Annual Report
FY2025

Clinical Research Institute
TEXAS TECH UNIVERSITY HEALTH SCIENCES CENTER™

STRATEGIC PLAN:

The CRI provides comprehensive support to faculty, trainees, and staff at the Health Sciences Center (HSC) in their efforts to conduct human subjects research, from conception to publication and beyond. Our primary goal is to enable scientific questions to become successful research projects through positive, motivating, and collaborative partnerships.

A critical component of our work involves regulatory oversight, which includes managing the Institutional Review Board (IRB) submission and approval processes on behalf of investigators across the institution. Secondly, the CRI offers coordinator support for clinical trials that involve consenting, interventions, assessments, and/or data collection. This includes documentation of study activities and compliance with national and institutional policies. Our team adheres strictly to the Code of Federal Regulations (CFR) and institutional regulations to ensure that all human subjects research is conducted ethically, safely, and in accordance with best practices.

Vision for Leadership and Strategic Growth

We aim to establish a vibrant and collaborative network that positions TTUHSC faculty at the forefront of discovery and healthcare innovation. This vision will be achieved by focusing on several key priorities:

1. **Fostering Collaboration and Building Relationships**
   Internally, we will prioritize developing strong and enduring relationships across academic departments, clinical specialties, and administrative teams. By fostering a culture of collaboration, the CRI can engage all stakeholders and empower them to contribute meaningfully to the research mission.
2. **Advancing Cancer Care**
   Within the UMC Cancer Center, our role is more focused, emphasizing the development, support, and facilitation of human-subjects research specific to oncology. Our overarching goal is to develop and sustain a robust research agenda that meets the rigorous standards required for a future National Cancer Institute (NCI) designation.
3. **Advancing Industry-Sponsored Research**
   A central component of the CRI's future will involve expanding its engagement with industry-sponsored research. By building trusted partnerships with pharmaceutical companies, medical device manufacturers, and biotechnology firms, the CRI will become a premier destination for high-quality clinical trials.
4. **Modernizing Systems and Embracing Innovation**
   To support the CRI's growth, we will work to modernize existing systems, adopt emerging technologies, and streamline processes to improve efficiency and outcomes. The CRI is taking a leading role in the development and planning for the conversion to

Epic for the institutional electronic health record at the Lubbock Campus. This involvement ensures we have the support and resources necessary to safely and efficiently engage in research activities.

5. **Strengthening Financial Stewardship**
   Financial stability is fundamental to the CRI's ongoing success. Careful fiscal management will ensure that growth is balanced with the responsible use of resources.
6. **Expanding biostatistical support**
   By expanding our biostatistical support across the campuses of TTUHSC, we aim to better serve the institution's scientists in their endeavors. Increasing the quantity and rigor of scientific outputs with expert analysis places TTUHSC faculty and staff at the forefront of scholarship.

Other areas that the CRI will work to strengthen include the continued provision of educational content for anyone at TTUHSC wanting to learn more about research and clinical trials. Grant writing and manuscript support are also areas in which we aim to increase our efforts. Ultimately, our mission within the CRI is to serve as a bridge between scientific innovation and real-world application. By providing strategic support, regulatory expertise, and logistical coordination, we empower investigators to bring their ideas to fruition. By doing so, we contribute to advancing the frontiers of medical knowledge, enhancing patient care, and promoting a culture of research excellence across the Health Sciences Center.

John Griswold, MD, FACS

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EXECUTIVE SUMMARY:

This fiscal year, we witnessed a change in leadership at the CRI with the retirement of Cathy Lovett after 26 years of service to TTUHSC, and the addition of Jenna Kesey, PhD, APRN, FNP-BC, CNE, as the new Managing Director. The CRI has also restructured and now formally recognizes an Oncology Division, separate from the Multidisciplinary Division, with its own leadership structure to help define the unique role it plays in the mission of TTUHSC and UMC Cancer Care. Mariana Fiori, PhD, CCRP, leads the Oncology Division as the Director of Oncology Research Operations. And Chris Scott-Johnson, MSN, RN, CCRP, continues to lead the Multidisciplinary Division as the Director of Multidisciplinary Research Operations.

The CRI is growing in size and institutional visibility, with members now serving on the following university- and institution-wide programs: Staff Senate, TTUHSC Research Council, UMC Medical Research Committee, TTUHSC & UMC Cancer Center Operations, and TTUHSC Cancer Care Coalition, all under the Office of the President. We were honored to receive funding to support the Cancer Division operations from the Comprehensive Cancer Care funding awarded to TTHSC from the Texas Senate. Additionally, our team participated in and contributed to 5 grant applications across various spheres at TTUHSC.

We are rapidly expanding our clinical trial portfolio on both Cancer and Multidisciplinary teams. We have achieved a steady workload of IRB submissions across the institution and its schools. The addition of a new biostatistician will enable us to better serve researchers across the schools. Lastly, we look forward to the addition of Epic Research Modules to our new EHR system, which will significantly enhance our ability to report on research activity and ensure accurate clinical trial billing. The CRI team is actively involved in leading the development of the Epic Research Modules, enabling us to maximize our benefits.

