



Annual Report

FY2024

Promoting Patient-Oriented Research and Training



EXECUTIVE DIRECTOR'S 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, daily 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 all human subjects research is conducted ethically, safely, and following best practices.

Vision for Leadership and Strategic Growth

We want to create a vibrant and collaborative network that positions TTUHSC faculty at the forefront of discovery and healthcare improvement. 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. Expanding Interdisciplinary Research Programs

To ensure the CRI remains at the cutting edge of scientific discovery, we will cultivate interdisciplinary research programs that reflect the diverse expertise of HSC faculty and staff. These programs will address emerging trends and opportunities in medicine while fostering mentorship, career development, and innovation. and internationally, enhancing its reputation for excellence and innovation.

3. Advancing Industry-Sponsored Research

A central component of the future of the CRI will involve expanding 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. 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 create and sustain a robust research agenda that meets the rigorous standards required for a National Cancer Institute (NCI) designation.

5. 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.

6. 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.

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 or research activities. 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. In doing so, we contribute to advancing the frontiers of medical knowledge, improving patient care, and fostering a culture of research excellence across the Health Sciences Center.

John Griswold, MD, FACS

SUMMARY:

FY 2024 saw the CRI move under the leadership Lance McMahon, PhD, Senior Vice President, of the Office of Research and Innovation. This fiscal year there were 151 CRI work orders approved requesting assistance with various aspects of clinical research from education, study design, statistical analysis, or Institutional Review Board (IRB) submission support. The CRI submitted 1,014 forms to the IRB; 118 of these were initial submissions of new studies; 345 were amendments; 74 were unanticipated events; 244 were submission responses; and the remaining were study closures, study cancelation forms, and continuing reviews. In this fiscal period, CRI helped 83 different principal investigators. Of those 83, 44 were novice principal investigators. Additionally, statistical analysis & reporting is up from 127 in FY23 to 205 in FY24; PubMed-indexed abstracts and manuscripts also increased this FY. *See also Table 1.*

The CRI's research volunteer database established in 2011 to allow the general public to independently sign up to be contacted about possible clinical research participation continues to grow, up to 778 volunteers this fiscal year. This database is queried periodically to help recruitment efforts for CRI-facilitated projects.

Grant support is a relatively new area of clinical research support for the CRI. CRI participated in 2 grants submitted through the Office of Sponsored Programs in FY23. Types of grants include clinical trials, biobanks, and registries. Participation included providing proposal review, statistical design, conducting pilot studies to provide supporting data for the grant, study support for funded grants, biostats support, and/or IRB work. One of the submissions was funded (NIH, Private, and Foundation), totaling \$450,000.00.

FY24 HIGHLIGHTS:

Achievements

- Successfully facilitated the contract execution with WCG Clinical, Inc. for statistical support services for TTUHSC.
- Successfully facilitated the finalization of Deep 6 AI integration, ready for go-live in Fall 2024.
- Odessa CRI worked with OB/Gyn department leadership to implement a monthly research hour to help with enthusiasm and facilitate clinical research.
- CRI held three retreats. The retreats helped foster communication with the CRI Executive Director, team building and inform staff of upcoming events and research studies in the pipeline.
- CRI welcomed five new staff members:
 - Veronica Janosick, Clinical Research Nurse
 - Monika Latour, Clinical Research Nurse
 - Julie McCloud, Clinical Research Nurse
 - Taylor Aldape, Clinical Research Nurse
 - Peyton Miles, Regulatory Specialist
- With the leadership of Dr. Jayne McCauley from the Department of Surgery, TTUHSC/CRI are collaborating with the University of Pittsburgh and the Department of Defense, to participate in the Calcium and Vasopressin following Injury Early Resuscitation (Cavalier) study. This is a randomized, placebo-controlled, double-blind study. The study will evaluate whether giving calcium, vasopressin, or both early in the course of treatment would help severely injured patients that lose a lot of blood survive their injuries. Normally, researchers must ask a person for their consent before they can be in a study. Because traumatic injuries must be treated right away, there may not be time to get consent, so a process called Exception from Informed Consent, or EFIC is used. Once the enrolled person is better and can consent or their family arrives at the hospital, the researchers will ask for consent to continue with the study. As part of EFIC, the federal regulations require each participating site to prepare and implement a public disclosure and community consult campaign. The purpose of this campaign is to notify the community of the project and get their feedback and thoughts about the project happening in their community by getting a survey completed. Anyone not wanting to take part in the study can request an “opt out” bracelet to wear to notify first responders/the hospital of their request not to be in the study. To date, the CRI presented CAVALIER clinical information at various venues and did a media blitz on English and Spanish radio, newspaper, billboards, and Facebook. The public activities included providing brochures and surveys to the public. The surveys were conducted by paper or electronically at the South Plains Fair, KCBD Health Expo, 100 Black Men conference, and various other public events. While implementation of the plan is not yet complete, our site has more surveys completed than any other site. Overall, community response to the study have been positive and supportive. We hope to get IRB approval to start the study in 2025.

Accolades

- The CRI facilitated UMC Cancer Center re-certifications
 - American College of Surgeons Committee on Cancer
 - NAPBC Accreditation (breast center)
- Mariana Fiori, PhD--- was awarded a 2024 TTUHSC Quality Staff Award
- The following CRI staff received their TTUHSC Years of Service Pins:
 - Staci Brown- 20 years
 - Veronica Janosick- 15 years
 - Rylee Law- 10 year
- Amanda West Romero, CRI Director/Monitor retired at the end of August after 14 years of service with TTUHSC CRI
- 2024 Lorenz O. Lutherer, MD, PhD, Clinical Research Award



Medical student Taha Hassan, BS won the 2024 Lorenz O. Lutherer, MD, Ph.D., Clinical Research Award for his work “*Altered Coagulation Activity in Burn Patients Treated with Albumin*”. The project was awarded during the 36th Annual Student Research Week, held from February 28 – March 1, 2024.

Challenges

Working with the new IRB system, Cayuse, continues to be a challenge for CRI and our researchers. While the system does not have the flexibility we have been used to, we continue to work closely with the IRB office to find better, more efficient ways of reporting and communicating using the system. The CRI has met with both the IRB chairs, IRB office staff, and the Research Integrity Office leadership to openly discuss how to improve efficiency and communication as we all work together to adapt to Cayuse.

MAJOR AREAS OF CLINICAL RESEARCH SUPPORT BY THE CRI:

The CRI continues to meet its objective of facilitating clinical research activities at TTUHSC. The activities of the CRI during FY24 as compared to FY23 are summarized in the following tables/graphs:

Table 1: Summary	*2023	2024	%Change
**Number of New Clinical Research Studies to the IRB	132	118	-10.61
Number of Novice Investigators	26	44	69.23
**Number of Forms Submitted to IRB	791	1010	27.69
Protocol reviews	309	190	-38.51
Study Design/Sample size/Analysis Plan	138	74	-46.38
Statistical Analysis & Reporting	128	206	79.13
Abstract/Presentation/Manuscript Development	88	35	-60.23
*Abstracts Presented	17	10	-41.18
% Abstracts Presented – PubMed Indexed	47.06%	50%	6.25
*Research Presentations	88	37	-57.95
*Published Manuscripts	28	74	164.29
% Published Manuscripts – PubMed Indexed	75%	64.86%	-13.52
Educational Presentations by CRI	49	32	-34.69
Total studies closed/canceled	17	17	0.0
Total studies completed	24	31	29.17

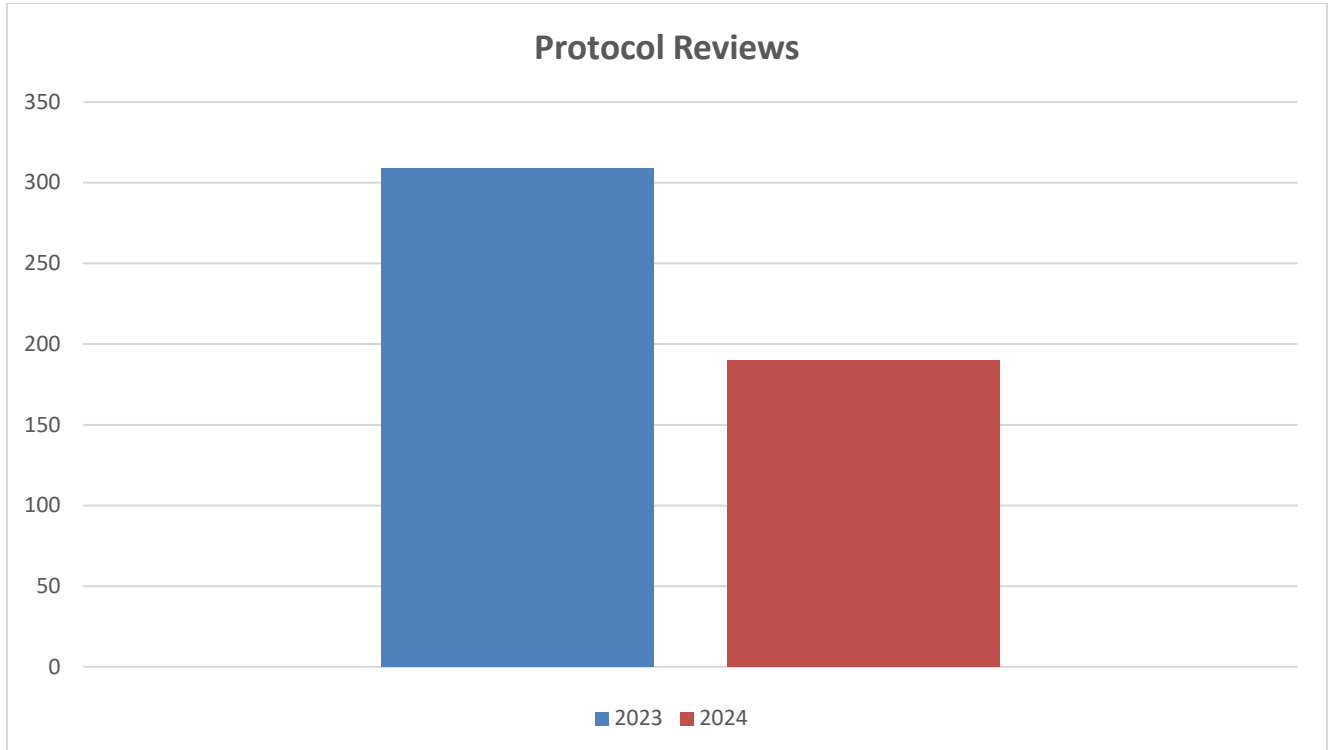
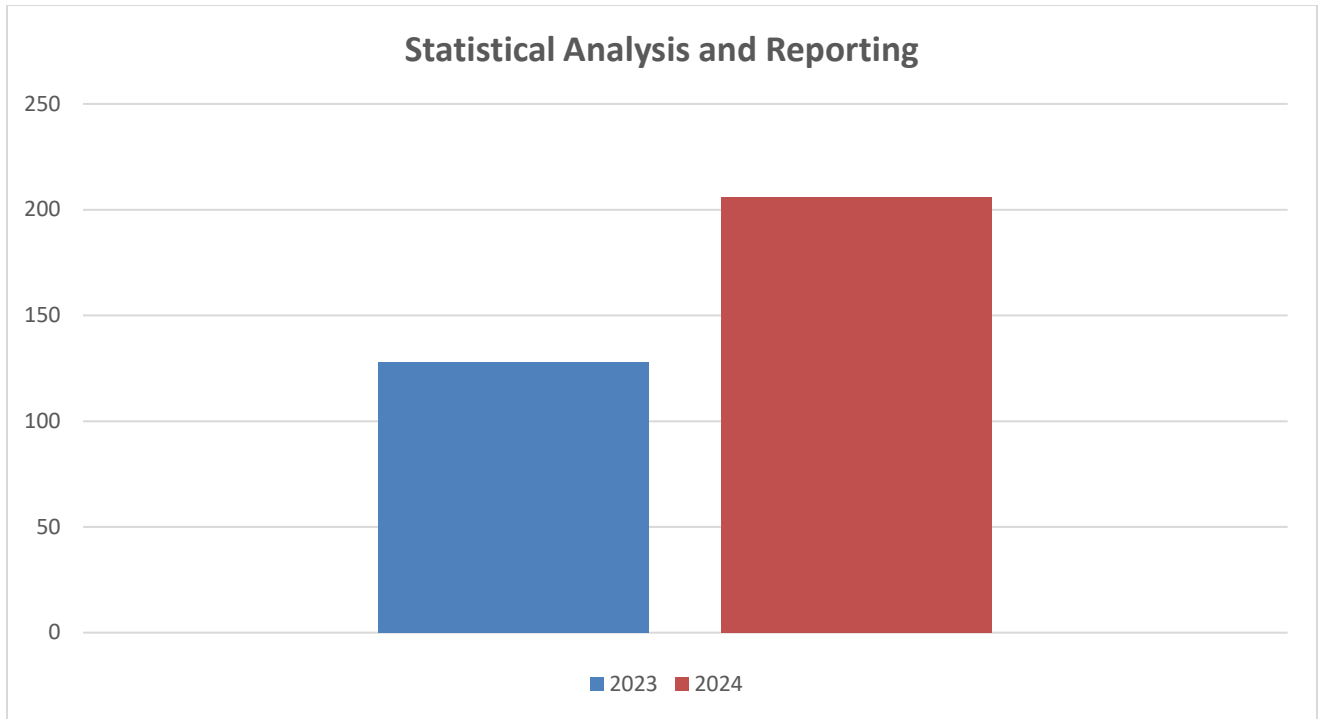
*Corrected numbers; *Number is dependent upon the CRI being notified of the abstract, presentation, and publication

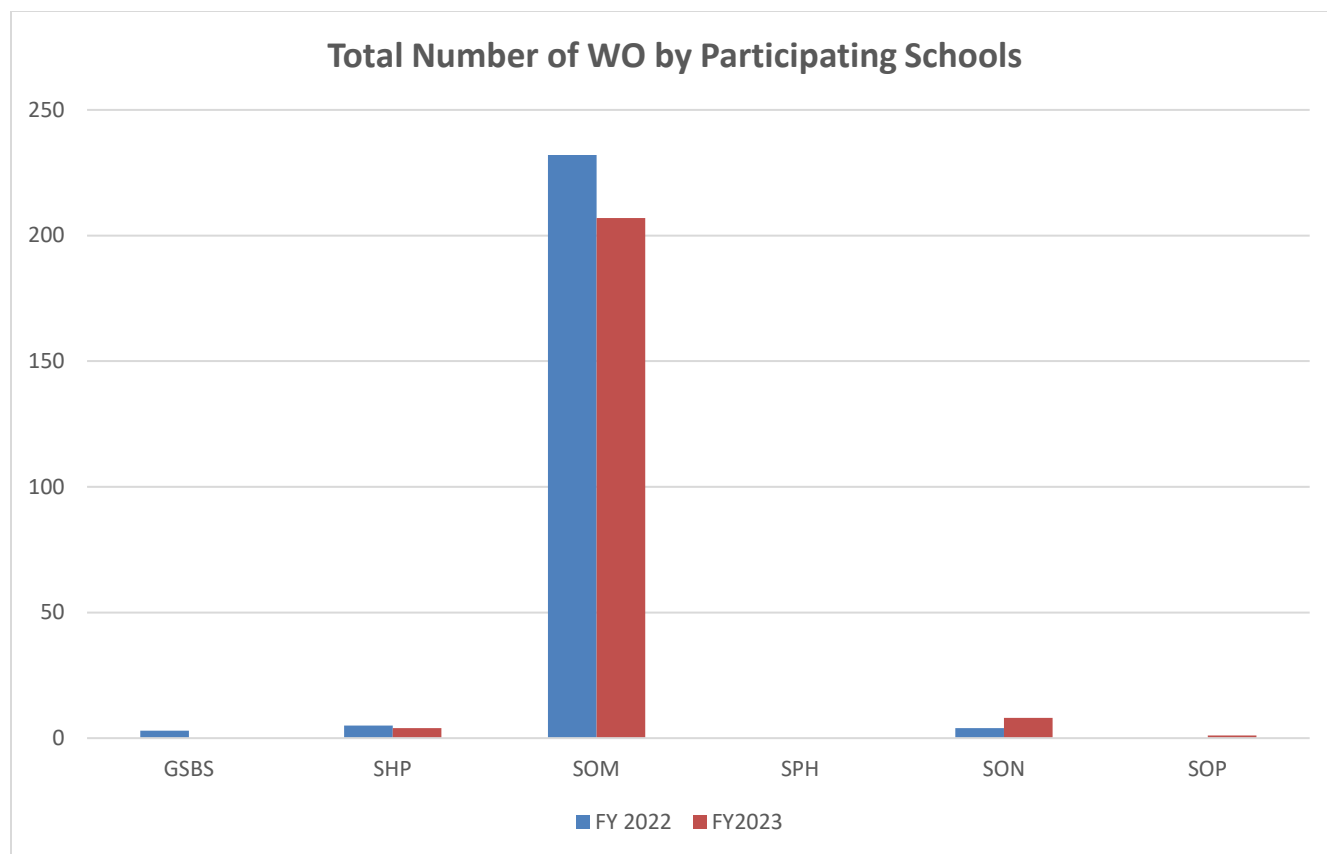
FY24 approved work orders by campus

Schools	Abilene		Amarillo		Dallas		Lubbock		Odessa		Total # of		% Total WO Per	
	FY 23	FY 24	FY 23	FY 24	FY 23	FY 24	FY 23	FY 24	FY 23	FY 24	FY 23	FY 24	FY 23	FY 24
SOM	0	0	7	9	0	0	178	122	11	6	196	137	87.11%	90.72%
SON	0	0	0	0	0	0	8	5	0	0	8	5	3.55%	3.31%
SHP	0	0	0	0	0	0	4	8	0	0	4	8	1.77%	5.29%
SOP	0	0	1	0	0	0	0	0	0	0	1	0	0.44%	0.00%
*GSBS	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	0.00%	0.00%
SPH	0	0	0	0	0	0	0	0	0	0	0	0	0.00%	0.00%
UMC Nursing Research	NA	NA	NA	NA	NA	NA	11	1	NA	NA	11	1	4.88%	0.66%
	0	0	8	9	0	0	201	136	11	6	220	151		

*GSBS primary appoints are in the School of Medicine

N/A Indicates the school does not have a presence on that campus.





FUNDING:

Primary funding for the CRI in FY24 came from Dr. John deToledo, Dean and Executive Vice President for Clinical Affairs, through the TTUHSC School of Medicine Office of the Dean. The School of Medicine medical practice income plan (MPIP) and clinical departments in Lubbock provide additional funding support. The Department of Psychiatry, through Senate Bill 11, provides CRI with funding assistance; and CRI residual funds from previous industry-sponsored research are also used. Moreover, the Dean of the School of Pharmacy contributes to the CRI overhead, along with a contractual arrangement between the CRI and the University Medical Center in Lubbock for the conduct of cancer studies. In the Permian Basin the School of Medicine Regional Dean's Fund, monies chiefly generated by the CMS uncompensated care program, finance much of the budget support for the Odessa CRI office.

MEMBERS OF THE CRI ADVISORY COMMITTEE:

All faculty and trainees at TTUHSC are considered customers of the CRI. The Clinical Research Institute is governed by an Advisory Committee that met three times during FY24. It is composed of faculty representatives from all schools and campuses, the TTUHSC President and Vice President for Clinical Affairs, the Senior Vice President for Research and Innovation, and the Executive Leadership team made up of the two Directors of the CRI: Executive Director John Griswold, MD, and Catherine Lovett, MSN, RN, Managing Director. The full list of FY24 CRI Advisory Committee members is provided in Appendix A.

CRI has 12 clinical research coordinator (CRC)/clinical research nurse (CRN) positions: 9 are in Lubbock and three are on the Permian Basin Campus. A Director for Regulatory Services/Monitor, a Director of Clinical Research Operations/CRN, a Section Manager/CRC for Regulatory Services, a Section Manager/CRC for Cancer Services, two regulatory specialists for submissions to the IRB, a Clinical Department Administrator, and an administrative assistant. We currently have one full-time statistician, Abdul Awal, BSC, MSC, MS and two PRN/as-needed statisticians: Milan Bimali, Ph.D., and Aya Bou Fakhreddine, MS. The full list of FY24 CRI staff members is provided in Appendix B.

EDUCATION:

In January 2024, The CRI held a Clinical Research Nurse/Coordinator Training Program, accredited for Nursing Continuing Education Units. This 2-month course held twice a week, included 4 weeks of didactic lectures and another 4 weeks of hands-on practice. Catherine Lovett, MSN, RN, and Mariana Fiori, PhD are co-chairpersons of the West Texas Chapter of the Society of Clinical Research Associates (SoCRA). Ms. Lovett was again on the Distinction in Medical Research program admissions committee. Further, leadership from CRI presents at New Faculty Orientation routinely, as well as, New Resident Orientation on both the Odessa and Lubbock campuses. The CRI helped students in the 2024 Medical Student Summer Research Program navigate clinical research protocol design, IRB submission, and data analysis.

The CRI continues individual interactions with investigators and trainees. These meetings involve protocol development, study design, conduct of the study, data analysis, presentations, and publications. Our experienced research coordinators and study monitor are available for clinical studies. The entire CRI team works closely with investigators to assist with study completion with the intent to publish in MEDLINE/PUBMED journals. The CRI leadership has contributed to the recruitment efforts of the institution by discussing the role of the CRI with potential faculty employees.

Presentations:

The CRI topics included but are not limited to the Faculty Development: Clinical/Translational Research Series, Medical Student Summer Research Program Orientation, P3 small groups, Medical Students year II, III, IV statistical sessions, Medical Students III EBM small groups, and various departmental research conferences.

DIRECT ASSISTANCE WITH THE STUDIES:

CRI personnel work with the investigators and trainees during each phase of a proposed study.

1. Each investigator submits a draft protocol, following the template provided on the CRI website. The protocol includes the research question/s, the background forming the basis for the question, objectives, the hypothesis, the study design, the methodology to be used, the statistics for analysis, and the potential significance of the study results. Members of the CRI team, including the biostatistician, work closely with the investigator's team during this process.
2. Assistance is given in developing documents such as informed consent forms, data collection forms, surveys, the IRB application, and subsequent amendments/reports to the IRB.
3. After IRB approval, the research coordinators consent and enroll subjects, collect samples, data, and essentially conduct the study under the direction of the Principal Investigator.

4. Once study accrual has been completed, the biostatisticians analyze the data, construct tables and figures, and assist in writing the presentation/manuscript. Members of the CRI Executive Leadership are available and often assist the principal investigators in completing or revising the articles prior to submission to the journal of their choice.

Currently, CRI services are provided at no cost to the investigators due to the funding mechanisms in place. This unique system allows investigators to obtain pilot data necessary to support future funding requests. The CRI resources are invaluable to faculty with busy schedules and help to partially offset the lack of protected time for research.

