

Position Summary

Employee Details

Employee First Name:

Employee Last Name:

Open Position

Employee ID:

Classification

Payroll Title:

ANALYST VII, SUPERVISOR

Payroll Title Code:

7272

Job Group:

B07

Overtime Eligible:
(FLSA)

Exempt

Employee Relations Unit:
(Bargaining Unit)

99

Representation:

Uncovered

Salary Grade:

7

Position Description

Position Number:
(Assigned when added to Library)

02012318

Dept:

IRB ADMINISTRATION - 061811

Position:

Associate Director

HEERA/Union Representation:

This position is not represented by a collective bargaining unit

IMMEDIATE SUPERVISOR

Supervisor Name:

Dan Redline

Supervisor Payroll Title:

Director, IRB

Supervisor Phone Number:

916-703-9157

POSITION DETAILS

Job Summary:

Reporting to the Director of the IRB Administration, the Associate Director is responsible for the oversight, administration, implementation, and management of policies and procedures related to human subject research conducted by UC Davis personnel. The Associate Director is also responsible for the supervision of approximately 10-14 FTE in support of three federally mandated human subject research review committees: two Clinical Institutional Review Boards, and one social/behavioral Institutional Review Board.

The Associate Director ensures program accountability for federally

mandated research review committees and maintains compliance with federal regulations and State laws applicable to research projects involving the participation of human subjects. Collaborates with the Director in developing and updating campus policies and procedures and implementing changes in federal, State, and University policies and regulations. Serves as a primary contact with federal agencies such as the Department of Health and Human Services-Office for Human Research Protections (HHS-OHRP) and the Food and Drug Administration (FDA). Primary administrative support for ad hoc auditing committees and Independent Safety Monitoring Boards.

Campus Job Scope:

Department Specific Job Scope:

Positions Supervised:
 Direct
 Analyst IV (2.0FTE)
 Analyst III (2.0FTE)
 Analyst II (2.0FTE)
 Analyst I (1.0FTE)
 __AIII (2.0 FTE)

Essential Responsibilities:

25% COMMITTEE MANAGEMENT & OVERSIGHT

- Work with Director to create a strategic plan for the development of electronic information systems to ensure program accountability for human research; and to develop and implement long range plans on enhancement of committee review.
- Prepare reports for the Director outlining statistical analyses of submissions to and actions of the OPRS supported committees by department and investigator.
- Prepare analysis on campus activity regarding new and ongoing research with human subjects.
- Work with the Director and in consultation with Campus Counsel, UC Counsel, and/or other named University legal representatives regarding lawsuits, pending legal action or inquiries related to human subject research.
- Report human subject legal actions to the appropriate IRBs and collaborate with legal counsel to ensure timely responses to requests for information.
- Manage retrieval and redaction of requested documents.

25% SUPERVISION & COMMITTEE SUPPORT

- Advise Director and IRB chairs regarding committee membership as it relates to federal requirements and University policy for committee breadth and expertise.
- Provide administrative support for the IRB Coordinating Committee. Attend committee and board meetings and oversees written communication to investigators ensuring that all concerns and technical questions of the Boards are documented.
- Oversee staff and preparation of material for committee and board meetings to ensure relevant documents are ready for committee review.
- Oversee the development of meeting agendas and manage confidential committee and board records.
- Take appropriate and necessary action to ensure operations are effectively managed relative to workload.
- Work with IRB Analysts, Coordinators and staff to resolve specific problems/issues not within their scope, experience or knowledge.
- Prepare statistical reports as needed.

20% POLICY DEVELOPMENT AND REVIEW

- Develop, implement, and update policies and procedures to provide guidance to staff for sufficient record keeping ensuring program

accountability and compliance with federal regulations and guidelines, State law, and university policies, in order to maintain federal assurances for the local review of human subject research.

- Develop and implement educational programs in human subject research for staff, IRB members and researchers.

- Develop policies and procedures for the administration of exemption categories for human subject research to ensure compliance with federal regulations with reports to IRBs regarding such actions as required.

- In collaboration with the Director develop a multi-level education program, promoting awareness, communication and understanding of the human subjects' research review process.

20% INVESTIGATOR GUIDANCE

- Resolve problems and discrepancies identified by the committee chairs and initiate resolutions.

- Provide advice and counsel to the university community.

- Act as primary resource for investigators and research staff regarding federal and state regulations and University policies and procedures governing human subject research.

- Provide assistance to investigators and the Investigational Pharmacy regarding emergency use of drugs, biologics and devices with human subjects to ensure compliance with applicable regulations.

10% SPECIAL PROJECTS

- Perform additional writing and administrative duties assigned by the Director, Assistant Vice Chancellor or Vice Chancellor.

- Represent the University at local and national meetings and conferences regarding federal regulations and policies governing human subjects in research.

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

Physical Demands:

- Lifts and carries stacks of files/documents weighing up to 25 lbs. Filing requires bending and lifting files.

- Work in an office environment with frequent interruptions and competing priorities.

- Restricted vacation during peak periods.

- Work occasional varied lunch hours.

- Must be able to travel to various UCD offices located on campus, at times on short notice.

Work Environment:

- Within one year of hire obtain certification for IRB Professional or Certification for ORB 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.

Background Check Required:

Yes

This position is a critical position and subject to a background check. Employment is contingent upon successful completion of background investigation

including criminal history and identity checks.

QUALIFICATIONS

Experience interpreting federal, state, and local regulations and policies governing human subject research including: the HHS-OHRP regulations, FDA regulations for the use of investigational drugs, biologics and devices.

Minimum of 3 to 5 years supervisory experience directing, guiding, training and evaluating the efforts of support staff.

Working knowledge of operational requirements related to the management and implementation of faculty committee review processes.

Leadership experience to effectively collaborate with various administrative departments and committees.

Excellent written and oral communication skills to compose detailed, grammatically correct technical and comprehensive letters, memos and reports to investigators and to produce accurate committee meeting minutes describing complicated and involved committee discussions.

Minimum Qualifications:

Working knowledge of laws, policies and regulations governing human research and experimentation such as: biosafety, the use of radiation and /or the review requirements of the National Cancer Institute, etc.

Strategic planning and development experience to envision and articulate future direction, develop and enhance systems that serve as effective tools for the staff and review committees, and develop policies and procedures that are comprehensive and practical.

Critical thinking and advanced writing skills to understand and formulate both graphical and narrative reports outlining the activity of the IRB and the relationship between other units or measurements.

Time management and organizational skills to successfully prioritize and complete workload and activities that have immediate and sometimes conflicting deadlines.

Minimum of 3-5 years of experience (or equivalent education and experience) or increasing responsibility, including at least 2 years in a management position in support of research compliance.

Preferred Qualifications:

Knowledge of California law on human experimentation, and university policy and additional regulatory knowledge for human research, such as: biosafety, the use of radiation, the review requirements of the National Cancer Institute, etc.

SIGNATURES

Employee

I have read this position description and understand its contents.

Date

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