ASPIRA WOMEN'S HEALTH

www.aspirawh.com

Clinical Research Coordinator

We are looking for a candidate with a medical background and excellent interpersonal skills for the position of Clinical Research Coordinator. The Clinical Coordinator is responsible for keeping all subject material and clinical records organized and accessible to the principle investigator and other members of the clinical research team. They must adhere to regulatory trial standards and participate in subject recruitment efforts, among other duties.

The Clinical Coordinator needs to engage with research subjects and other medical professionals, and explain what is expected and understand their concerns, requiring great interpersonal and communicative skills.

Major Areas of Responsibility

Major areas of responsibility include:

- Overseeing multiple clinical trials and keeping records organized.
- Collecting and analyzing data obtained from subject's medical records.
- Informing participants about study objectives.
- Reviewing paperwork returned and verifying all forms are complete. If not complete, missing information needs to be retrieved.
- Assists Principal Investigator with scientific and compliance reporting requirements in accordance with Federal regulations and company and sponsoring agency policies and procedures
- Promotes the ethical conduct of research by reporting good faith suspicions of misconduct in research as defined within Companies Research Integrity Policy and other misconduct as described in Companies Code of Conduct.
- Prepares, maintains all study materials These study materials include, but are not limited to, the informed consent document, case report forms (CRFs), enrollment logs, accountability logs.
- Liaison to laboratory regarding test results.
- Participating in subject recruitment efforts.
- Assisting laboratory with sample archival and storage.
- Engaging with subjects and understanding their concerns.
- Maintains effective and ongoing communication with sponsor, research participants and PI during the course of the study.
- Works with study clinics on study subjects for eligibility using protocol specific inclusion and exclusion criteria, documenting each potential participant's eligibility or exclusion.
- Assists PI in communication of study requirements to all individuals involved in the study. Provides appropriate training and tools for study team members.
- Attends investigator meetings as required or requested by the PI.
- Registers each participant in the billing matrix to ensure billing of study procedures to the appropriate funding source.
- Collects data as required by the protocol.
- Maintains study timelines.
- Maintains adequate inventory of study supplies (i.e research kits, study materials etc)

- Works with the PI to manage the day to day activities of the study including problem solving, communication and protocol management.
- Works closely with the Director of Quality Affairs to establish all IRB materials, and ensures all ongoing studies meet the FDA guidelines for clinical trials.

Education and Experience Requirements

- Candidates with a Bachelor's degree in a scientific, health related, or business administration program, preferred. At minimum, a candidate must have a Bachelor's degree.
- At minimum, candidates must have at least two years of experience in a clinical research environment. Preferred candidates will have three or more years as a clinical research professional (certification as a CCRC is desired).
- Knowledge of medical terminology, clinical medicine, clinical trials and GCP concepts
- Experience handling biospecimens.
- Ability to prioritize and perform multiple tasks in a dynamic environment.
- Basic computer skills-MS Office suite.
- Strong interpersonal, management, critical thinking, decision making skills.
- Strong verbal and written communication skills.
- Solid interpersonal skills.
- Calm and reasoned judgment.
- Analytical mindset.
- Excellent organizational skill and attention to detail.
- Strong sense of ethical and moral attitudes necessary for maintaining the confidentiality of patient information.
- Ability to work overtime hours, as required.
- Ability to read, understand, and follow SOPs, validation protocols, etc. and to complete documentation in a clear, accurate manner.
- Willingness to continually self-educate.

Aspira Women's Health, Inc. (formerly known as, Vermillion inc., Nasdaq: VRML) is transforming women's health with the discovery, development, and commercialization of innovative testing options and bio-analytical solutions that help physicians assess risk, optimize patient management, and improve gynecologic health outcomes for women. ASPIRA is particularly focused on closing the ethnic disparity gap in ovarian cancer risk assessment and developing solutions for pelvic diseases such as pelvic mass risk assessment and endometriosis. OVA1® plus includes our FDA-cleared products, OVA1®, and OVERA® to detect risk of ovarian malignancy in women with adnexal masses. ASPIRA GenetiXTM testing offers both targeted and comprehensive genetic testing options with a gynecologic focus. With over 10 years of expertise in ovarian cancer risk assessment, ASPIRA is delivering a portfolio of pelvic mass products over a patient's lifetime with our cutting-edge research. The next generation of products in development are OVASightTM and EndoCheckTM. Visit our website for more information at **www.aspirawh.com**.