Position Description

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<td>Position Number:</td>
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<td>Dept:</td>
<td>IRB ADMINISTRATION - 061811</td>
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<td>Position:</td>
<td>Research Analyst</td>
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**POSITION DETAILS**

**Job Summary:** Independently pre-review research proposals and make requests for necessary, additional information from researchers prior to review; evaluate actions taken by investigators in response to reviewers' requests. Review and Edit research proposals and amendments to existing projects. Perform detailed analyses of full committee, expedited, and modification applications. Act as a resource for staff and committee reviewers and faculty members engaged in research. Assist the IRB with audits, ensuring completeness of compliance documentation for approved protocols. Lead inquiries into expired or out-of-status research studies, assess such studies, and recommend a final disposition. Manage documentation of IRB reliance documentation.

**Campus Job Scope:**

**Department Specific Job Scope:**

**Positions Supervised:**

75% PROTOCOL ANALYSIS AND MANAGEMENT
- Independently perform pre-analysis of research proposals; identify problems, contact investigators and request additions/corrections (to proposal, informed consent forms, etc.); secure additional information; bring projects to completeness for IRB review.
- Perform analyses of full committee, expedited, and modification submissions to ensure consistency with federal and state laws and regulations, and university policies as they pertain to the protection of Human Subjects.
- Make informed, accurate, and verifiable determinations for projects that are not "Human Research" studies, or eligible for exemption (under categories defined by federal regulations) and UC Davis SOPs.
- Produce standard reports (adverse events, expirations, monthly expedited/exempt determinations, progress, and restricted PIs)
- Manage researcher certifications and conflict of interest disclosures relevant to IRB functions.
- Prospectively counsel investigators about submission requirements (e.g. composition of detailed medical information consent forms).
- Use federal, state and local regulations, policies and guidelines governing human subject to determine the most expeditious, allowable review process for projects; assist investigators with the preparation of IRB...
Essential Responsibilities:

- Identify, review, and approve documents where codicils were imposed/approved by the IRB.
- Prepare written communications (electronic and/or hard-copy) to distribute to researchers that include technical and scientific terminology.
- Issue and distribute project documents such as notifications of impending expiration of approvals; minimize lapses of approval for active research.
- Identify and archive reports of new information associated with specific research projects.
- Identify expired and closed studies and coordinate record-keeping and storage of archived studies. Oversee migration of paper records to electronic records series.
- Contribute to management of IRB reliances; update new studies with NCI/CIRB, Quorum, NeuroNEXT, UConn, Federal Agreements with NAVY (NAMRU-6 umbrella) Air Force, ARMY, SHRINERS Hospital of Northern California, CHOP, NOIA, Univ. of Nevada-Reno, etc.
- Maintain a database of studies in which external institutions or investigators rely on the UC Davis IRB; ensure appropriate documentation is entered into the electronic protocol management system; provide information to other departments that rely on the system for reporting and billing purposes;
- Maintain a database of studies in which UC Davis relies on external institutions for IRB oversight; ensure all required reliance forms are reviewed, completed, signed, and entered in IRBNet.

15% ADMINISTRATIVE SUPPORT

- Assist in prioritizing IRB work; accommodate urgent requests from researchers.
- Manage research personnel changes in the electronic protocol management system.
- Communicate and interact with the IRB Chairs, Vice Chairs, IRB members, and serve as backup to the Committee Analysts.
- Establish, update and/or maintain accurate hard and/or electronic filing system for large volume of research protocols/studies ensuring confidentiality of all records.
- Attend meetings with investigators and research staff to address issues, concerns, and procedural modifications in order to comply with federal, state and local regulations governing research with human subjects.
- Communicate with excellent oral and written skills; interact with diverse groups of individuals; secure and/or provide information, clarify situations, resolve problems, and ensure cooperation and confidentiality among individuals.

10% SPECIAL TRAINING/PROJECTS

- Assist with the implementation, effective use, and maintenance of the electronic protocol management system.
- Provide administrative support on special projects and assignments as identified by designate staff.

Physical Demands:

- Sit at a computer/workstation for extended periods of time working with a computer/mouse, (6-8 hrs. per day). Stare at display monitors for extended periods of time.
- Move/manipulate supplies and equipment of various weights (up to 25 lbs.) using maneuver boxes of paper or files weighing up to 20 lbs (hand/file cart cart available).

Work Environment:

- Work with constant interruptions, work at a computer for extended periods of time.
- Provide own transportation to off-site events and meetings.
- Work evenings and weekends and/or holidays to meet business needs. 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: Yes
### QUALIFICATIONS

#### Minimum Qualifications:
- Experience working with federal regulations, state statutes and institutional practices regarding research involving human subjects.
- Knowledge of the IRB application and submission process, renewal procedures, and submission of reports.
- Analytical skills to anticipate/identify problems, perform research, and develop creative solutions.
- Experience presenting complex technical and legal materials.
- Experience composing and editing technically complex documents and correspondence for accuracy, consistency of format, spelling and grammar, language and professional appearance and style.
- Experience using advanced features of word processing, spreadsheets, email, presentation and web-based software specifically working with relational databases for information organization, exchange, storage, and retrieval of human subjects records.
- Experience managing/organizing details of meetings including taking and disseminating concise minutes/notes.
- Experience establishing and maintaining filing systems (electronic and paper).

#### Preferred Qualifications for Selection:
- Knowledge of medical terminology.
- Experience working with sensitive and confidential information.
- Experience working in a higher education environment.
- Interpersonal oral and written communications skills.
- Organizational and time management skills.

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### SIGNATURES

**Employee**
I have read this position description and understand its contents.

**Supervisor**
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.