HEALTH SCIENCES
CLINICAL & TRANSLATIONAL SCIENCE CENTER

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CTSC Grant Number: UL1TR001449
KL2 Grant Number: KL2TR001448

Clinical & Translational Science Center Newsletter

June 2022

Letter from the Director

Dear Colleagues,

Summer is almost here and hopefully it won't get too hot. We are entering into the final month of FY2022, time to start closing out old projects and get ready to launch new ones for FY2023. New funding opportunities can now be found online at https://hsc.unm.edu/research/news/funding-opps.html.

I would like to invite all faculty, staff, and students to Joseph V. Scaletti Memorial Lecture on Friday, June 24th, at 12:00 PM – 1:00 PM, as part of a Special CMBD Lecture Series. The presenter will be Manisha Jhamb, MD, MPH. Dr. Jhamb's talk will focus on innovations in population health that are improving outcomes in patients with chronic kidney disease. The presentation will be in-person at the College of Pharmacy and College of Nursing Auditorium or can be watched online at Zoom: https://hsc-unm.zoom.us/j/91217781015.

I am also pleased to tell you about some of the high impact studies that the CTSC is supporting.

Our Community Engagement and Research Core (CERC) team contributed to the authorship of a manuscript that has recently been accepted for publication in Female Pelvic Medicine & Reconstructive Surgery. The research for this manuscript involves women with interstitial cystitis/bladder pain syndrome (ICBPS). This study examined centering models of group medical visits and their impact on ICBPS therapy. The manuscript focuses on the qualitative information for the Centering Group and a Control Group of women with ICBPS. This analysis provided advantages and limitations to ICBPS Centering therapy.

Thais Schwartz of the CTSC BERD Core assisted Dr. Sophia Markee and her research mentor Jean Lowe in completing the analyses for her study entitled: The Influence of Maternal-Child Interactions During Early Child Development and the Impact on Anterior Cingulate Cortex Volumes. Their study aimed to identify early imaging biomarkers of later cognitive function. This research found a negative correlation between the right Anterior Cingulate Cortex volume in children that received more negative directing behaviors from their mother during play at 18-months.

Participation Clinical Interactions (PCI) would like to share the work of their team member Vanessa Garcia is doing with her nonprofit Safe Space New Mexico Fire Relief Fund, which helps people affected by the recent wildfires in New Mexico. Safe Space collects donations and grants to pay for shelter for evacuees of New Mexico fires while working with a network of local hotel owners. They speak to all evacuees that they assist, and in partnership with other organizations provide, other personal needs. To date Safe Space has assisted 125 families with multiple nights of hotel shelter. The majority of the evacuees they help are elderly.

In great news for UNM HSC researchers CTSC's Good Clinical Practice (GCP) training is now recognized by the pharmaceutical industry, reducing the amount of work researchers must do to prove ethical compliance. Prior to May 2022, CTSC researchers had to do double the work in proving their GCP compliance when working with Pharma and the NIH. While the NIH had previously accepted CTSC's GCP training, pharma companies did not recognize it as meeting their regulatory needs. Please note only certificates issued after May 1, 2022 are accepted by TransCelerate.

Every part of the CTSC is integral to our purpose and funding, and we aim to update each section of the CTSC newsletter monthly. Each PI has a personal, professional investment in the information we provide. Please submit that information to our team. The CTSC is here for your support.

The dedicated faculty, staff, and students at CTSC continue their research projects and look for innovative ways to support our communities. If you are interested in a rigorous quantitative rural research project focused on COVID-19, please contact me (RLarson@salud.unm.edu) to start a dialogue.

Masks are still required indoors for all staff in all clinical areas at the HSC, but are now optional for staff in non-clinical areas. Stay abreast of the current policies by exploring the University's Bring Back the Pack COVID-19 guidance: https://bringbackthepack.unm.edu.

The Health Sciences Center Office of Research website contains information on specific research-related updates (including the Research Continuity Guidelines for both Laboratories & Research Facilities and Clinical Trial Research Faculty & Staff) and can be accessed through the following link: https://hsc.unm.edu/research/.
All standard CTSC services are available. We encourage PIs to reach out to our Research Concierge (HSC-CTSCResearchConcierge@salud.unm.edu) with questions and/or to setup a consultation with the CTSC team.

If you have any questions about our assets and services, please contact the CTSC Research Concierge at HSC-CTSCResearchConcierge@salud.unm.edu. If you have any issues finding the information that you need, please reach out to the CTSC Newsletter Team and they will get back to you.

As always, thank you so much for your continued support of the Clinical & Translational Science Center!

Warm regards,

Richard S. Larson, MD, PhD
PI, CEO and Director, Clinical & Translational Science Center

CTSC Leadership

CTSC Director, CEO & Principal Investigator: Richard S. Larson, MD, PhD
Associate Director, CTSC: Matthew Campen, PhD
Associate Director, CTSC: Nancy Pandhi, MD, PhD, MPH
Chief Administrative Officer: Carla Cordova, MPH
Administrative Component Director: Beth Tigges, PhD, RN, PNP, BC
Tracking & Evaluation Module Lead: Beth Tigges, PhD, RN, PNP, BC
Quality & Efficiency Module Lead: Beth Tigges, PhD, RN, PNP, BC
Informatics Component Director: Christophe Lambert, PhD
Community & Collaboration Component Director: Mark Unruh, MD
Community Engagement Module Lead: Robert Rhyne, MD, MPH
Collaboration and Commercialization Module Lead: Eric Prossnitz, PhD
Translational Endeavors (TE) Component Director: Craig Wong, MD, MPH
Translational Workforce Development (TWD) Module Lead: Karlett Parra, PhD
Pilot Translational & Clinical Studies (PTC) Module Lead: Corey Ford, MD, PhD
Research Methods (RM) Component Director: Mark Unruh, MD
Biostatistics, Epidemiology & Research Design (BERD) Module Lead: Mark Unruh, MD
Regulatory Knowledge & Support (RKS) Module Lead: Susan Kunkel, PharmD
Hub Research Capacity (HRC) Component Director: Nancy Pandhi, MD, PhD, MPH
Integration of Special Populations (ISP) Module Lead: Nancy Pandhi, MD, PhD, MPH
Participant Clinical Interactions (PCI) Director: Christos Argyropoulos, MD
Network Capacity (NC) Component Director: Hengameh Raissy, PharmD
Trial Innovation Network (TIN) Module Lead: Hengameh Raissy, PharmD
Drug Discovery & Repurposing Core Lead: Angela Wandinger-Ness, PhD
Opioid-Use Populations with Integration, Outreach, Informatics, and Drug Discovery (OPIOIDD) Module Lead: Kimberly Page, PhD, MPH
KL2 Mentored Career Development Component Director: Matt Campen, PhD
Clinical Laboratory Medical Director: Qian-Yun Zhang, MD, PhD

