

OOCE Job Posting

Department: OOCE Corporate Clinical

Reports To: Clinical Director and Foundation Board

Title: Certified Clinical Research Coordinator **Hours:** Hours will be based on coverage needs but generally Monday through Friday, 40 hours per week.

General Description:

- Position is responsible for the Initiation and management of clinical research activity in concert with OOCE physicians.
- Research activity may be retrospective, prospective, physician or industry initiated, or device or pharmaceutical in nature.
- Assist with manuscript preparation and submission to peer reviewed journals.
- Assist in the development of podium or poster presentation.
- Follow ethical and legal research guidelines according to the Declaration of Helsinki, US FDA Regulations for pre, post and investigator research, and the ICH Tripartite Guideline on Clinical Safety Data Management.

Duties and Responsibilities:

- Manage clinical research studies conducted by principal investigator(s). Management will include but is not limited to; collection, compilation, documentation and analysis of clinical research data.
- Development of study protocols including budgetary aspects.
- Coordinate the development of forms, questionnaires and the application of research techniques.
- Review journals, abstracts and scientific literature to keep abreast of new developments and to obtain information regarding previous studies to aid in the planning of new studies.
- Evaluate and interpret collected clinical data in conjunction with principal investigator(s) as appropriate.
- Prepare poster or podium presentations, written reports, preparation of manuscripts for publication. Such preparation will include setting forth the study design, literature review, results, discussion and appropriate recommendations or conclusions.
- Confer with principal investigator(s) to assist in developing plans for research projects and to discuss the interpretation of results.

- Facilitates steps to gain IRB approval or waiver. Implement study protocol. Assures case report forms and adverse event forms reporting. Assure compliance with IRB, FDA and other reporting requirements.
- Provide guidance to appropriate internal and external personnel involved in planning, implementation and evaluation of clinical studies.

Education/Certification or Experience Required:

- A minimum of a Bachelor's Degree in Life Science, Biology, Physiology or Nursing degree program plus two years of healthcare experience.
- Experience in orthopedics, IDE or pharmaceutical research highly desirable.
- Candidates must additionally possess two to five years of recent clinical research experience to include study protocol development, IRB processes, and manuscript preparation.
- Certification CRC or CTI from the Association of Clinical Research Professionals or CCRP from the Society of Clinical Research Associates required.
- A command of the English language and various formatting techniques such as MLA.

To apply please submit your resume to Amy Kimmel in Human Resources via email at akimmel@ohio-ortho.com or through fax at 614-827-8653

Posting Dates: March 24 - 26, 2009

An Equal Opportunity Employer

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