CRI Advisory Committee

Alyce Ashcraft, PhD, RN, CNE, FNGNA, ANEF, School of Nursing
Ronald Hall, PharmD, MSCS, School of Pharmacy
Troy Hooper, PT, LAT, ATC, PhD, School of Health Professions
Leslie Shen, PhD, CCRP, School of Medicine
Lavi Oud, MD, School of Medicine, Permian Basin Campus
Phil Sizer, Jr., PhD, Associate Vice President for Research Innovation
Lance McMahon, PhD, Senior Vice President, Office of Research and Innovation

CRI Team

Administration:
John Griswold, MD, FACS, CPI, Executive Director
Jenna Kesey, PhD, APRN, FNP-BC, CNE, Managing Director

Lubbock:
Milan Bimali, PhD, PRN Biostatistician
Abdul Awal, BSC, MSC, MS, Biostatistician
Josie Martinez, Clinical Department Administrator
Staci Brown, Administrative Assistant
Rylee Law, LVN, BS, CCRC, Section Manager, Regulatory Affairs, Research Monitor
Peyton Miles, BS, Regulatory Specialist
Eric Soto, BS, Regulatory Specialist
Mariana Fiori, PhD, CCRC, Director of Clinical Research Operations, Oncology Division
Nadia Jimenez, BS, Clinical Research Coordinator
Priscilla Garcia, RN, Clinical Research Nurse
Chris Scott Johnson, MSN, RNC, CCRC, CA/CP, SANE, Director of Clinical Research Operations, Multidisciplinary Division
Lane Young, BA, CCRC, Clinical Research Coordinator
Melanie Baccus, MPA, BSN, RN, Clinical Research Nurse

Permian Basin
Jammie Holland, RN, CCRC, Clinical Research Nurse
Veronica Janosick, RN, Clinical Research Nurse

Trial Activity

ONCOLOGY

Clinical Trials

Category	Clinical Trials	Patients Enrolled
Total Clinical Trials	12	166
SWOG	5	8
Sponsored	2	16
Investigator-Initiated	5	142
Total Treatment Trials	6	13
Newly Opened in FY	7	
Total Patients Screened	N/A	636

Institutional Impact

Department	Clinical Trials Supported
Internal Medicine (oncology)	6
Internal Medicine (pulmonology)	0
Internal Medicine (basic science)	2
Surgery	1
CBB	1
GIA	2

Tumor Type	Clinical Trials Supported
Genitourinary	4
Breast	3
Lung	0
Head & Neck	0
Gastrointestinal	0
Hematologic	2
Other	3

• Eight additional treatment trials are in the pipeline across stages of IRB approval, contracting, and negotiation.
• Current sponsored trial relationships include HiberCell, **Pfizer**, **Merck**, and **AstraZeneca** (with newly added partners since January 2025 in bold).

Trial Activity

MULTIDISCIPLINARY

Clinical Trials

Category	Clinical Trials	Patients Enrolled
Total Clinical Trials	16	220
Sponsored	2	20
Investigator-Initiated	14	200
Total Treatment Trials	7	160
Total Device Trials	1	1
Newly Opened in FY	9	
Total Patients Screened	N/A	2251

Institutional Impact – Lubbock

Department	Clinical Trials Supported
Internal Medicine (pulmonology/cc)	1
Family Medicine	1
Surgery	3
Ophthalmology	2
Allergy Immunology	1
Urology	0
Dermatology	0
CBB	0
TTU	0
SLP	1

Diagnosis/Disease	Clinical Trials Supported
Coronary Artery Disease	0
Diabetes Mellitus	3
Trauma/Injury	0
Burns/Wounds	2
Ophthalmology	1
Surgery	1
Pain/Myopathy	2
Allergy/Immunology	1
Dermatology	0

Institutional Impact – Odessa

Department	Clinical Trials Supported
Internal Medicine (pulmonology/cc)	1
Family Medicine	1
OB/GYN	1
TTU	1

Diagnosis/Disease	Clinical Trials Supported
Diabetes Mellitus	3
COVID	0
Valley Fever	1
Depression	1

• Current sponsored trial relationships include the University of Pittsburgh (DOD), Dexcom, **Amgen**, and **Avita** (with newly added partners since January 2025 in bold).

CRI Regulatory Affairs & Biostatistics

Activity	FY2025
Study design / IRB protocol review	97
Statistical analysis design	40
IRB new applications	75
IRB stipulations	488
IRB amendments	311
IRB continuing review	48
IRB reported events (UA/PD/AE/SAE)	54
Study closure	26
Statistical analysis	58
Results/Tables/Figures	51
Abstract/Manuscript development	18
Monitoring activity	76

Institutional Impact – Regulatory Affairs & Biostatistics

Department	IRB Applications Supported
School of Nursing	9
School of Pharmacy	2
School of Medicine	92
MSSRP	36
School of Health Professions	9
Graduate School of Biomedical Sciences	3
School of Public Health	0
Library Services	2
UMC Nursing	2
TOTAL	**116**

CRI Research Support Services

The Clinical Research Institute (CRI) is committed to supporting high-quality, ethical, and innovative clinical research at TTUHSC. The CRI offers a menu of services to support research for faculty, staff, trainees, and students across the institution, encompassing all six schools. The CRI can also offer some central services across the regional campuses.

