Career Center

Research Compliance Officer

General Dynamics Information Technology

Description:

General Dynamics Information Technology (GDIT) is hiring for full-time **Compliance Officer** to join the GDIT team at the Naval Medical Center Portsmouth (NMCP).

As the U. S. Navy's oldest, continuously-operating hospital since 1830, Naval Medical Center Portsmouth (NMCP) proudly serves past and present military members and their families. The nationally acclaimed, state-of-the-art medical center, including its nine branch clinics located throughout the Hampton Roads area, additionally offers premier research and teaching programs designed to prepare new doctors, nurses and hospital corpsmen for future roles in healing and wellness

The **Compliance Officer** Initiates and executes scientific research and/or development studies; Analyzes problems and applies theoretical techniques to develop solutions.

Responsibilities Include:

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Details

Posted:
September 27, 2017

Location:
Portsmouth, Virginia

Salary:
Open

- Conducts routine audits of NMCP IRB approved research; ensures investigator compliance with local protocol and NMCP RSPD standards and DON HRPP/ Federal regulations and policies
- Evaluates research activity; inspects regulatory documentation and reviews recruitment and data collection processes; verifies source documentation and subject eligibility when applicable
- Audits signed consent forms for completeness and temporal accuracy; observes and evaluates investigator subject consent process
- Reviews data security procedures including secure storage and transfer to ensure protection of PII/PHI; confirms data collection methods against study protocol; reviews study document maintenance and disposition at final report
- Prepares audit reports to include findings and follow up corrective/ preventative actions plans; debriefs investigators and releases final closure of audit reports upon completion and final IRB/CO approval
- Presents audit findings and corrective action at bi-monthly IRB meetings; prepares Research Compliance update for IRB meeting minutes
- Reviews IRB procedures and policies; reviews membership rosters and appointment letters; attends IRB meetings and meets with chairpersons as needed; provides feedback to Head, RSPD
- Provides ongoing guidance regarding policy updates and identified deficiencies; updates Research Compliance Program policies as part of RSPD Standard Operating Procedures (SOPs); maintains internal audit database
- Facilitates effective communication between PI/AIs and CID
- Provides education and guidance to new investigators including review and/or preparation of study documents; reviews regulatory requirements for documentation of study records, proper data security methods, and adherence to IRB/DON HRPP policy; may mentor new research coordinators
- Oversees investigator compliance with BUMED required training; maintains oversight of training database
- Supports Command appointed Research Integrity Leader; documents ongoing research ethics training, maintains oversight of training database, and updates Research Integrity SOPs as needed
- Provides training and workshops for investigators; participates in CID Research Orientation and other hospital department orientations; assists in the development of new training programs
- Attends monthly IACUC (Institutional Animal Care and Use Committee) meetings; attends facility inspections and participates in bi-annual protocol review

Type:
Full Time - Experienced

Category:
Quality/Risk Management

- Provides compliance oversight and education to other Navy Medicine East (NME) Commands through remote audit process and site visits as directed
- May perform Investigational Drug accountability for studies involved in Investigational New Drug (IND) research. (The FDA requires that the NMCP Pharmacy be in control of IND drugs; "control" pertains to where and how drugs are stored and maintained and who is responsible, ie: the Pharmacy or the Principal Investigator may store the drugs in a manner acceptable to the Pharmacy.) The Compliance Officer may be required to confirm how both the investigator and the Pharmacy are accountable for IND drugs
- May audit CID research files and/or assist in preparation of protocol folders for 2nd level review for submission to BUMED
- May provide compliance oversight and training of research assistants when applicable.
- Will oversee the query resolution processes when required
- Will assist in preparation and response to Federal regulatory audits
- Will attend training, conferences, and other meetings as required
- Will work off-site as required (telework, if permitted via modification).

Education:

- A Master's Degree, preferably in life sciences.

Qualifications:

- Must be US Citizen / Must be able to maintain a National Security Clearance.
- A minimum of 4 to 6 years of monitoring experience in a clinical research environment. Administrative IRB experience preferred.
- Have a sound knowledge of medical terminology and clinical monitoring process, and possess in depth therapeutic and protocol knowledge.
- Ability to communicate effectively, both orally and in writing.
- Possess effective organizational and analytical skills.
- Ability to work independently and in a team environment.
- Proficient with Windows based computer systems including Microsoft Office.
- Will complete research subject protection training developed by the Collaborative Institutional Training Initiative (CITI), and NMCP research integrity training within one month from start date and additional protocol specific training as required.

As a trusted systems integrator for more than 50 years, General Dynamics Information Technology provides information technology (IT), systems engineering, professional services and simulation and training to customers in the defense, federal civilian government, health, homeland security, intelligence, state and local government and commercial sectors. With approximately 32,000 professionals worldwide, the company delivers IT enterprise solutions, manages large-scale, mission-critical IT programs and provides mission support services. GDIT is an Equal Opportunity/Affirmative Action Employer - Minorities/Females/Protected Veterans/Individuals with Disabilities.

Internal Number: 2017-27014

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About General Dynamics Information Technology

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