Featured Stories

Joseph V. Scaletti Memorial Lecture as Part of a Special CMBD Lecture Series

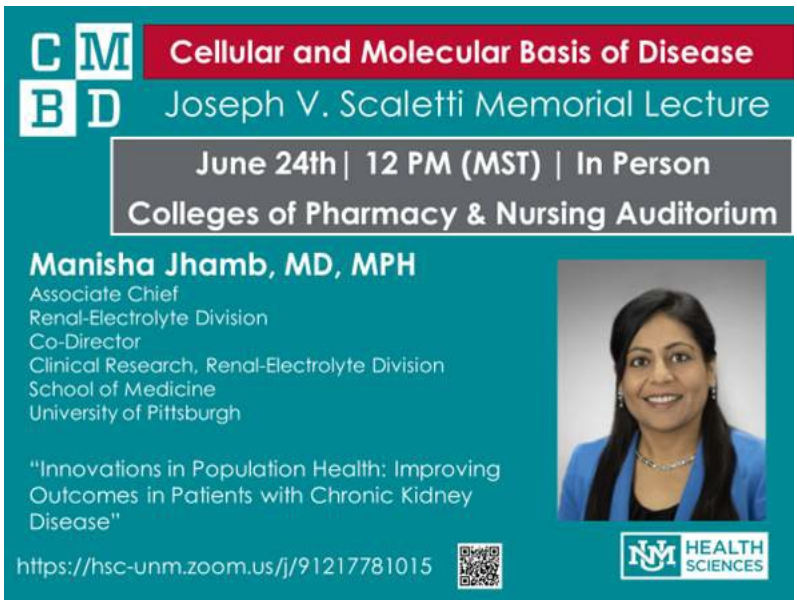
Please join us on Friday, June 24th for the Joseph V. Scaletti Memorial Lecture as part of a Special CMBD Lecture Series with presenter Manisha Jhamb, MD, MPH. Dr. Jhamb's talk will focus on innovations in population health that are improving outcomes in patients with chronic kidney disease.

Dr. Jhamb is the Associate Chief for the Renal-Electrolyte Division, Director for the Center for Population Health Management, Co-Director for Clinical Research in the Renal- Electrolyte Division, and an Associate Professor of Medicine (with Tenure) at the University of Pittsburgh School of Medicine.

Dr. Jhamb is an academic nephrologist, with over 10 years' experience conducting clinical research in patients with Kidney Disease. Her research is aimed at understanding and improving patient-centered outcomes in patients with advanced kidney disease. Dr. Jhamb has also been researching the use of electronic health records to improve delivery and safety of chronic kidney disease care, especially to

vulnerable populations who are at the highest risk of developing end-stage kidney disease and do not have access to timely nephrology care.

What: Joseph V. Scaletti Memorial Lecture
When: June 24, 2022 12:00 PM – 1:00 PM
Location: In Person at College of Pharmacy and College of Nursing Auditorium
Zoom: https://hsc-unm.zoom.us/j/91217781015
Topic: Innovations in Population Health: Improving Outcomes in Patients with Chronic Kidney Disease



Community Engagement and Research Core (CERC)

The CTSC Community Engagement and Research Core (CERC) contributed to the authorship of a manuscript that has recently been accepted for publication in Female Pelvic Medicine & Reconstructive Surgery. The CERC team worked along with the study PI, Kate Meriwether, Assistant Professor, Department of Obstetrics and Gynecology. The research for this manuscript involves women with interstitial cystitis/bladder pain syndrome (ICBPS). This study examined centering models of group medical visits and their impact on ICBPS therapy.

ICBPS affects up to one in 10 women. While treatment does exist for ICBPS, it can be complex and ineffective. The chronic pain that women experience due to ICBPS can lead to opioid use, thereby contributing to the opioid crisis.

Centering models are medical visits that emphasize community and peer collaboration to advance health education and wellness. These visits consist of a standard medical visit along with interactive learning and community building in a group setting facilitated by a credentialed provider.

The manuscript focuses on the qualitative information for the Centering Group and a Control Group of women with ICBPS. This analysis provided advantages and limitations to ICBPS Centering therapy. Those attending Centering appreciated that they were able to learn from other women in

the group, that the Centering group was safe and supportive, and they were receptive to novel and alternative treatments that were advocated by other patients or the group leader.

The manuscript also highlights the advantages of utilizing qualitative research in ICBPS. Qualitative data collection allowed the researchers to hear the patient narratives regarding the strengths and shortcoming of Centering intervention.