General responsibilities of the CRI research team

- Conduct clinical studies and fulfil job responsibilities according to FDA and DHHS regulations and guidelines, ICH GCP, SOPs of this clinical site, the policies and procedures of TTUHSC, and the TTUHSC Human Research Protection Program Manual.
- Ensure that the PI is informed in a timely manner of all study-related activities verbally, or via meetings, e-mail, memos, and reports.
- Ensure the safety and welfare of study subjects by being knowledgeable about ongoing study protocols and investigational articles.
- Ensure source documentation is complete and accurate as appropriate for each study protocol, and PI oversight/interaction with participants is sought and documented.

CRI Leadership

The CRI leadership is here to facilitate any scholarship activity across the institution. This may include the following job roles, but also consider the CRI team as a resource to help answer any research-related questions or point you in the right direction.

- Participate as appropriate in the hiring, training, disciplining, and evaluating of individuals recruited as employees of CRI.
- Assign trained and appropriately qualified staff to manage assigned tasks for each clinical study planned or ongoing at this site.
- Manage the business aspects of clinical trials, including developing and negotiating study budgets, ensuring proper invoicing and payment of services provided, and bridging the gap between finance and clinical operations with transparency.
- Work with other departments inside and outside of TTUHSC to facilitate research activity
- Promote the CRI
- Communicate with providers, sponsors, and IRB as appropriate.

Regulatory Affairs

The CRI regulatory team is a centralized resource to assist with protocol & document development, as well as IRB submissions. Regulatory services are available to any researcher across all campuses and schools to facilitate the submission of IRB applications.

- Facilitate IRB application and submission for any CRI office/study.
- Assist CRI Research Nurses/Coordinators/Associates with maintaining regulatory documents.

- Facilitate ongoing and timely communication with the IRB via the institutional software system for any project.
- Submit Amendments, Unanticipated Event Reports, Monitoring Reports, Study Closures, Continuing Reviews; all IRB required/appropriate correspondence.
- Develop study documents as needed, such as informed consent forms, information sheets

Clinical Research Nurse (CRN)/Clinical Research Coordinator (CRC)

The CRI offers coordinator services for non-funded, investigator-initiated trials internally as a means of supporting scholarship among our busy clinical faculty. For projects in which the CRI provides study coordination support and external funding is available, an internal **Memorandum of Understanding (MOU)** will be prepared. This MOU will be signed by the study's Principal Investigator and the CRI Executive and/or Managing Director. It will clearly define the responsibilities of each party as well as the associated financial arrangements.

- Comply with all federal guidelines in preparing and sharing with sponsors applicable FDA forms with signatures (i.e., form 1572, Investigator Agreement, form 3454, form 3455, etc.)
- Prepare the delegation of authority log
- Participate, as appropriate, in the training of individuals recruited as members of the research team.
- Meet with auditors (internal, sponsor, and FDA) at the conclusion of their audits to review findings.
- Collection of complete and accurate study data.
- In-service affiliated hospitals and/or TTUHSC clinics/staff on studies being done in their area prior to the start of enrollment, and document attendance.
- Enroll eligible subjects in studies and manage their participation according to ethical, regulatory, and protocol-specific requirements.
- Work with the Regulatory Specialist to communicate with the IRB as appropriate and per the TTUHSC Human Research Protection Program Manual.
- Prepare Unanticipated Event Reports and work with the Regulatory Specialist to submit to IRB.
- Maintain regulatory and other study files for each research project.
- Participate in quality assurance activities (i.e., monitoring visits, internal and external audits, sponsor audits, FDA audits).

Biostatistician

The CRI team's biostatisticians are available to researchers across all six campuses of the TTUHSC system for research projects, both small and large. Workload is managed in our work order system and depends on the work queue and the complexity of the project.

- Determine the most appropriate study design based on options for statistical analysis.
- Determine which statistical tests are most appropriate for the proposed study design.
- Perform analyses for assigned studies.
- Assist with the development of material for the dissemination of study results.

CRI Education and Training

Date	Educational Activity	Audience
February 26, 2025	Surgery Resident Education Seminar	Residents
March 28, 2025	Office of Research Connect	Faculty, Residents, Students
May 14, 2025	SurgiCure Cadaver	Faculty, Residents, Students
May 18, 2025	Center of Excellence for Nursing Research, Collaboration, and Innovation-Spring Research Symposium	Nursing Faculty, Students
May 21, 2025	B&W Fellowship Interviews	Residents
June 10, 2025	Cell Biology & Biochemistry Faculty Meeting	CBB Faculty
June 26, 2025	Burn Fellowship Orientation	Surgery Residents
July 18, 2025	Office of Research Connect	Faculty, Residents, Students

Dissemination activity

	Disseminations
Publications	3
Podium Presentations/Abstracts	2
Posters	21
TOTAL	**26**