TEXAS HEART® INSTITUTE

Clinical Research Nurse Coordinator Training Skills Program
Stem Cell Research Clinical
(Fulltime-Regular 170123)

COMPANY SUMMARY
The mission of the Texas Heart® Institute is to reduce the devastating toll of cardiovascular disease through innovative programs in research, education and improved patient care. Texas Heart® Institute is a nonprofit organization founded by Dr. Denton A. Cooley in 1962.

For more information, please visit our website at www.texasheart.org

POSITION SUMMARY
The Clinical Research Nurse Coordinator Training Skills program at Texas Heart Institute in the Stem Cell Center is made possible by a grant from the National Heart Lung Blood Institute (NHLBI) of the National Institutes of Health (NIH) as part of the Cardiovascular Cell Therapy Research Network. The goal of the program is to provide a training environment which nurse participants will develop the comprehensive skills and research competencies necessary to become an independent clinical research nurse coordinator in cardiovascular stem cell research. Training will emphasize the care of subjects in clinical stem cell trials, solving problems that may arise regarding the logistics of coordinating these trials, data accuracy, establish clinical research standards, regulatory guidelines, ethical principles, competency and the protection of human research subjects. This program is a 16-month training core.

The Research Coordinator RN assists investigators with the conduct of clinical research studies in compliance with approved protocols institutional policies and procedures and federal regulations. Coordinates study start-up (including preparation of materials required for IRB and administrative reviews) data collection maintenance of files and communications among investigators IRB sponsors and other staff for assigned projects. Some duties require current RN license.

PRIMARY RESPONSIBILITIES
- Assists investigators with preparation of clinical research protocols and related documents (including consent forms and study budgets) according to institutional and IRB policies and procedures, and FDA regulations; coordinates submission of protocol documents for IRB and administrative reviews, and assists with responses to questions and revisions. 10%
- Coordinates effective subject recruitment, screening, consenting, and enrollment; performs proper assessment of potential subjects for acceptable inclusion criteria. 20%
- Coordinates data collection, for assigned studies, from various sources, including medical records, hospital computer system and department forms; completes study case report forms and other documents according to approved protocol.25%
- Maintains study files according to Good Clinical Procedures for clinical research (GCP), and in an organized and efficient manner. 15%
- Maintains database and logs of patients enrolled into studies, and produces summary reports of ongoing clinical research programs. Distributes reports to PIs, sponsors and other key personnel as directed. 10%
- Administers study medication/biologic/device and maintains study inventory logs as required and directed. Performs study specific procedures, including tasks requiring RN license, as directed and according to approved protocol. Operates investigational devices and provides technical assistance (as to protocol) to other staff involved in use of investigational devices and drugs; may include training other staff in proper operation and use of investigational devices. 10%

- Assists investigators, study monitors and others during protocol audits, including providing necessary documents as needed. 5%
- Assists investigators with preparation of presentations and publications of study results. 5%

QUALIFICATIONS AND EDUCATION REQUIREMENTS

- Minimum Education: Two (2) Year Degree
- Registered Nurse (RN) – Current Texas Board of Nursing license is required
- Minimum Experience: Two (2) years' work experience (Preferably clinical experience working in CV ICU, CCU, or Cath lab)
- Applicants should have zero or less than 1 year of clinical research coordination experience without previous cardiovascular cell therapy research
- Must possess excellent written and verbal communication skills
- Experience with Microsoft Office; Clinical Conductor

HOW TO APPLY

All qualified candidates please submit your resume to: careers@texasheart.org with subject title "**Research Coordinator RN – Stem Cell Research**"