TITLE: Clinical Trials Quality & Compliance Coordinator
DEPARTMENT: Clinical Trials & Corporate Compliance
REPORTS TO: Oncology Service Line Director & Corporate Compliance Officer
FLSA: Non-Exempt

SUMMARY OF JOB:
The Clinical Trials Quality and Compliance Coordinator will be responsible for the overall operations of the clinical trial / research program. Coordinator will oversee the development, implementation, support and maintenance of the growing research program at Grand Valley Oncology (GVO). Coordinator will provide leadership, direction and support to Physician Investigators and Clinical Trials Staff as well as foster relationships with ancillary departments, sponsors, vendors, partnerships and affiliations. He / She will support and promote ethical and legal research practices at GVO, in affiliation with Huntsman Cancer Institute (HCI), with regard to policies, procedures, regulations and laws concerning Human Subject Research. Coordinator will provide support and assistance to overarching entities for investigations, audits and regulatory affairs.

RESPONSIBILITIES:
Colorado West Healthcare System expects job performance to be consistent with its mission and believes that each Employee contributes to improve performance by continuously searching for ways to increase efficiencies and enhance fiscal performance and viability.

ESSENTIAL DUTIES AND RESPONSIBILITIES:
(The following statements are illustrative of the essential functions of the job and do not include other non-essential or marginal duties that may be required. Community Hospital reserves the right to modify or change the duties or essential functions of this job at any time. All responsibilities may not be performed by all incumbents.)

Maintain research related Federal Wide Assurance (FWA) requirements and renewal, including managing correspondence with Federal agencies and offices such as OHRP, FDA, DEA, DOD, etc.

Serve as the Point of Contact between the Clinical Trails, GVO, CWHS, HCI and the Sponsor.

Oversee Clinical Trials Staff

Oversee the day to day operations of the Clinical Trials including Investigator support, protocol adherence and quality / compliance measures.

In consultation with the principal investigator and GVO leadership, develop and manage strategic plans, project budgets and feasibility assessments.

Ensure compliance with regulatory and institutional policies. Ensure program data and progress are reported to the funder and other program stakeholders, including CWHS and community partners.
Take ownership of the project(s), proactively consulting other project team members and department representatives for information or guidance, as necessary to make the best informed decision for the safety of patients, the organization and the resources available.

Maintain active role on administrative and executive committees, task forces, evaluate processes and procedures for effectiveness and efficiency. Implements quality improvement practices and acts as a “change agent” for the department.

Review monitoring reports, review, investigate and resolve discrepancies in clinical data, patient eligibility and protocol deviation issues. Oversee reporting of data and study progress, toxicity summaries and quality and compliance issues to appropriate individuals, committees, organizations and/or regulatory bodies. (Compliance Officer, Affiliate Site, IRB, DSMC, etc.)

Coordinate the development of program materials including educational materials, marketing materials, websites, forms and reports.

In collaboration with the Principal Investigators, provide oversight and assist internal and external auditors to ensure compliance with protocols, regulations and hospital policies.

Responsible for research related quality assurance and quality improvement, including managing research related accreditation activities in coordination with overarching and/or collaborative entities.

Maintain current knowledge of regulations regarding research (International Commission of Harmonization (ICH), Good Clinical Practice (GCP), Institutional Policies, State and Federal Regulations). Develop, coordinate and / or participate in education and training to enhance compliance and awareness of compliance.

Collaborate with CWHS Compliance department to develop and maintain effective research compliance communication program within CWHS. Work with the Principal Investigator, Manager(s), Director(s), Compliance Officer and /or Human Resources, as appropriate, to identify and resolve research related compliance issues by assisting with the review, investigation and analysis of findings, where appropriate. May recommend the initiation of investigative procedures. Collaborates with Compliance Officer to direct compliance issues to appropriate existing channels for investigation and resolution, including uniform handling of such violations.

Collaborate with billing and accounting teams for pre-award research activities such as Medicare Coverage Analysis (MCA) and Budget Review / Negotiations as well as post-award administration of research activities, reconciliation of payments and sponsor invoicing. Identify potential areas of compliance vulnerability and risk within clinical trials.

Ensures that corrective action plans are developed and implemented for resolution of problematic issues, and provide general guidance on how to avoid or deal with similar situations in the future.

Provides reports on a regular basis, and as directed or requested, to keep the Oncology Service Line Director and Compliance Officer informed of the operation and progress of compliance efforts.
In consultation with the Manager(s), Director(s) and the Compliance Officer, helps ensure that there is a mechanism in place for disciplining instances of non-compliance (including the failure to prevent, detect, or report any non-compliance), appropriate to the nature and extent of the deviation. Disciplinary action itself will be identified and carried out per institutional policies / by authorized individuals.

