Position Description

VCOM
Edward Via College of Osteopathic Medicine
VIRGINIA • CAROLINAS AUBURN • LOUISIANA

Job Title: IRB Administrator		
Department: Research	Date: May 2022	
FLSA: Exempt	Work Location: Virginia Campus	
Employee Category: Administrative Staff	Work Schedule: M-F, 8a – 5p	
Reports to: Administrative Director for	Percent Employment: 100%	
Research		
Direct Reports: N/A		

I. Job Summary:

This person will serve as the Institutional Review Board Administrator and report to the Administrative Director for Research. This position is responsible for managing the IRBNet portal, reviewing complex educational, clinical and biomedical research protocol documents submitted to the Institutional Review Board (IRB) to ensure that IRB members have all the requisite information to review human subject research, enabling the IRB board members, including the IRB Chairs, to perform their review tasks by providing the necessary documents and education. This position will also act as intercessory between the boards, researchers and other involved institutions, and performing other related duties as assigned.

II. Job Duties:

- Reviews all applications to the IRB, including informed consent, to determine
 completeness and consistency with federal guidelines and institutional requirements;
 determines whether research proposed projects are exempt from further review
 and/or determine level of review required according to federal regulations and
 institutional policy; assign designated reviewers.
- Verifies that appropriate documentation is obtained before final IRB approval is
 issued, including ensuring presence of education requirements for all research team
 members, required documentation for all external performance sites and required
 documentation for investigational drug or device numbers.
- 3. Prepares items for review by IRB Chair and Co-Chairs, obtaining any needed information and material from investigators.
- 4. Manages IRBNet portal, retrieves reports, troubleshoots user issues.
- 5. Determines and compiles meeting agendas to meet distribution deadline, disseminates meeting agendas and packets, coordinates and attends meetings.
- 6. Records in meeting minutes the decision-making process of the IRB in official minutes, capturing and documenting summarization of any controverted issues and their resolution, clearness about the actions of the IRB and exactly what the IRB approved and other regulatory requirements.
- 7. Provides guidance and training to investigators and research team members regarding procedural requirements for submission to the IRB.
- 8. Ensures that protocols undergo continuing review within current approval period and issues expiration letters for those whose approval lapses.
- 9. Communicates results of IRB reviews to Principal Investigator and drafts other correspondence as needed in an organized, clear, concise manner.

- 10. Assists with revisions and implementation of IRB forms, Policies and Procedures, as well as other resources for the research community.
- 11. Gathers information and material in response to inquiries and responds to requests for information regarding IRB review.
- 12. Assists in identifying areas of focus for education topics for the college community on IRB policies and procedures.
- 13. Maintains and audits IRB records and files.
- 14. Interacts positively with research participants, and the research community, and appropriately addresses issues, including complaints.
- 15. Maintains strict confidentiality.
- 16. Maintains VCOM Federalwide Assurance and IRB registration; Maintains and updates the IRB member information including rosters, CVs and training records; trains new IRB members.
- 17. Prepares IRB annual report, maintains office filing system and databases, assists in arranging accommodations for site visitors and guest speakers.
- 18. Identifies program problems, determines appropriate action and makes recommendations for problem resolution; assists in the implementation of program enhancements and service improvements
- 19. Defines reporting and information needs and coordinates systems modifications to continually refine computerized databases.
- 20. Performs other duties as assigned.

III. Required Qualifications:

Education: Requires a bachelor's degree or suitable equivalent academic qualification, plus a minimum of five years of relevant professional experience. Preference given to experience in human subjects research administration.

Licensure or certification: IRB certification within the first week of appointment is required.

Experience:

- Regulatory compliance or client education, or some combination of the two, with the required skill sets as described.
- Knowledge of human subjects regulatory compliance.
- Exceptional computer skills including word processing, database and presentation skills.
- At least one year of experience in an Institutional Review Board office in addition to the appropriate skill sets of this position as described preferred.

Other skills important to this position:

- Requires ability to work with IRB committees, manage complex administrative tasks, and set priorities under deadline pressure, including the ability to communicate well.
- Strong team player
- Commitment to college values
- Basic computer proficiency in Microsoft Office programs
- Certified IRB Professional (CIP®) credential preferred

Preference will be given for compliance/IRB experience and familiarity with IRBNet.

The successful candidate will be subject to a criminal history background check.

Regular, reliable, or predictable attendance is an essential function of the job.

IV. **Working Conditions and Efforts:** The physical demands and work environment characteristics described here are representative of those that must be met by an employee to successfully perform the essential functions of this job. Reasonable accommodations may be made to enable individuals with disabilities to perform the essential functions.

Physical demands: While performing the duties of this job, the employee is occasionally required to sit; use hands and vision for office equipment such as computers; talk or hear; moderate telephone usage.

Work environment: Office environment. Outside travel required 10% of time. The noise level in the work environment is usually minimal.

This position is classified as an exempt position because it requires that the candidate/employee exercise independent judgment and discretion regarding matters of significance.

Employment with VCOM is "at-will". This means employment is for an indefinite period of time and it is subject to termination by the employee or by VCOM, with or without cause, with or without notice, and at any time. Nothing in this position description or any other policy of VCOM shall be interpreted to be in conflict with or to eliminate or modify in any way, the "at-will" employment status of VCOM employees.

V. VCOM Core Values: The employee is expected to adhere to all VCOM polices. As the environment is a professional college, VCOM faculty/ staff are expected to dress and behave in a professional manner at work. VCOM faculty / staff are expected as VCOM employees, to be a person who obeys all laws and professional expectations of an upstanding citizen of the community. VCOM expects all employees to maintain a positive attitude in all working relationships with all VCOM departments, employees, medical students, prospective medical students, interns, and residents and to treat all others engaged in the duties of the employment, with mutual respect.

I am notified that the College is an equal opportunity employer and does not discriminate on the basis of age, sex, sexual orientation, ethnicity, religion, or disability.

I have been made aware of the College's most recent campus safety report, the location of the college policies and procedures document, and the appropriate handbook for my position. I recognize my responsibility to be aware of the policies and procedures and I am in agreement to follow the policies and procedures as written.

I have read and understand this explanation and job description. I also understand that the job duties and description or the existence of the need for the position may be changed at any time as required by the College where growth of the institution or change in direction of the institution may change the duties of my department or the need for the position.

Employee Signature:	Date:
Approvals:	
Immediate Supervisor:	Date:
Division Officer:	Date:
President:	Date: