Office of Research

Clinical Research Development Program

The Office of Research is aware of the important challenges an academic health center may face in its quest to ensure that high quality research is being conducted by its researchers. The financial support, the time and financial demands of clinical practice, inexperienced researchers, a lack of support personnel, and the time spent on patient recruitment efforts can all act as barriers to clinical research. The Office of Research is in the process of assessing and evaluating the clinical research infrastructure at TTUHSC in order to provide solutions to overcome these barriers and develop strategies and initiatives to create systems and optimize resources to support clinical research and related compliance activities. Here, we provide some of the steps we will be taking to promote quality clinical research at TTUHSC:

SHORT TERM GOALS

RESEARCH SEMINAR SERIES

- The Office of Research will launch a Research Seminar and Lecture Series
  - This series will entail a monthly presentation by staff, fellows, students and invited speakers to cover a broad range of research topics. This seminar series will be designed to spotlight outstanding work, as well as foster new initiatives and collaborations among TTUHSC faculty, business, industry, private and public organization and other academic institution.

INVESTIGATOR DATABASE

- Build an enhanced research expertise interactive database for TTUHSC Research Faculty
  - Identify TTUHSC research experts
  - Find TTUHSC researchers for collaboration on research opportunities
  - Allow TTUHSC investigators to track all TTUHSC publications
  - Explain connections within and between departments to facilitate collaboration
  - Find expertise data for further analysis

INCREASING PARTNERSHIPS WITH INDUSTRY

The Office of Research will continue to facilitate relationships and increase collaboration with industry. A key focus area will be sponsored investigator-initiated research in order to conduct clinical research with the common goal of improving the health of patients and providing access to new medical treatments, technologies and devices. The Office will also continue to offer support for industry sponsored research which allows TTUHSC clinicians to conduct quality clinical research which translates to the clinical practice as they seek the best possible healthcare outcomes for our patients.

INVESTIGATOR MENTORING

The main objective of the TTUHSC Investigator Mentor Program is to build the baseline knowledge and skills for outstanding scientific future leaders at TTUHSC e and cultivate their research careers.

The three main goals of the Mentor program are as follows:

- Establish core of research mentors who would assists less experience faculty and students in developing skills for conducting clinical research.
- Partner more experienced senior investigator mentors with a less experienced faculty and student researchers in order to enhance accelerated knowledge of approaches to cutting edge translational science.
- To drive retention of future leaders in research.

The phases of the program

Initial Phase

- A mentoring committee will Identify junior investigators and their mentors for a 6 months-3 year commitment (depending on the research).
- Each mentor will be required to complete an application form detailing contact information, area of research expertise, therapeutic area, and number of years of experience in research. Mentors could be chosen based on criteria such as:
  - Research professionals who have at least five years of experience in clinical research
  - An expertise in a particular area of clinical research
  - Interest, willingness and availability to provide mentoring to less seasoned clinical research staff
- The information in the application forms would be used to develop the Expertise Core.
- Each mentee would provide information regarding a therapeutic areas of interest in which they would like to receive mentoring.

Phase 2

- The mentor will work with the mentee to develop research proposals, budget development and a research plan.
- Follow-through on the research and grant submission process, including revision and re- submission, as well as mid-point reporting on outcomes.

Phase 3

- The research team will conduct the research, reporting on research milestones, progress, setbacks/ problems.

Final Reporting

- Report research outcomes/findings.
- Disseminate and/or publish research results.

Final Survey

- At the end of the research project, a survey/evaluation will be sent to both the mentor and the mentee to evaluate the effectiveness of the mentor/mentee collaboration.

CLINICAL RESEARCH EVALUATION COMMITTEE

- Review protocols to ensure that clinical trials are scientifically sound.
- Monitor approved trials to ensure patient accrual goals are being maintained.
- Review findings and scientific progress.

- This committee will operate in collaboration with the Office of Research and report to the

Senior Vice President for Research.

- The CSEC would meet once a month to review proposed TTUHSC investigator-initiated clinical trial (IIT) protocols seeking industry funding.
- The CSEC will meet once or twice a month depending on volume to review all IIT protocols.
- All IIT research would be required to have prior CSEC approval before the protocol can be submitted to the IRB.

- **CSEC Mission:**
  i. To establish and maintain a review committee of sufficient size and breadth of expertise to conduct a critical and fair scientific review of institutional research protocols involving human subjects.
  ii. To conduct a thorough scientific review of all non-peer-reviewed, clinical protocols conducted at the TTUHSC based on specific, pre-determined review criteria.
  iii. To oversee the prioritization of competing protocols, thus ensuring optimal use of the TTUHSC's clinical resources for the achievement of its scientific goals.
  iv. To establish clear criteria for determining whether ongoing clinical trials are making sufficient scientific progress, including the attainment of adequate patient accrual rates.
  v. To monitor all research protocols based on the criteria established by the CSEC and to terminate protocols that do not meet these expectations.

OOR would provide a Protocol Review Process in order to pre-review all submissions to ensure it complies with CSEC guidelines.

CONTACT

For questions regarding these Clinical Research Development Program can be directed to Pam Frazier, 806-743-4367 or pamela.frazier@ttuhsc.edu.