Appendix

A. FY24 CRI Advisory Committee Members

Alyce Ashcraft, PhD, RN, CNE, FNGNA, ANEF, School of Nursing

John deToledo, MD, Vice President of Clinical Affairs and Dean, School of Medicine

John Griswold, MD, FACS, Executive Director, CRI

Ronald Hall, PharmD, MSCS, School of Pharmacy, Dallas Campus

Troy Hooper, PT, LAT, ATC, PhD, School of Health Professions

Catherine Lovett, MSN, RN, CCRC, CCRP, Managing Director, CRI

Lance McMahon, PhD, Senior Vice President, Office of Research and Innovation

Lavi Oud, MD, School of Medicine, Permian Basin Campus

Lori Rice-Spearman, PhD, President

Leslie Shen, PhD, CCRP, School of Medicine

Phil Sizer, Jr., PhD, Associate Vice President for Research Innovation

B. FY24 Clinical Research Institute Team

Lubbock:

Taylor Aldape, RN, Clinical Research Nurse

Abdul Awal, BSC, MSC, MS, Biostatistician

Milan Bimali, PhD, PRN Biostatistician

Destiny Carr, RN, Clinical Research Nurse

Aya Bou Fakhreddine, MS, PRN Biostatistician

Staci Brown, Administrative Assistant

Mariana Fiori, PhD, CCRC, Section Manager, Cancer Studies/Clinical Research Coordinator

John Griswold, MD, FACS, CPI, Executive Director

Nadia Jimenez, BS, Clinical Research Coordinator

Monika Latour, RN, Clinical Research Nurse

Rylee Law, LVN, BS, CCRC, Section Manager, Regulatory Affairs/Clinical Research
Coordinator

Catherine J. Lovett, MSN, RN, CCRC, CCRP, Managing Director

Josie Martinez, Clinical Department Administrator

Julie McCloud, RN, Clinical Research Nurse

Peyton Miles, BS, Regulatory Specialist

Amanda Romero, MS, RN, CCRC, Director of Regulatory Affairs/Monitor

Chris Scott Johnson, MSN, RNC, CCRC, CA/CP, SANE, Director of Clinical Research
Operations

Eric Soto, BS, Regulatory Specialist

Lane Young, BA, CCRC, Clinical Research Coordinator

Permian Basin

Jammie Holland, LVN, CCRC, Clinical Research Coordinator

Veronica Janosick, RN, Clinical Research Nurse

Evangelina Santiago, LVN, CCRC, Clinical Research Coordinator

C. Dissemination of Information

Abstract (10) PubMed (5)

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Rizvi M, Alshaikhsalama M, Brown E, Pang A, Bharadia DR, Griswold JA. Symptomatology of Hypertrophic Scarring in Full and Partial Thickness Burns Using Autologous Keratinocyte Suspension in Conjunction with Split-Thickness Skin Grafts. *Journal of the American College of Surgeons*, 236(5), S137-S137

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Presentation (37)

Adams E, Agyare K, Nwankpa C, Aickareth G, Sauers D, Garcia A, Griswold J, Pang A. A retrospective study analyzing anesthesia intubation criteria in burn patients. TTUHSC Student Research Week, February 28, 2024 - March 1, 2024, Lubbock, TX

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Bingi S, Vojtkofsky N, Azzam S, Clark J, Pang A, Griswold J. Analyzing the relationship between administration of postoperative antibiotics and graft outcomes in a burn center, TTUHSC Student Research Week, February 28, 2024 – March 1, 2024, Lubbock, TX

Buccoliere A, Tran V, Helo N, Awal A, Stroever S, deRiese W. Novel clinical risk calculator for improving cancer predictability of mpMRI fusion biopsy in prostates. TTUHSC Student Research Week, February 28, 2024 - March 1, 2024, Lubbock, TX

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Kroll T, Fredman T, Coneway B. Responsive parenting and parent coaching: They go together like biscuits and gravy. Texas Speech Language Hearing Association convention, Austin, TX, February 26, 2023

Kroll T, Fredman T, Corwin M, Wi H, Coneway B, Garrison M. The sweet to your tea: Using joint engagement to promote language development. Texas Speech Language Hearing Association Convention, Austin, TX, February 23, 2023

Kroll T, Palafox P, Morgan M. Roles, boundaries and lack of support: Why school based SLPs struggle and are overwhelmed. TTUHSC Center for Speech, Language and Hearing, Lubbock, TX, December 2, 2022

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