Position Title: Coordinator, Clinical Research Program  
Department: Department of Gynecologic Oncology & Reproductive Medicine  
Division: Surgery  
Reports to: Project Manager, Innovative Therapy

MISSION STATEMENT

The mission of The University of Texas M. D. Anderson Cancer Center is to eliminate cancer in Texas, the nation, and the world through outstanding programs that integrate patient care, research and prevention, and through education for undergraduate and graduate students, trainees, professionals, employees and the public.

SUMMARY

The primary purpose of the Coordinator, Clinical Research Program is to support the clinical research activities and regulatory affairs of the Developmental Therapeutics and Immunotherapy program of the Department of Gynecologic Oncology and Reproductive Medicine. Responsibilities include protocol development, research program support, and regulatory management.

CORE VALUES

Caring Behaviors

- Courtesy: Is respectful and courteous to each other at all times
- Friendliness/Teamwork: Promotes and rewards teamwork and inclusiveness; Is sensitive to the concerns of our patients and our co-workers

Integrity Behaviors

- Reliability: Communicates frequently, honestly and openly
- Accountability: Holds self and others accountable for practicing our values
- Safety: Notices a safety concern and brings it to someone’s attention; Models safe behaviors (wears badge, washes hands, keeps work area clean and orderly)

Discovery Behaviors

- Responsiveness: By his/her actions, creates an environment of trust; Encourages learning, creativity and new ideas
- Personal Leadership/Self-Initiative: Helps others to identify and solve problems; Seeks personal growth and enables others to do so

KEY FUNCTIONS

Protocol Development and Processing
- Responsible for revising, developing and/or composing key and supporting documents for investigator-initiated clinical trial protocols and associated projects
- Transcribes sponsored trials into the required MD Anderson formats
- Prepares assigned protocols and amendments for successful submission to internal and external systems
- Interfaces with internal departments and external programs, committees, boards, etc.
- Utilizes technical writing skills to compose and abstract medical and scientific information for preparation of written correspondence, reports, and other documents under the direction of the Principal Investigators, managers, and supervisors
- Interacts with protocol sponsors (industry, government, and cooperative groups)
- Knowledgeable regarding pharmaceutical protocol submission process, formatting requirements, deadlines, and regulatory issues.
- Responsible for ensuring that all regulatory and institutional requirements are met before study activation.

Research Program Support
- Provides administrative support for program activities and projects for the department’s Clinical Research Program.
- Attends departmental research program meetings to assist in providing oversight and/or support for all designated site specific research programs and committees including, but not limited to, Developmental Therapeutics (DT) and Early Drug Development and Immune Therapy (EDDIT).
- Works closely with Project Manager, Innovative Therapies to prepare data, reports, and other information for Research Administration Committee (RAC), DT, EDDIT and other meetings.
- Coordinates collaborative meetings and other communications with the PI and clinical trial sponsors to evaluate and audit existing studies and to make recommendations for process improvement.

Regulatory Management
- Composes the correspondence accompanying protocol submissions and ensures that the submissions are prepared properly.
- Maintains regulatory files for all assigned studies.
- Interacts and provides appropriate correspondence to industry trial monitors, IND office monitors and institutional auditors.
- Addresses continuing review and/or CRC/PBHSRC/IRB contingencies or forwards to the study manager or Principal Investigator for completion.
- Forwards copies of IRB approval memos to outside agencies (NCI, CROs, or pharmaceutical firms) as needed.
- Performs other duties as assigned.

QUALIFICATIONS
- Ability to impact both strategically and tactically planning and administration
- Demonstrated strong communication skills, interpersonal skills, and a superior drive for results
- Excellent written, oral, interpersonal and presentation skills and the ability to effectively interface with senior management and staff
- Demonstrated skills and comfort in proactively building relationships with potential partners.
- Excellent judgment and creative problem-solving skills, including negotiation and conflict resolution skills
- Ability to operate as an effective tactical, as well as strategic, thinker.

CORE COMPETENCIES
- IC – Build Relationships:
• Initiate, develop, and manage relationships and networks; and
• Show sincere interest in others and their concerns.

• IC – Provide Direction:
  o Provide clear direction and priorities toward a common vision;
  o Clarify roles and responsibilities for employees; and
  o Promote empowerment.

• IC--Self-Adaptability:
  o Work in situations involving uncertainty, shifting priorities, and rapid change; deal constructively with mistakes and setbacks; demonstrate flexibility.

• IC--Innovative Thinking:
  o Approach problems with curiosity and open-mindedness; offer new ideas, solutions, and/or options.

• IC--Strategic Thinking:
  o Define strategic goals and issues clearly; apply broad knowledge and experience when addressing strategic issues; foresee obstacles and opportunities relating to change or improvement.

• IC--Self-Motivation:
  o Set high standards of performance; pursue goals with energy and persistence; drive for results and achievement.

EDUCATION

Required: Bachelor’s degree in Business, Healthcare Administration or related field.

Preferred: Masters Level degree or Ph.D. in molecular and cell biology focused on cancer research.

LICENSE/CERTIFICATION

Required:  N/A.

Preferred:  N/A

EXPERIENCE

Required:  With Bachelor’s degree, six years’ experience in area of research study obtained from nursing, data gathering or other related experience. With preferred degree, three years’ experience in area of research study obtained from nursing, data gathering or other

Preferred:  Experience with M.D. Anderson clinical research protocols and institutional protocol processing procedures.

WORKING CONDITIONS
This position requires:

<table>
<thead>
<tr>
<th>Working in Office Environment</th>
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<tbody>
<tr>
<td>Working in Patient Care Unit (e.g. Nursing unit; outpatient clinic)</td>
<td>X</td>
<td>No</td>
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<tr>
<td>Exposure to human/animal blood, body fluids, or tissues</td>
<td>X</td>
<td>No</td>
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<tr>
<td>Exposure to harmful chemicals</td>
<td>X</td>
<td>No</td>
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<tr>
<td>Exposure to radiation</td>
<td>X</td>
<td>No</td>
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<tr>
<td>Exposure to animals</td>
<td>X</td>
<td>No</td>
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PHYSICAL DEMANDS
Indicate the time required to do each of the following physical demands:

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<thead>
<tr>
<th></th>
<th>Time Spent</th>
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<tbody>
<tr>
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<td></td>
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<tr>
<td>Activity</td>
<td>Never 0%</td>
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<td>---------------------</td>
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<tr>
<td>Standing</td>
<td>X</td>
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<tr>
<td>Walking</td>
<td>X</td>
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<tr>
<td>Sitting</td>
<td>X</td>
</tr>
<tr>
<td>Reaching</td>
<td></td>
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<tr>
<td>Lifting/Carrying</td>
<td></td>
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<tr>
<td>Up to 10 lbs</td>
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<tr>
<td>10lbs to 50 lbs</td>
<td>X</td>
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<tr>
<td>More than 50 lbs</td>
<td>X</td>
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<tr>
<td>Pushing/Pulling</td>
<td></td>
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<tr>
<td>Up to 10 lbs</td>
<td></td>
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<tr>
<td>10lbs to 50 lbs</td>
<td>X</td>
</tr>
<tr>
<td>More than 50 lbs</td>
<td>X</td>
</tr>
<tr>
<td>Use computer/keyboard</td>
<td></td>
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