For more information about CERC services, please contact Donna Sedillo at: dlsedillo@salud.unm.edu

Biostatistics, Epidemiology, and Research Design (BERD)

Thais Schwartz of the CTSC BERD Core assisted Dr. Sophia Markee and her research mentor Jean Lowe in completing the analyses for her study entitled: The Influence of Maternal-Child Interactions During Early Child Development and the Impact on Anterior Cingulate Cortex Volumes. Dr. Lowe is an Associate Professor of Pediatrics, Neonatology Developmental Care SOM - Pediatrics. Their study aimed to identify early imaging biomarkers of later cognitive function, the risk for behavior, and psychiatric or neurodevelopmental disorders. This research found a negative correlation between the right Anterior Cingulate Cortex volume in children that received more negative directing behaviors from their mother during play at 18-months, as measured by the Maternal Attention Directing Manual.

Please visit our web site: http://hsc.unm.edu/research/ctsc/biostatistics/index.html.

Participation Clinical Interactions (PCI)

PCI would like to share the work of their team member Vanessa Garcia is doing with her nonprofit Safe Space New Mexico Fire Relief Fund, which helps people affected by the recent wildfires in New Mexico.

Safe Space New Mexico Fire Relief Fund a 501 (c)(3) nonprofit charity (tax deductible) that provides sanctuary hotel shelter and other needs that emerge for evacuees from New Mexico wildfires. For four weeks Northern New Mexico community residents have been, and are continuing to be, evacuated from their homes due to Hermit's Peak and Calf Canyon fires. Residents that are affected by the Cerro Pelado Fire are on ready status. Safe Space collects donations and grants to pay for shelter for evacuees of New Mexico fires while working with a network of local hotel owners. They speak to all evacuees that they assist, and in partnership with other organizations provide, other personal needs. To date Safe Space has assisted 125 families with multiple nights of hotel shelter. The majority of the evacuees they help are elderly. In partnership with the Elks Lodge #461 they have also provided gloves, sleeping bags and personal items for fire fighters. The Safe Space motto is "Seeing the need, meeting the need with care and compassion; making a difference one life at a time."

Because of Safe Space many families are able to have safe shelter without needing to keep moving from place to place minimizing trauma caused by the wildfires and to help to begin the healing.

Thanks Vanessa and Safe Space for all the incredible work being done to help New Mexicans in their time of need. For more information please see their website https://www.nmfirerelief.org/.

If you have any questions about PCI services, please contact George Garcia, gemgarcia@salud.unm.edu.

http://hsc.unm.edu/research/ctsc/participant-clinical-interactions/index.html

CTSC Good Clinical Practice Training Accreditation

CTSC's Good Clinical Practice (GCP) training is now recognized by the pharmaceutical industry, reducing the amount of work researchers must do to prove ethical compliance. Prior to May 2022, CTSC researchers had to do double the work in proving their GCP compliance when working with Pharma and the NIH. While the NIH had previously accepted CTSC's GCP training, pharma companies did not recognize it as meeting their regulatory needs. Thus, CTSC researchers had to complete both CTSC's in-house GCP training and the CITI GCP training.

With the recognition of the CTSC's training by pharma, compliance training requirements for CTSC researchers has been reduced. Specifically, all CTSC GCP certificates issued after May 1, 2022 are now recognized by the TransCelerate GCP Mutual Recognition Program. The TransCelerate GCP Mutual Recognition Program is an industry program which allows sponsor companies to know that GCP trainings meet the ICH E6 R2 minimum criteria.

Only certificates issued after May 1, 2022 are accepted by TransCelerate. There is no retroactive acceptance. Investigators with CTSC GCP training certificates prior to May 2022 can retake the training if they want to receive a TransCelerate-accepted certificate. But if an investigator has their CITI GCP training certificate already, pharma acceptance is already achieved. This will ensure that future GCP certification will be easier for pharma trials. *Please note that all CTSC Active Investigators are required to take the CTSC GCP training regardless of whether they already have their CITI GCP training certificate*.

When should I recertify?

- Researchers receiving NIH or other federal funds should recertify in CTSC GCP training at the expiration of their certificate.
- Researchers who receive pharma funding should examine their sponsor requirements:
    - If a researcher's pharma sponsor accepts CITI training, then they can wait until their CITI expires and then recertify with CTSC GCP.
    - If the sponsor *does not* accept CITI training (or requires another training), then a researcher should take that opportunity to recertify via CTSC GCP training.

To view CTSC's training calendar and register for the CTSC GCP course: https://unmevents.unm.edu/site/hsc?category=e80bcc4a-124b-494d-8945-054a0092ef35&view=grid

To learn more about the TransCelerate GCP Mutual Recognition program: https://transcelerate-gcp-mutual-recognition.com

Menu of Services & Resources

- Biostatistics Support
- Brain & Behavioral Disorders
- Citing the Clinical & Translational Science Center
- Clinical Trials Participant Clinical Interactions
- Community Engagement
- Community Health Network
- Database Mining
- Drug Repurposing
- KL2 Scholars
- Intramural Funding
- Laboratory Services
- Pilot Funding
- Trial Innovation Network
- Quality & Efficiency
- Regulatory Knowledge & Support
- Rural Health Research
- Team Science & Commercialization
- Training
- Vulnerable Populations

Administration

Tracking & Evaluation (T&E)

The Tracking and Evaluation Team is piloting a new "Common Metric" called the Median Accrual Metric. This metric is intended to look at our CTSC's ability to recruit and retain research participants. This metric will look at the entire calendar year for 2020 and will be reported in fall 2021.

Quality & Efficiency (Q&E)

The Quality and Efficiency Team continues to work on two specific process improvements initiatives. These two projects concluded in June of 2021 and will be evaluated for how the projects impacted our CTSC.

Informatics

The CTSC Biomedical Informatics group (BMI) helped organize and teach an in-person workshop on May 16 and 17 which was open to all HSC faculty, staff and students on R for reproducible scientific analysis. The workshop taught basic R and programming skills using a hands-on and interactive methodology geared towards the needs of researchers at HSC.

The Institute for Public Health was particularly well represented. ESPCOR, the New Mexico smart grid project supported the workshop with catering and travel reimbursement.

