Job Description: Clinical Research Coordinator

This position is located in Boulder, CO and may be either a 4 day, 32 hour work week in Boulder or a 5 day, 40 hour work week with one day in our main office in Denver doing data entry.

Education and Experience:
1. 2-3 year's oncology experience required.
2. Preferred clinical research experience.

Qualifications
1. High degree of planning and organizational skills.
2. Ability to work well in a team and manage conflicts and resolve problems effectively.
3. Excellent interpersonal skills with proven written, presentation and verbal competencies.
4. Strong ability to work autonomously.
5. Strong ability to multi-task and manage competing priorities while demonstrating excellent customer service behavior.
6. Ability to drive own vehicle for work (to and from clinics).
7. Ability to attend tumor board meetings.
8. Ability to attend research base meetings.
9. Preferred ability to type and have basic word processing, internet access and some computer skills.

Statement of Employee & Behavioral Expectations
As an employee of the Colorado Cancer Research Program (CCRP), the Full-Time Clinical Research Coordinator (CRC) supports the mission, vision, and standards of Good Clinical Practices (GCP) as set forth by the FDA, the OHRP, and CCRP. The CRC is also familiar with all of CCRP’s policies and procedures. As a service organization, CCRP employees serve as a goodwill ambassador to promote and maintain positive, professional relationships with all patients, their families, physicians and staff.

General Dimensions/Responsibilities
1. Provides overall coordination of the study aspects of patient care enrolled in cancer research studies through CCRP.
2. Assists CCRP Investigators in the identification, recruitment, and education of patients onto CCRP research studies as per HIPAA guidelines.
3. Serves as an educational resource to participating patients, physicians and associate staff in cancer research.
4. Demonstrates knowledge and understanding of GCP guidelines and regulatory requirements to maintain patient safety, confidentiality, and the integrity of the clinical trial process.
5. Demonstrates behaviors that reflect quality, professionalism, team work and excellence.
6. Maintains patient confidentiality at all times.
7. Develops, establishes and maintains productive relationships with CCRP staff and all external customers and contacts to achieve essential research outcomes.
8. Collaborates closely with the CCRP Clinical Research Team, which may include Clinical Research Coordinators, Clinical Research Associates, the Principal Investigator, the Manager of Operations, the Manager of Clinical Oncology Research Services, the Quality Assurance Manager, Regional Manager of Drug Accountability, Investigators and regulatory staff to ensure key federal/state/local regulatory objectives are met and that ethical obligations are kept.

**Essential Functions of the Full-Time Clinical Research Coordinator (CRC)**

These functions are including but not limited to:

1. Responsible for screening potential patients which includes obtaining HIPAA authorization, informed consent for the study, reviewing medical records to determine eligibility, communication with the investigator and patient re: additional tests to be completed.
2. Prepare patient information for registration/randomization.
3. Notify the investigator and patient of assigned treatment and coordinate treatment start date.
4. Responsible for ordering and/or transporting study drug, documentation of receipt and dispensing of the study drug on the Drug Accountability Record Forms (DARFs).
5. Responsible for calculating drug dosages per protocol requirements.
6. Responsible for obtaining required specimens per protocol and transport of said specimens to research office for processing and shipment.
7. Must monitor the patient throughout the active treatment phase of the study. This includes patient visits, providing investigators and clinic staff with treatment sheets/calendars of the required treatment per protocol.
8. Collaborate closely with the investigator and clinic staff in scheduling future appointments, explaining patient diaries and/or QOL questionnaires, reporting of adverse events, recognizing serious adverse events, and the need for dose modification.
9. Responsible for ensuring protocol adherence by understanding, communicating and making sure the study parameters are ordered and carried out per protocol requirements.
10. Closely monitor the patient’s response to treatment. This is accomplished through communication with the investigator, tracking results of imaging scans as per RECIST guidelines as applicable and provide the investigator with information from the protocol explaining the appropriate response.
11. Inform and educate the investigator and/or clinic staff regarding study drug administration requirements, including required pre-medications, order of administration, monitoring time points, and the need for infusion start/stop times.
12. Obtain all required source documentation.
13. Responsible for preparing the research chart for internal audits.
14. Assist the clinical research team in preparation for external audits.
15. Responsible for evaluation and reporting serious adverse events and expedited reporting of such events if required (ADEERs).
16. Any protocol violation/deviation will be reported to the Manager of Operations, the Manager of Oncology Research Services and the Quality Assurance Manager.
17. Additional tasks and/or special projects as requested by Management.