This position requires strong customer focus, accurate attention to detail, analytical thinking and problem solving skills, ability to build trust and communicate openly and regularly about multiple projects with multiple stakeholders, internal and external.

Develop, initiates, maintains and revises policies and procedures for the daily operations of research and uses data obtained from monitoring and compliance activities to revise existing policies, guidance and direct future educational efforts.

Other duties as assigned.

QUALIFICATIONS:
To perform this job successfully, an individual must be able to perform each essential duty satisfactorily. The requirements listed below are representative of the knowledge, skill, and/or ability required. Reasonable accommodations may be made to enable individuals with disabilities to perform the essential functions.

EDUCATION and/or EXPERIENCE:
Associate’s Degree in Health Sciences or related field, Bachelor’s Degree preferred. With a minimum 3 years of Oncology Human Subject Research Experience including medical/research terminology, healthcare related project management and/or participation in multi-department collaboration projects, Research implementation (regulatory, data, coordination)

OR
equivalent combination of education and experience.

SPECIAL SKILLS:
10-key (by touch)

CERTIFICATES/LICENSES:
ACRP or SOCRA (SOCRA Preferred)
Must obtain National Certification in Research Compliance within 3 years of hire.

LANGUAGE SKILLS:
Must be able to speak, read and write English. Ability to read and interpret documents such as physician orders, medical charts, safety rules, operating and maintenance instructions, and procedure manuals. Ability to write routine reports and correspondence. Ability to effectively present information in one-on-one and small group situations to supervisors, patients, patient's family and other employees of organization. Able to work in a team-oriented environment.

MATHEMATICAL SKILLS:
Ability to add, subtract, multiply, and divide in all units of measure, using whole numbers, common fractions, and decimals. Ability to compute rate, ratio, and percent.
REASONING ABILITY:
Ability to solve practical problems and deal with a variety of concrete variables in situations where only limited standardization exists. Ability to interpret a variety of instructions furnished in written, oral, diagram, or schedule form.

INTERPERSONAL SKILLS:
Demonstrates exceptional customer service skills using the “Whatever It Takes” philosophy; builds relationships and proactively respects others. Requires adaptability with regular interpersonal contact.

DECISION MAKING ABILITY:
Work limited by standards and procedures. Adapts to recurring operational situations using formal and informal channels. Unusual situations are reviewed with a manager.

ANALYTICAL ABILITY:
Apply basic business or technical principles to routine and moderately complex problems. Concentrates and pays close attention to detail.

COMPUTER SKILLS:
To perform this job successfully, an individual should be computer-literate and have working knowledge of Microsoft Office applications.

PHYSICAL DEMANDS:
The physical demands described here are representative of those that must be met by an employee to successfully perform the essential functions of this job. Reasonable accommodations may be made to enable individuals with disabilities to perform the essential functions.

While performing the duties of this job, the employee is regularly required to sit; have manual dexterity; handle or feel; talk and hear. The employee is occasionally required to stand; walk; reach with hands and arms; climb or balance; and stoop, kneel, crouch, or crawl. The employee must regularly lift and/or move up to 20 pounds. Specific vision abilities required by this job include close vision, distance vision, color vision, peripheral vision, depth perception, and ability to adjust focus.

WORK ENVIRONMENT:
The work environment characteristics described here are representative of those an employee encounters while performing the essential functions of this job. Reasonable accommodations may be made to enable individuals with disabilities to perform the essential functions.

While performing the duties of this job, the employee is occasionally exposed to moving mechanical parts, risk of electrical shock, exposure to infectious diseases, and transmission of airborne disease. The noise level in the work environment is usually moderate.

GENERAL COMPLIANCE REQUIREMENTS FOR ALL EMPLOYEES:
Attends annual compliance and privacy training.
Responsible for complying with all federal, state and local rules and regulations.
Must comply with the Code of Conduct Guide.
Reports any observation of fraud, waste, abuse, and/or privacy violations to HR or CCO.
Reports any conflict of interest or relationship immediately.
HIPAA:
Ensures and adheres to strict confidentiality when handling patient information, according to the HIPAA Privacy Act and hospital policy and procedure regarding confidentiality. Complies with all hospital information security practices.

Has knowledge of and adheres to all compliance regulations, policies and procedures.

**Final Section** I understand that my employment is for an indefinite period of time and that his facility can change wages, benefits, and conditions of employment at any time.

___________________________________________________ _______________________
Employee Name & Signature Date

___________________________________________________ _______________________
Supervisor Name & Signature Date