The CTSC was able to use its extensive experience in getting and analyzing the data to inform its teaching. Pre and post-survey results showed a strong impact on students who attended in improving their programming and data analysis skills. Another similar workshop is being planned for Fall 2022.

If you would like to get a research question feasibility count or have potential research data questions please contact Marguerite Valencia-Reed mvalencia-reed@salud.unm.edu or Harry Snow hsnow@salud.unm.edu.

https://hsc.unm.edu/research/ctsc/informatics/index.html

Community & Collaboration (C&C)

Team Science & Commercialization

"Science doesn't happen in a vacuum (unless your experiment requires vacuum conditions). The whole philosophy of scientific investigation requires every idea to go through validation and scrutiny by many scientists. This process can be a bit time-consuming, and sometimes harsh, however it serves to improve not only the results, but the entire process."

Myth of the genius solitary scientist is dangerous
Ken Clark Professor of Astroparticle Physics
https://theconversation.com/myth-of-the-genius-solitary-scientist-is-dangerous-87835

CTSC Team Science Activities

CTSC Education and Training. CTSC courses focus on building a strong foundation and skill set in research through special training seminars focused on Team Science and Commercialization. New courses opened in April 2022 and are open to all staff, faculty, and students. More information and Registration can be found on the CTSC Training Catalog webpage.

CTSC Annual BioVenture Partnership Event. Save the Date for Friday, November 11, 2022 for the annual CTSC BioVenture Partnership event, which is open to faculty, residents, students, and the community. BioVenture aims to create important connections between UNM HSC Research and local biotech business to build long-term interorganizational relationships, while boosting the state's biotech economy and expanding health care innovation in our state. The event activities include a Scientific Poster session and Pitch Competition. More information will be forthcoming, bookmark the CTSC BioVenture webpage to find the latest information.

CTSC Translation Synergy Meetings. These meetings welcome both specific and interdisciplinary research communities, from early-career scientists, established investigators, to students, as we strive to enable better networking, collaboration, teaching, and leadership. ***If you would like to be a speaker or are seeking collaboration opportunities*** contact the CTSC Team Strategist, about the Fall 2022 CTSC Synergy Meetings.

ASCEND Hub (Accelerating Solutions for Commercialization and Entrepreneurial Development). ASCEND is a Regional Technology Transfer Accelerator Hub for the seven Mountain West IDeA States: Alaska, Hawaii, Idaho, Montana, Nevada, New Mexico, and Wyoming. ASCEND programs promote entrepreneurship, technology transfer, and other skills needed to move discoveries and technologies out of the lab and into commercial products that address human health. Recent CTSC activities with ASCEND have included:

- May 16, 2022 *ASCEND Office hours with John Chavez*. Virtual opportunity for faculty to meet one-on-one with John Chavez, Managing Director of New Mexico Start-Up Factory and former President of New Mexico Angels, to work on commercializing their technology or learning about the start-up ecosystem.
- April 28 2022, *ASCEND Webinar: Funding Your Startup*. Webinar about funding options available to startups in the biosciences.

13th Annual International Science of Team Science Conference. This conference is scheduled for July 31 to August 3, 2022, in Bethesda, MD. The SciTS 2022 conference is the premier annual gathering of scholars, practitioners, and providers in the field of Team Science. Bringing together a broad range of disciplines to share and advance the latest evidence-based methods in team collaboration and transdisciplinary research. For more information about the conference visit the ISciTS website, (https://sts.memberclicks.net/)

For more information about any of the CTSC Team Science activities, contact Melanie Hazlett, CTSC Team Strategist.

https://hsc.unm.edu/research/ctsc/programs/team-science.html

Translational Endeavors (TE)i

Translational Workforce Development (TWD)

Translational Workforce Development has numerous course offerings and can even provide consultations as requested to assist you in your goals! Please request a consultation or additional information on any courses offered. The TWD team may be reached via HSC-CTSCTWDTraining@salud.unm.edu.

For information regarding TWD, please visit our webpage:
https://hsc.unm.edu/research/ctsc/training/index.html

Pilot Awards

The UNM Clinical & Translational Science Center (CTSC) is soliciting applications from all HSC faculty members– senior as well as junior investigators– in response to the following pilot Request For Application.

We strongly encourage investigators to meet with the CTSC Research Concierge, HSC-CTSCResearchConcierge@salud.unm.edu, early in the planning and writing phases of their proposals in order to discuss CTSC resources required. If you have any questions please do not hesitate to contact Christina Anderson, CTSC Pilot Program Specialist, at ChAnderson@salud.unm.edu.

Reminder of the new timeline for pilot submissions in March.

November 11, 2021	**Request for Applications Release Date**
January 21, 2022	IRB Submission Deadline *Note: Any application without IRB submission prior to this date will be administratively disqualified*
March 18, 2022	**Application Deadline in Camino** IRB Approval Deadline *Note: Any application without IRB approval by this date will not be considered for funding.*
April 11, 2022	Notice of Intend to Fund/Decline
May 13, 2022	Announce Awards
June 1, 2022	**Funding Begins**
May 31, 2023	**Funding Ends**

Pilot Award

As part of our CTSC award, NIH has identified the need to speed the movement of clinical research findings into the everyday practice of health care delivery. The purpose of this award is to support pilot projects that utilize CTSC infrastructure to produce preliminary data for competitive NIH grant proposals in clinical and translational (T1, T2, T3, and T4) research.

Linking Clinical Trials to Drug Discovery and Repurposing Award

This RFA is a solicitation of applications from active CTSC investigators for projects that will link clinical research with drug discovery efforts in the Center for Molecular Discovery. The goal of this program is to: 1) develop cell-based assays for use in high-throughput screening, 2) to use these cell-based assays for the identification of drugs for clinical repurposing efforts, and 3) to utilize these previously FDA

CTSC/DCI Kidney Pilot Project Award

The CTSC, in conjunction with Dialysis Clinic, Inc. (DCI), are soliciting applications for pilot projects that will exemplify the CTSC mission of developing clinical and translational research with an emphasis on kidney disease, hypertension, and/or kidney transplantation. The purpose of this RFA is to support pilot projects that utilize the CTSC infrastructure to produce preliminary data for competitive NIH grant proposals in kidney disease, hypertension, and/or kidney transplantation clinical and translational (T1, T2, T3, and T4) research.

