

**JOB DESCRIPTION**

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| **Employee Name** |  | **PS Dept & Program #/Name** | 6285-62851 Research and Sponsored Programs/Research Compliance |
| **Current Job Title** | IRB/FCOI Administrator | **Current Working Title** | IRB/FCOI Administrator |
| **Supervisor Name** | Cathryn Lucas | **Supervisor Title** | Associate Director, Research Compliance |
| **Work Hours per Week** | 40 | **Position type** | Full-time |

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| **Position Summary** |
| Lead regulatory and administrative oversight of Chapman University’s Institutional Review Board (IRB) and Financial Conflict of Interest Oversight Committee (FCOI) daily and long-range activities to ensure efficient and effective research compliance. Provide independent analysis of protocols and records to ensure completeness and compliance with appropriate federal and state regulations and university policy, including OHRP, FDA, PHS, and NSF. Advise faculty, students, ORSPA leadership and senior campus administration of critical and/or sensitive issues related to protection of human research subjects. Participate in the development and implementation of proposed or revised Chapman policies and procedures to maintain regulatory standing and integrity of the Chapman University research program. Provide administrative and committee support to the IRB and FCOI Chairs and Committee members. Assess educational needs of the constituency (faculty, staff and student researchers) and committee members and provide ongoing education and training. Perform other related duties assigned. |

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| **Duties and Responsibilities Assigned to the Position.**  *List the duties in descending order of importance starting with the most essential duties. To add a row, highlight entire row, click on Table in the menu bar, then select insert rows above or below.* | | | | |
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| **% of Time** | **Frequency**  **(D, W, M, A)** | **Duties No.** | **Essential**  **(Yes/No)** | **Detailed Duties** |
| 30% |  | I. | Yes | **Unit Management and Planning**   * Serve as key member of the Office of Research and Sponsored Programs Administration (ORSPA) Compliance team. * Lead Human Subjects Research and Financial Conflict of Interest Oversight programs including managing daily activities. * Work with Director to plan and implement short-term and long-range planning on research compliance related to human and animal research. * Make strategic recommendations on research protections operations and management and work with Director, Associate Director and campus administration to integrate recommendations. * Conduct continuous assessments of the IRB & FCOI administrative offices’ ability to maintain high-quality, value-added services in response to the workload volume and complexity of research activities; implement efficiencies including new and creative approaches where necessary to address increases in workload volume or complexity. * Develop, coordinate and implement Chapman University’s Institutional Review Board (IRB) and Financial Conflict of Interest Oversight (FCOI) activities including but not limited to standard policies and procedures (SOPs), manuals/guidelines and website communication and instructions affecting the research committees, it’s appointed Chairs and voting board members, and ancillary staff. * Serve as an expert resource for the unit, coach staff on problem solving and decision making, and facilitate the implementation of effective and creative solutions. * Provide administrative and committee support to IRB/FCOI Chairs and committees. Assess educational needs of the constituency (faculty, staff and student researchers) and committee members and provide ongoing education and training. * Assist Director and Associate Director with training, orientation, development and assessment of office personnel. |
| 50% |  | II. | Yes | **Institutional Review Board and Financial Conflict of Interest Oversight Committee Administration**   * Serve as primary administrator within ORSPA responsible for the overall administration and support of the IRB and FCOI, and alternate member when a quorum is not present. * Provide independent analysis and ethical and regulatory review of exempt and expedited research protocols, and modification and continuation requests when applicable; * Provide assistance in pre-reviewing all expedited, full and ad-hoc protocol applications and supporting documentation to ensure completeness, regulatory and ethical compliance with appropriate regulations, guidelines and institutional policies and risk to the subject and university. * Advise faculty, ORSPA management, and senior academic and campus administration of critical and/or sensitive issues related to human research and human subject protections, and conflict of interest. * Communicate IRB and FCOI concerns and issues to ORSPA. * Advise ORSPA management, IRB and FCOI Chairs and members, and other campus officials of potential impacts of new or proposed regulatory changes, policies or procedures. * Assist Director and Associate Director with the development and implementation of proposed or revised Chapman policies and procedures to maintain regulatory standing and integrity of the Chapman University research program. |
| 15% |  | III. | Yes | **Internal and External Relations**   * Establish and maintain effective, productive and collaborative working relationships and communications with other Chapman University research oversight offices and regulatory compliance committees and groups outside of the Office of Research and Sponsored Programs Administration ( e.g. Radiation Safety, Institutional Biosafety Committee, Laboratory Safety Officer, Environmental Health and Safety, Risk Management, etc.). * Facilitate and promote effective, productive and collaborative working relations and communications within and between the IRB and FCOI administrative unit, with the IRB and FCOI chairs and members, with staff from other colleges, institutes and departments at Chapman University. * As a representative of ORSPA, serve on campus-wide committees as needed to address IRB and FCOI research issues and work with appropriate academic and non-academic units to implement committee recommendations and outcomes. * Represent Chapman University at meetings and teleconferences, and attend meetings and conferences of research administration and research societies and associations. |
| 5% |  |  |  | **Perform other related duties as assigned.** |

