTIGATOR GUIDANCE & SUPPORT
- Establish rapport with the research community & provide excellent customer service & 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 & rules & also sensitivity to the impact of non-favorable IRB determinations & actions;
- Relate education & training needs to IRB Education Staff as manifested in review of projects & discussions with the research community;
- Provide support & training to IRB staff members, as applicable.

10% POLICY REVIEW/DEVELOPMENT
- Participate in review & evaluation of proposed changes in federal regulations & how they impact local policies & SOPs;
- Review & revise SOPs to ensure adequate human subject protections in a highly transactional, multi-step & branched decision-making environment, while maximizing efficiency;
- Assist with the development & 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 & analytical support for the Director & Assoc Director, including special project.

Work at a computer video display for extended periods of time.

**Physical Demands:**

Lift and carry stacks of files/documents weighing up to 25 lbs.

Filing requires bending and lifting files.

Restricted vacation during peak periods.

Work occasional varied lunch hours, evenings and weekends to meet operational needs.

Travel to various UCD offices located on and off campus locations, at times on short notice, to attend meetings.

**Work Environment:**

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.

- Working 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.

- Working knowledge of ethical principles related to human subject research.

- Experience with word processing, spreadsheet, email, database, and presentation software programs.

- 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.

**Preferred Qualifications for Selection:**

- Knowledge of anatomy and physiology and disease processes.

- Expertise in 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.

**SIGNATURES**

______________________________________________
Employee

____________________
Date

I have read this position description and understand its contents.
Supervisor
This position description accurately describes the essential responsibilities assigned to this position.

Date

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

Date