Innovation & Commercialization Award

The purpose of this RFA is to support innovative, high-risk/high-reward pilot projects to produce preliminary data for competitive NIH proposals in clinical and translational research. Most awards will be expected to seek NIH funding, most likely through an SBIR/STTR mechanism. These projects are intended to provide the preliminary data and initial corporate relationships to develop technology and move it towards successful commercialization.

Wicked Problems: Target Pilot Project Award

The National CTSA Network has identified a list of common and/or emerging problems (“wicked problems”) that require urgent scientific solution. The purpose of this RFA is to support pilot projects that tackle one of the targeted wicked problems listed below relating to data sharing and protection, big data, datasets or research collaboration:

- Data Sharing
- Big data to alter practice/diagnosis
- Use of multiple datasets
- Access to resources to address labor-intensive activities
- Privacy and data protection for research
- Removing institutional bottlenecks/sharing of resources
- Evaluating the impact of translational research efforts
- Implementing scientific review before studies are performed
- Dissemination and implementation Science
- EHR data integration
- Defining Impact for the CTSA Program
- Building a KL2 Scholar Community
- Addressing challenges in recruiting from rural sites
- Hub Stability

Mentored Career Development Program (KL2)

The KL2 program equips a cohort of independent faculty with the training and support needed to conduct exceptional clinical and translational research. KL2 Scholars receive training and mentorship in multi-disciplinary, team-based, and patient-oriented clinical and translational research. KL2 Scholars become leaders and innovators in their respective professional fields and departments.

Based on a NIH-style competitive application process, a scientific review panel selects scholars to develop their research portfolios by receiving 75% salary support for up to five years. The goal of this program is to foster the discipline of clinical research and, by increasing clinical research capacity, to expedite clinical and translational research.

https://hsc.unm.edu/ctsc/programs/mentored-career-development.html

Research Methods (RM)

Biostatistics, Epidemiology, and Research Design (BERD)

Biostatistics Consultation Services Available at CTSC

The Biostatistics, Epidemiology, and Research Design (BERD) Core provides consultation and services, novel tools and methods intended to solve problems, and address barriers to the conduct of clinical and translational research. Services are open to all Health Sciences investigators (staff, students, and faculty) to understand the methodological aspects of their research for planning their projects, including power analysis, sample size, and research design for intermural and extramural grant submissions.

If you have a current pilot study that requires biostatical support, please schedule appointments as soon as possible.

Are you interested in applying for a pilot study? It is strongly recommended that you make an appointment with one our biostatisticians prior to your submission. Our expert biostatisticians can help in the initial stages of project development.

Appointments are available; but do fill up quickly. To schedule an appointment, please contact HSC-CTSCbiostats@salud.unm.edu. Services are offered Monday through Friday.

Please visit our web site: http://hsc.unm.edu/research/ctsc/biostatistics/index.html.

Regulatory Knowledge & Support (RKS)

The clinical research community is supported by the Federal Regulatory Support. This no cost service at the UNM HSC provides assistance with sponsor-investigator IND or IDE applications. This includes personal consultation and helpful templates through online modules on a range of topics related to FDA regulated studies. The goal is to provide the research community with the tools, training and support needed to navigate the complex regulatory pathways that accompany translational research. As part of this support, the UNM CTSC regulatory manager, Samiha Mateen, serves as a liaison to assist investigators in 4 key areas:

1. **Early Regulatory Strategy Development:** We encourage early interaction as a means to develop a regulatory strategy that is appropriate for the complexity of each research project.
2. **Regulatory Submissions and Maintenance:** We provide templates and consultation in preparation, submission, and maintenance of regulatory applications to the FDA.
3. **ClinicalTrials.gov:** PRS administration that includes user account creation, maintenance, updates and consultation.
4. **Regulatory Education and Training:** We provide a variety of educational programs, including tailored educational seminars and recorded FDA webinars.

Assisting in these areas helps keep research studies on track and ensures a fluid process while developing each project. The goal of the UNM CTSC Regulatory Department is to help make each research project a success in translational science.

For more information on how we can help, please contact Samiha Mateen at smateen@salud.unm.edu

Hub Research Capacity (HRC)

Integrating Special Populations (ISP)

The aim of the CTSC ISP team aim is to identify, develop, and deploy strategies to involve populations who are underserved or otherwise underrepresented in all stages of research. Urging investigators to design scientifically sound CTR that includes special populations from the outset is of critical importance. To aid investigators in these efforts, ISP has developed the new specialized Rurally Engaged, Spanish speaking or Network Specialized Experts (RESPONSE) team led by experienced faculty with mixed-methods CTR expertise. This group will provide pre-proposal consultations. Consultations will focus on best practices and considerations in New Mexico's special populations, and identify and connect investigators to potential engagement partners, collaborators, and UNM CTSC resources and

services. The team coordinates closely with other CTSC cores (e.g., CERC, Translational Endeavors, KL2). Consults are currently available via web-based technology.

For more information on Integrating Special Populations, please use the following link: https://hsc.unm.edu/research/ctsc/Community-Engaged-Research-Core/integrating-special-populations.html

CHN (Community Health Network)

In January 2020, Cynthia Killough, the Community Health Network's program manager, conducted focus groups with community health workers in Albuquerque, NM, in collaboration with some folks from Dr. Page's Southwest Clinical Trial Node's Community Engagement team. Although the pandemic made things harder to finish the analysis and write up of the results of this study, the team was able to come together to finish this important contribution to health research. The purpose of the focus groups was to ask community health workers what they thought were some of the barriers and challenges for their patient populations to engage in health research like clinical trials. Representation of diverse populations in clinical and translational research enhances our ability to understand the factors that impact health and generalize results. Community health workers are of particular interest to the Community Health Network because they are uniquely positioned as gatekeepers in their communities while also being knowledgeable of health systems and resources for patients.