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| **Qualifications for the Position: Experience, Skills, Knowledge, and Abilities.**  *Indicate the importance of each by designating it as required (R), desired (D), or will train (WT). In addition, for each item, indicate the corresponding essential function number from above.* | | |
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| **Duties No.** | **Importance**  **(R, D, WT)** | **Skills, Knowledge and Abilities** |
| All | R | Bachelor’s degree with minimum of five years of related experience or equivalent combination of education and experience; |
| All | D | Master’s degree. |
| All  All | R  R | Experience with social science and behavioral human research;  Experience with conflict of interest oversight; |
| All | D | Experience with pre-clinical, clinical and biomedical research |
| All | D | Certified IRB Professional (CIP) Certification |
| All  All  All | R  R  R | Breadth of knowledge regarding state and federal regulations relating to human subjects use in research, with experience in interpreting guidelines, policies and federal/state guidelines/regulations.  Breadth of knowledge regarding state and federal regulations relating to conflict of interest in research with experience in interpreting guidelines, policies, and federal/state guidelines/regulations.  Experience and knowledge of federal oversight committees related to human research, human, and human subjects protection. |
| All  All | R  R | Demonstrated time management skills.  Demonstrated written communication skills to prepare clear, concise, and grammatically correct business and technical correspondence. |
| All  All | R  R | Strong verbal communication and interpersonal skills to maintain collaborative working relationships with University constituency, regulators, investigators, etc.  Commitment to high ethical standards in research. |
| All  All  All  All  All | R  R  R  R  R | Demonstrated ability to use independent judgment in interpreting and applying policies and procedures and prioritize workload to meet turnaround time requirements.  Experience in handling complex situations and confidential material.  Experience in research and/or regulatory environment.  Experience with computerized databases, the Microsoft Office Suite and Adobe Professional is essential.  Strong quantitative skills. |
| All | R | Technical skills to learn and use enterprise systems |
| All | R | Ability to demonstrate tact and diplomacy and maintain confidentiality |
| All | R | Strong analytical skills and detailed oriented. |
| All | R | Proven ability to use sound judgment. |
| All | R | Strong knowledge of the best practices for IRB and FCOI standard operating principles. |

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| **Special Conditions of Employment for the Position.**  *Chapman University requires that all new hires and existing employees moving into a new position have completed a successful background check. If this position requires additional checks or licenses, please check the appropriate box on the left.* | | | | | |
|  | **Credit check**  Positions that are managerial; involve regular access to confidential or proprietary information; have signatory authorization on a bank or credit card info with SSN and DOB; access to cash totaling ten thousand dollars or more; or can enter into financial transactions on behalf of the company |  | **On-call rotation duties**  Positions that require employee to be available during on-call shifts. |  | **Some evening and weekend work hours** |
|  | **DMV check**  Positions that drive 500 miles or more per year in personal, Chapman-owned or rental transportation for business purpose. Or positions that involve driving a university-owned vehicle or electric cart. |  | **Different work shifts**  Standard hours of the university are 8:00 a.m. to 5:00 p.m., Monday thru Friday. **Please list work schedule if different: 9 am to 6pm** |  | **Grant funded.**  Continued employment is dependent on continuing grant funding after specific end date. |
|  | **Occupational license or certification**  Positions that require licenses for the job, such as nursing. **Please list: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** |  |  |  | **Others, please list:**  **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** |

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| **Type of Supervision Required for the Position.**  (Choose one; see detailed definitions of categories in guideline section) | | | | | | | | | |
|  | Close Supervision |  | Supervision |  | General Supervision |  | Direction |  | General Direction |
|  | Assigned duties based on specified procedures |  | Assigned routine duties within established policies and procedures |  | Develop own procedures to perform a variety of duties, or complex duties within established policies. |  | Develop departmental procedures to attain specific goals within established policies. Typically for directors and managers. |  | Formulate university-wide policies and goals, and establish procedures. Typically for senior staff. |
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| **Positions that are Supervised by this Position**  IRB Graduate Assistant and Ancillary staff | | | | | | | | | |

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| To comply with the provisions of the Americans with Disabilities Act, specify the physical, mental, and environmental conditions of the essential functions of the job by using these codes to complete the sections below:  "**C**" = constantly, 6-8 hours/day; "**F**" = frequently, 3-6 hours/day; "**O**" = occasionally, up to 3 hours/day; and "**N**" = never. | |
| **Physical requirements of the Job**: | **Mental Requirements of the Job**: |
| Bending [neck]  Bending [waist]  Climbing  Crawling  Kneeling  Pushing/Pulling  Sitting  Squatting  Standing  Twisting [neck]  Twisting [waist]  Walking  Handling Objects  Using fine finger movements [manual dexterity]  Reaching above/below shoulder [circle]  Using foot controls [repetitive foot movement]  Other  Must carry/lift loads of: [also select carry &/or lift]  Up to 25 lbs  carry /  lift  25 - 50 lbs  carry /  lift  over 50 lbs  carry /  lift | Reading & Comprehending  Writing  Performing Calculations  Communicating Orally  Reasoning & Analyzing  Other  **Environmental Working Conditions**:  Is exposed to excessive noise  Is around moving machinery/equipment  Is exposed to variation in temperature &/or humidity  Is exposed to dust, fumes, gases, chemicals, radiation or microwaves [circle]  Is exposed to bio-hazards such as: blood borne pathogens, sewage, hospital waste, etc.  Drives motorized equipment  Walks on uneven ground  Works in confined quarters  Works in an elevated work site  Is exposed to building construction  Contact with water/liquids  Uses special visual or auditory protective  Other |

I understand that I am responsible for adhering to the University Injury and Illness Prevention Program (SB 198 Guidelines) in performing the essential functions assigned on this job description. I understand that I am responsible for complying with and incorporating University safety policies and procedures into my job.

           

Employee Signature & Date Supervisor Signature & Date Department Head Signature & Date

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| **or Human Resources Use Only:** | | | | | |
| New or Updated: |  | Approved Job Title: |  | Position Control No: |  |
| Approval Date: |  | Approved By: |  | Job Category: |  |
|  |  |  |  | FLSA Exemption: |  |