JOURNAL OF CLINICAL RESEARCH BEST PRACTICES

Vol. 5, No. 4, April 2009 "Can You Handle the Truth?"

Study Coordinator Wanted

A challenging position is open for a qualified study coordinator.

Do not miss this opportunity!

Applicants must possess the following personal attributes: accurate, active, adaptable, agreeable, alert, analytical, articulate, assertive, attentive, aware, broadminded, businesslike, calm, capable, careful, cheerful, clear-thinking, compassionate, confident, conscientious, considerate, consistent, constructive, cooperative, creative, credulous, curious, decisive, dedicated, deliberate, dependable, desperate, detail-oriented, determined, diligent, discreet, efficient, empathetic, energetic, ethical, fair-minded, flexible, focused, foolhardy, friendly, good-natured, hallucinatory, hard-working, healthy, helpful, honest, illusory, imaginative, independent, industrious, intelligent, intuitive, inventive, kind, knowledgeable, level-headed, likable, logical, meticulous, motivated, observant, open-minded, optimistic, organized, outgoing, patient, perseverant, personable, persuasive, pleasant, poised, polite, practical, precise, principled, productive, professional, proficient, prudent, punctual, rational, realistic, reflective, reliable, resilient, resourceful, respectful, responsible, responsive, self-directed, sensible, sensitive, serious, sincere, sociable, stable, supportive, sympathetic, tactful, team player, tenacious, thorough, thoughtful, tolerant, trustworthy, unaffected, understanding, unhinged, versatile, warm, well-connected, and well-informed. In addition, applicants must be a good listener, a problem solver, a quick learner, able to multitask (preferably in two or more places at once), accepting of constructive criticism, concerned for others, a critical thinker, able to handle conflicts well, hold self to high standards, negotiate effectively, take initiative, and possess integrity, a good sense of humor, common sense, fluency in local Unanga language, and excellent communication, interpersonal and mind-reading skills.

Applicants must be experienced in clinical research, with expert knowledge of good clinical practice, including current governmental regulations and guidances, International Conference on Harmonization (ICH) guidelines, and the Shen-nung Pen Ts'ao Ching.

Applicants must have physician, nurse and/or allied health professional credentials. Required certifications include CCRC (Certified Clinical Research Coordinator), CCRP (Certified Clinical Research Professional), RAC (Regulatory Affairs Certification), and SPC (Shamanic Practitioner Certification). In addition, CPR, first aid, phlebotomy, hazardous materials handling, universal precautions, and site SOP certifications are required.

Applicants must have experience conducting clinical trials in the therapeutic areas of cardiology, dermatology, endocrinology, gastroenterology, gynecology, hematology, hepatology, immunology, infectious disease, neurology, oncology, ophthalmology, orthopedics, psychiatry, pulmonology, reanimation, rheumatology and urology.

Applicants must be proficient in the following responsibilities:

- Ensure the safety and welfare of study subjects.
- Conduct clinical studies according to governmental regulations and guidelines, International Conference on Harmonization (ICH) regulations, GCP guidelines, and site SOPs and other policies and procedures.
- Read, understand and implement protocols, informed consent forms, investigator's brochures, and other study instructions.
- Prepare IRB submission materials.

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- Attend investigator meetings.
- Document special requirements for the study, e.g., manner of measuring blood pressure or entering data in source documents.
- Train other site personnel and other medical staff in understanding and implementing protocols.
- Develop and implement plan to recruit subjects for the study.
- Materialize subjects from air at sea level with high humidity.
- Screen and enroll subjects according the protocol's eligibility criteria.
- Obtain informed consent from study subjects, with participation of Principal Investigator. Ensure that the original signed and dated informed consent form for each subject is filed correctly.
- Maintain a recruitment log detailing who was contacted for enrollment and why people declined to participate.
- Liaise between subjects and Principal Investigator.
- Develop and implement plan to retain subjects in the study.
- Ascertain the reason for premature withdrawal from the study by any subject. For subjects who drop out, (a) document their reason(s), if available, (b) record attempted contacts, and (c) obtain all follow-up information or document subject as "lost to follow-up."
- Ensure that Principal Investigator is available during study visits to perform required tasks.
- Maintain a screening & enrollment log.
- Maintain all other required documentation.
- Assign study numbers and randomize subjects.
- Schedule and conduct study visits.
- Dispense medications and devices, educating subjects on their use.
- Maintain complete and accurate source documentation (any document, form or record where subject's data is first recorded).
- Maintain a complete and accurate CRF for each subject that records all observations and data during the study.
- Record and report all adverse events and serious adverse events to the Principal Investigator, sponsor and IRB, as appropriate.
- After obtaining written authorization from the subject, inform the subject's primary physician about the subject's enrollment and completion in the study, and any significant events.
- Document any deviations from the protocol.
- Document and explain any premature unblinding of the study drug.
- Maintain complete and accurate records of the receipt, dispensing, retrieval and return of all clinical supplies. Identify and document any discrepancies.
- Ensure that Principal Investigator reviews and signs required documents.
- Keep the Principal Investigator informed of study activities and any issues that may arise.
- Document substantive study-related conversations.
- Communicate with sponsor's representatives regarding study activities.
- Prepare for and host site selection, initiation, monitoring and close-out visits.
- Respond to data queries on a timely basis.

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- Anticipate amendments to protocol.
- After close-out, inventory, organize and pack study materials for long-term storage. Destroy study materials properly, when appropriate.
- Supervise preparation for site visits from regulatory agencies by collecting and organizing all subject data pertinent to the inspection.

Attractive compensation based on local standards and benefits, including fresh salmon (seasonal) and subsidized kerosene. We are an equal opportunity employer.

Serious applicants meeting the above requirements are invited to apply in person by April 1, 2009 at:

Aleutian Institute of Clinical Research
1 Shipwreck Cove
Cape Wrangell, AK 99659

Author

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