A total of 42 community health workers agreed to participate in the focus groups. After thematic analysis of the focus groups were done, several themes emerged. Community health workers mentioned *Transparency* in all aspects of research as an important factor for patient participation in health research. As one community health worker commented, "*I think that you should clarify well the concept of what you want to investigate and clarify it well to the community, at the level, because it is not due to the lack of education or anything. So, they don't know anything about what an investigation… is*." While this is well documented in health research literature, it was still an important aspect community health workers wanted us to know.

Another theme that came out from the focus groups was that community health workers see themselves as both gatekeepers and facilitators. As gatekeepers, some community health workers feel that they must protect their patient populations from health research trauma; while as facilitators, they ensure their patient populations attain resources they need and also benefit from the research they are participating in. The results of the study have been submitted for peer-review and we excitedly wait to hear back and will share more about this study down the road.

http://hsc.unm.edu/research/ctsc/community-health-network/index.html

Network Capacity (NC)

Trial Innovation Network (TIN)

The Trial Innovation Network is a collaborative initiative within the CTSA Program and is composed of three key partners: the CTSA Program Hubs, the Trial Innovation Centers (TICs), and the Recruitment Innovation Center (RIC).

The vision for the Trial Innovation Network is to innovatively address critical roadblocks in clinical research and accelerate the translation of novel interventions into life-saving therapies.

The Trial Innovation Network is a collaborative national network with a focus in three main areas: operational innovation, operational excellence, and collaboration. The Trial Innovation Network will leverage the expertise and resources of the CTSA Program. The Trial Innovation Network will feature a single IRB system, master contracting agreements, quality by design approaches, and a focus on evidence-based strategies to recruitment and patient engagement.

The goal of the Trial Innovation Network is to not only execute trials better, faster, and more cost-efficiently but, importantly, to be a national laboratory to study, understand and innovate the process of conducting clinical trials.

The University of New Mexico CTSC has been a part of the Trial Innovation Network and as a result has been a participating site in several studies that impact a variety of disease states. This import work has helped connect physicians at the University of New Mexico with the clinical trials specific to their specialty. This effort has encouraged new investigators to become engaged in clinical research. This collaboration is part of the larger mission to move innovated research from the bench, to the bedside, and ultimately out into the communities in which we live.

For more information on the Trial Innovation Network, please contact George Garcia at gemgarcia@salud.unm.edu.

Drug Discovery & Repurposing Core (DDRC)

The DDRC is a Resource for Rapidly Translating Existing Drugs into New Clinical Trials

Do you have ideas about ways to repurpose existing FDA-approved drugs? The CTSC is here to help. The Drug Discovery and Repurposing Core DDRC collaborates with UNM investigators other CTSCs to improve health outcomes by providing unique resources for rapidly translating existing drugs for use in new clinical trials. DDRC provides access to and operation of state-of-the-art technology in drug rescue, repurposing, and repositioning through innovative tools that support investigators and start-up companies. Additionally, DDRC provides support and guidance in translating pilot projects from preclinical proof-of-principle to clinical proof-of-concept as well as helps to develop first-in-human clinical trials.

For additional information or to become a DDRC member, please visit the DDRC (formerly DR3N) webpage: https://hsc.unm.edu/research/ctsc/dr3n/index.html.

Clinical Laboratory (T-Laboratory)

Elevated low-density lipoprotein cholesterol (LDL-C) is associated with an increased risk of coronary heart disease (CHD) and stroke. The Chackerian laboratory has developed a nanoparticle-based vaccine that targets PCSK9, a molecule that is critically involved in the regulation of LDL-C levels. In collaboration with the California Primate Center, we have tested the efficacy of PCSK9-targeted vaccines in non-human primates and have shown that immunization can significantly lower LDL-C levels and increase expression of the LDL receptor. In collaboration with the CTSC, we have performed studies on liver tissue from immunized and control macaques in order to determine whether vaccination also modulates the mRNA levels of genes that are involved in cholesterol and fatty-acid synthesis. Debbie Lovato at the CTSC has successfully used taqman quantitative PCR on cDNA to quantitate mRNA levels for six different genes.

For questions, please contact HSC-CTSCResearchConcierge@salud.unm.edu.

Opioid-Use Populations with Integration, Outreach, Informatics, and Drug Discovery (OPIOIDD)

The Southwest Node of the Clinical Trials Network (SW CTN) and the OPIOIDD Function recently presented a *Fentanyl Updates* Panel on April 20th. Expert panelists were Dr. Sandra Comer, Professor of Neurobiology at Columbia University Department of Psychiatry; Dr. Brandon Warrick, Associate Medical Director of the New Mexico Poison and Drug Information Center; and Dr. Scott Jeansonne, Medical Provider at the First Choice Community Healthcare. The training was attended by clinicians, researchers, social workers, and policy workers around New Mexico. The panelists discussed current concerning trends in fentanyl addiction both nationally and within New Mexico, the

pharmacodynamics of fentanyl, and clinical treatment considerations. The event was the Southwest CTN's highest-attended event to date, with over 150 attendees.

A follow-up panel is in development to address the benefits of MOUD, commonly held misconceptions about MOUD, and barriers to access with emphasis on rural communities. If you would like to receive communications about future training opportunities, please email SouthwestCTN@salud.unm.edu.

Funding Opportunities Specific to COVID-19

There are several significant funding opportunities available through the CTSC to address the COVID-19 pandemic. CTSC monitors these opportunities for our HSC faculty on a weekly basis and includes additional information from the NIH COVID-19 funding site for your convenience.

