Oxford University Clinical Research Unit, Viet Nam

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JOB DESCRIPTION

Post: Clinical Research Coordinator

ORGANIZATION & RESEARCH BACKGROUND	Oxford University has two Clinical Research Units in Viet Nam: one in Ho Chi Minh City and one in Hanoi (www.oucru.org) Oxford University Clinical Research Unit Vietnam (OUCRU-VN) has been working in Viet Nam for more than 20 years on infectious diseases studies and has a well-established research program, facility and partnership with the National Hospital for Tropical Diseases and a network of hospitals across Viet Nam and Asia to conduct a wide range of clinical studies including clinical trials of drugs . The Unit's main focus of work is in Dengue, Infections of the Central Nervous System, Respiratory Infections, Antibiotic Resistance, Influenza, HIV and Tuberculosis.
OVERVIEW OF THE ROLE	A highly motivated Coordinator is required to manage the implementation of research projects; to support and develop the current activities of the Researches; ensure efficient and high quality research operations in line with international standards; to contribute to the continued growth and development of the Research team and will be responsible for coordinating a number of trials across Viet Nam
LOCATION	OUCRU-VN office at the National Hospital for Tropical Diseases, Bach Mai Hospital, 78 Giai Phong, Dong Da, Hanoi. Travel to hospitals or units around Hanoi will be required regularly. Travel within Viet Nam or internationally will be required.
LENGTH OF CONTRACT	One year contract and extension based on annual performance appraisal and Research approval
PROBATION PERIOD	Two months.

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REPORT TO	Heiman Wertheim, Director of Hanoi Unit
HOURS OF WORK	37,5 hours/week – Monday to Friday
BENEFIT	• Contracted salary: Negotiate (depending on actual experience and education) • Health insurance through AonCare: In-patient and out-patient medical coverage; Personal accident insurance coverage • 13th month salary (annual bonus) • One month salary for annual clothes • Annual leave 18 days/year (increased to 21 days in year three, 28 days in year four and 30 days from year five). • Vietnam Social & Health insurance, Sick leave, Personal leave, Maternity leave and National holidays will be based on Vietnam Labor Law
JOB DUTIES/ RESPONSIBILITIES	**General Responsibilities** • Maintain an up-to-date understanding of local and international trial regulations, train investigators on regulatory changes and ensure that these standards are implemented in all research studies. • Implement the Unit's policies on the conduct of clinical trials. • Contribute to the development of quality and efficiency within the Research Unit. • Coordinate all regulatory, logistical, training and reporting tasks associated with running a clinical study/trial. • Liaise with colleagues in pharmacy, monitoring, data management and laboratory departments to ensure quality and harmonious execution of study procedures. • Be a part of a team that provides training for senior hospital staff on the ICH

guidelines of Good Clinical Practice.

Key duties/tasks:

- Understand relevant clinical research protocols and regulatory requirements.
- Translate study documents (Vietnamese - English – Vietnamese).
- Develop standard operating procedures to control the quality of study conduct.
- Organize logistics of study materials including drugs, files, test kits, patient samples, data and other materials.
- Plan, implement and coordinate all aspects of data collection, recording and source documentation, as per hospital and unit policy and ICH GCP guidelines.
- Train study staff and investigators in protocol relevant procedures including those for laboratory samples, data collection and recording, medication and patient assessment.
- Execute study-related administrative tasks, such as collection of data and regulatory documents, managing reimbursement for patients and study staff, filing or retrieving files, maintaining patient charts and supply inventories, etc.
- Verify that data entered on to the CRFs is complete and consistent with patient clinical notes, known as source data/document verification.
- Coordinate patient visit schedule as per study protocol.
- Supervise the conduct of the study to ensure compliance with the principles of Good Clinical Practice, which will involve visiting the study sites on a regular basis.
- Track study progress and identify problems. Report to stakeholders as required.
- Liaise with sponsor for monitoring/audits. Write, file and collate trial documentation and visit reports with respect to monitoring.
- Participate in study team meetings to share experience and contribute to the knowledge of others in the team.
- Develop the skills of a Clinical Research Monitor. Become a member of a team of Monitors responsible for verifying the quality and compliance of research projects.
- Attend career training to improve skills and update relevant knowledge.
- Other tasks as required.

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REQUIRED COMPETENCIES	**Essential Criteria:** • Medical Doctor or degree in Pharmacy, Science, Public Health or a related field. • Strong diplomatic skills. • Proven oral and written presentation skills. • Excellent communication and interpersonal skills. • High level of organizational and record keeping skills. • Knowledge of ICH GCP guidelines. • Excellent Vietnamese and English language skills. **Desirable Criteria:** • Experience in conducting clinical trials compliant with ICH-GCP guidelines. • Experience conducting or managing clinical trials • Industry experience • Work experience of a Health Research Institution
Deadline for application	Interested candidates are invited to send curriculum vitae, application* and copies of relevant certificates, either by email or by post to Bui Huyen Trang Oxford University Clinical Research Unit Vietnam National Hospital for Tropical Diseases Bach Mai Hospital 78 Giai phong, Dong da, Ha noi Email: trangbh@oucru.org Deadline: 20 September 2012. ** The cover letter should detail: What part of your education, training or employment history has best equipped you for this position?* • *Why you would make a good candidate for this position?* • *Names of two referees who can provide details of relevant experience* ** Only short-listed applicants will be contacted for interview. Please no telephone contact after submitting the application*