



Copernicus Group IRB is a dynamic, fast-growing organization whose main goal is the protection of research subjects. We believe the success and potential of CGIRB has no limit and is driven by the employees and their efforts. We're looking for dynamic, self-motivated and hard working people to join our mission.

Our corporate mission is “to protect the rights and welfare of human subjects involved in clinical research trials by providing the highest quality ethical review available in the Industry.”

CGIRB carries out this Mission statement by strict adherence to the federal regulations governing clinical research, a stringent selection process of qualified and knowledgeable IRB members, our dedication to the training and continuing education of both our IRB members and support staff and our commitment to continual process evaluation and improvement as we strive to protect subjects involved in clinical trials. Copernicus Group IRB offers competitive benefits and compensation and is an Equal Opportunity Employer.

We currently have the following position available: [Associate Project Administrator I](#)

Essential Duties:

- Ø Maintain and promote positive working relationships with clients by providing timely and professional service to their needs within the scope of company mission and accompanying regulations.
- Ø Ensure 100% accuracy in all work performed, including investigator packets and all associated regulatory documents, and understand the importance of accurate information as it pertains to strict confidentiality standards of the company.
- Ø Act as the liaison between sites, CRO's, Principal Investigators with study related information.
- Ø Review new Principal Investigator Submissions and ensure they are complete and accurate according to internal standards. Monitor licenses and credentials of new investigators listed on the FDA Form 1572, identifying issues identified and notifying the Quality Improvement Coordinator, as well as the Director/Asst. Director of Project Management.
- Ø Act as a back up to Document Specialists when needed, accurately processing all documents and ensuring the “24 hour service standard” for new investigator packets, as well as the “72 hour service standard” is met.
- Ø Work as a team with colleagues to ensure all project team efforts are completed according to company policies and procedures and all departmental goals and objectives are achieved.
- Ø Enter new Principal Investigators and new study information into Access Data Base.
- Ø Review and process expeditable subject recruitment materials, revisions to form FDA 1572 and revisions to information and subject consent form.
- Ø Generate approvals and letters, as needed.
- Ø Review SAE and IND Safety Reports ensuring they are assessed in preparation for board review and accurately enter information into Access Data Base.
- Ø Provide excellent customer service to all staff and/or board members for project related inquiries and/or needs.
- Ø Recommend modifications to proposed advertisements, as appropriate, to ensure clarity, subject safety, and compliance with regulations.
- Ø Coordinate changes in studies, documents, and/or contact info entering changes accurately into access data base and communicating changes to necessary departments in the company.
- Ø Review any information received from clients and follow-up in order to ensure data capture.
- Ø Demonstrate competency in processing all types of submissions with minimal errors.

Qualifications for this position include, but are not limited to, a Bachelor's degree or equivalent experience plus minimum of 6 months to one year experience in clinical trial setting, review board, CRO, and/or pharmaceutical industry. Knowledge of FDA regulations as they relate to research is preferred, but our ideal candidate must have advanced knowledge of Microsoft Word, Excel, Outlook and Access. The ability to work independently, utilize discretionary judgment, possess strong verbal and written communication skills, and be a pro-active team player is required. Experience working with Medical terminology is preferred; however, great attention to detail and strong written skills are a must!

If you meet the requirements listed and are seeking an opportunity, please send your cover letter with resume, including salary expectations, to the ATTN: HR at hr@cgirb.com or via fax at 919-465-4308. If CGIRB sees a match between your qualifications and current hiring needs, we will contact you.