Some of these funding opportunities require an active grant or cooperative agreement. They may also need a Letter of Support from Dr. Larson, the CTSC PI. Please contact Michelle Parra (MMParra@salud.unm.edu) if you are interested in applying for any of the COVID-19 funding opportunities listed below.

Recent Active Funding Opportunities Specific to COVID-19 are listed below:

Title	Notice Number	Organization(s)	Release Date	RFA/PA/ PAR #	Expiry Date	Activity Code(s)
NICHD Program Project Grants for HIV Research (P01 Clinical Trial Optional)	RFA-HD-23-026	NICHD	May 23, 2022		Aug 11, 2022	P01
Notice of Special Interest: Administrative Supplements to Advance Precision Medicine Using the All of Us Research Programs Data	NOT-PM-22-002	OD, NCATS, NCCIH, NCI, NEI, NHGRI, NHLBI, NIA, NIAAA, NIAID, NIAMS, NIBIB, NICHD, NIDA, NIDCD, NIDCR, NIDDK, NIEHS, NIGMS, NIMH, NIMHD, NINDS, NINR, NLM, OAR, OBSSR, ODSS, ORWH, RM, SGMRO	May 20, 2022		Jul 6, 2022	333

Limited Competition: Clinical and Translational Science Award (CTSA) Program: Collaborative and Innovative Acceleration Award (UG3/UH3 Clinical Trial Optional)	PAR-22-167	NCATS, NIAMS, NICHD, NIDCR, NIGMS, NIMHD, OBSSR, ORWH	May 9, 2022		Oct 18, 2024	UG3/UH3
NICHD Maternal-Fetal Medicine Units (MFMU) Network: Data Coordinating Center (U24 Clinical Trial Optional)	RFA-HD-23-017	NICHD	May 6, 2022		Aug 12, 2022	U24
Policy and Alzheimers Disease (AD) and Alzheimers Disease-Related Dementias (ADRD) Healthcare Disparities: Access, Utilization, and Quality (R01 Clinical Trial Not Allowed)	RFA-AG-23-024	NIA	May 6, 2022		Oct 21, 2022	R01
Notice of Special Interest (NOSI): IMPROVE Initiative: Implementation Science to Advance	NOT-OD-22-125	OD	May 5, 2022		Jul 17, 2022	R01, R03, R21

Maternal Health and Maternal Health Equity						
Notice of Special Interest (NOSI): Administrative Supplements to Support "All of US" and Health Disparities-Related Pilot Research Projects at NIMHD-Funded Research Centers in Minority Institutions (RCMI)	NOT-MD-22-015	NIMHD	May 3, 2022		Jun 28, 2022	333
Notice of Special Interest: Research on Alcohol and Coronavirus Disease (COVID-19) within the Mission of NIAAA	NOT-AA-22-012	NIAAA	Apr 29, 2022		Mar 6, 2024	R01, R03, R21, K99/R00
Notice of Special Interest (NOSI) - Administrative Supplements for Research of Emerging and Existing Issues of COVID-19 Related to the Health and Well-Being of Women, Children and Individuals with	NOT-HD-22-003	NICHD, NIAAA, NIDA, NINDS, OBSSR, ORWH	Apr 19, 2022		Jun 6, 2024	333

Physical and/or Intellectual Disabilities						
Notice of Special Interest (NOSI): Promoting Health, Safety, and Recovery Training for COVID-19 Essential Workers and their Communities	NOT-ES-22-005	NIEHS	Mar 29, 2022		Jun 7, 2022	333
Notice of Special Interest (NOSI) - Emerging and Existing Issues of Coronavirus Disease 2019 (COVID-19) Research Related to the Health and Well-Being of Women, Children and Individuals with Physical and/or Intellectual Disabilities	NOT-HD-22-002	NICHD, NIDA, NIEHS, NINDS, OBSSR, ORWH	Mar 28, 2022		Jun 6, 2024	R01, R21
Understanding and Addressing Misinformation among Populations that Experience Health Disparities (R01 - Clinical Trials Optional)	RFA-MD-22-008	NIMHD, NCI	Mar 22, 2022		Nov 14, 2022	R01

Accelerating the Pace of Child Health Research Using Existing Data from the Adolescent Brain Cognitive Development (ABCD) Study (R21-Clinical Trial Not Allowed)	PAR-22-138	NIMH, NIAAA, NIEHS, ORWH	Mar 15, 2022		May 8, 2025	R21
Accelerating the Pace of Child Health Research Using Existing Data from the Adolescent Brain Cognitive Development (ABCD) Study (R01-Clinical Trial Not Allowed)	PAR-22-137	NIMH, NIAAA, NIEHS, ORWH	Mar 15, 2022		May 8, 2025	R01
Notice of Special Interest (NOSI): Addressing Accessibility Inequities with COVID Home-Based Testing for Individuals with Visual Impairment	NOT-EY-22-010	NEI	Feb 4, 2022		Mar 9, 2024	R41/R42, R15, 333, R01, R43/R44, R21
Urgent Award: COVID-19 Mental Health Research (R01 Clinical Trial Required)	PAR-22-112	NIMH	Jan 31, 2022		Dec 24, 2022	R01

Urgent Award: COVID-19 Mental Health Research (R01 Clinical Trial Optional)	PAR-22-113	NIMH	Jan 31, 2022		Dec 24, 2022	R01
Notice of Special Interest (NOSI): Research on barriers to care and risk of HIV-associated comorbidities among vulnerable population groups	NOT-HL-22-010	NHLBI	Jan 31, 2022		May 8, 2025	R01
Notice of Special Interest (NOSI): Enhancing Research on Deciphering Mechanisms of COVID-19-Associated Coagulopathy	NOT-HL-23-003	NHLBI	Jan 21, 2022		Jul 6, 2022	R01
Notice of Special Interest (NOSI): COVID-19 Pandemic Mental Health Research	NOT-MH-22-100	NIMH	Jan 19, 2022		Jan 8, 2025	R21, R34, R01
Notice of Special Interest: Administrative Supplements and Urgent Competitive Revisions on Coronavirus Disease 2019 (COVID-19) within the	NOT-AA-22-002	NIAAA	Dec 2, 2021		May 8, 2024	333

Mission of NIAAA						
Notice of Special Interest (NOSI): Administrative Supplements for Research on Sex and/or Gender Influences (Admin Supp Clinical Trial Optional)	NOT-OD-22-030	ORWH, NIDA, NEI, NIDCD, NIEHS, NHGRI, NIMH, NIAID, NINR, NICHD, NHLBI, NCCIH, NIAAA, SGMRO, NCATS, NIDCR, NIAMS, ORIP, NIDDK, NIBIB, NIA	Dec 2, 2021		Jan 27, 2023	333
Notice of Special Interest (NOSI): Telehealth Strategies for Individuals with HIV and Substance Use Disorders	NOT-DA-21-019	NIDA	Feb 10, 2021	PA-20-184 PA-20-183 PA-20-200 PA-20-195 PA-20-194 PA-20-196 PA-20-146	Sep 8, 2024	R01, R03, R21
Notice of Special Interest (NOSI): Medical Consequences of Smoking and Vaping Drugs of Abuse in Individuals with HIV and COVID-19	NOT-DA-21-017	NIDA	Feb 4, 2021	PA-20-184 PA-20-183 PA-20-200 PA-20-195 PA-20-194 PA-20-196	Sep 8, 2024	R01, R02, R03
Notice of Special Interest (NOSI):	NOT-AI-21-008	NIAID	Feb 4, 2021	PA-20-185	Jan 8, 2023	R01, R21

Complement in Basic Immunology (CIBI)				PA-20-195		
Notice of Special Interest (NOSI): Long-Term Neurocognitive Consequences of COVID-19 in Individuals Living with HIV and Substance Use Disorders	NOT-DA-21-018	NIDA	Feb 3, 2021	PA-20-184 PA-20-183 PA-20-200 PA-20-195 PA-20-194 PA-20-196 PA-20-146	Sep 8, 2024	R01, R03, R21
Notice of Special Interest (NOSI): Administrative Supplements for the Clinical and Translational Science Award (CTSA) Program to Address COVID-19 Public Health Needs	NOT-TR-21-017	NCATS	Feb 3, 2021	PA-20-272	Aug 17, 2024	333
Notice of Special Interest (NOSI): NIDCR Support for Research on the Physiological Involvement of Oral Cavity in Coronavirus Disease 2019 (COVID-19)	NOT-DE-21-001	NIDCR	Jan 26, 2021	PA-20-185 PA-20-195	May 28, 2023	R01, R21

Notice of Special Interest (NOSI): Aging-Relevant Behavioral and Social Research on Coronavirus Disease 2019 (COVID-19)	NOT-AG-21-015	NIA	Jan 26, 2021	PA-20-183 PA-20-184 PA-20-185 PA-20-200 PA-20-194 PA-20-196 PA-20-195 PAR-19-374 PAR-19-314 PAR-19-070 PAR-19-071 PAR-20-070	May 28, 2023	R01, R03, R21, U19, P01, R21/R33
Notice of Special Interest (NOSI): Effects of smoking and vaping on the risk and outcome of COVID-19 infection	NOT-DA-21-011	NIDA	Jan 26, 2021	PA-20-184 PA-20-183 PA-20-200 PA-20-195 PA-20-194 PA-20-196 PA-20-146	Sep 8, 2024	R01, R03, R21
Notice of Special Interest: Administrative Supplements for COVID-19 Impacted NIMH Research	NOT-MH-21-120	NIMH	Dec 23, 2020	PA-20-272	Jun 2, 2023	333

Notice of Special Interest (NOSI): Effects of smoking and vaping on the risk and outcome of COVID-19 infection	NOT-DA-20-084	NIDA	Oct 27, 2020	PA-20-183 PA-20-200 PA-20-195	Sep 8, 2024	R01, R03, R21
Notice of Special Interest (NOSI): Simulation Modeling and Systems Science to Address Health Disparities	NOT-MD-20-025	NIMHD, NCI, NIDA, NLM, ODP, OBSSR, NIMH, NIAMS	Aug 13, 2020	PA-20-185	May 8, 2023	R01
Notice of Special Interest (NOSI): NIDCD is Interested in Supporting Research on the Impact of COVID-19 on Mission Specific Sensory and Communication Disorders	NOT-DC-20-008	NIDCD	Jun 4, 2020	PA-18-334 PA-20-185 PA-20-184 PA-20-196 PA-20-195 PA-19-270 PA-19-271 PA-19-273 PA-19-272	Sep 8, 2022	R01, R21, R41/R42, R43/R44
Emergency Competitive Revision to Existing NIH Awards (Emergency Supplement - Clinical Trial Optional)	PA-20-135	NIH, NCATS, NCCIH, NCI, NHGRI, NIA, NIAAA, NIAID, NIAMS, NIBIB, NICHD, NIDCD, NIDDK, NIEHS, NIGMS, NIMH, NIMHD, NINR, NLM, ORWH, OSC	Mar 10, 2020	PA-20-135	Sep 8, 2025	333
Notice of Special Interest (NOSI):	NOT-HD-21-038	NICHD	June 28, 2021	PA-20-200, PA-21-	May 8, 2024	R03, R21

Promoting Vaccine Access, Acceptance and Uptake among Children, Adolescents, Pregnant and Lactating Women, and Persons with Disabilities				221, PA-20-195, PA-20-194		
Notice of Special Interest (NOSI) HIV/AIDS in the Era of COVID-19: When Pandemics Collide	NOT-AI-21-057	NIAID, NIMH, NIDA	June 25, 2021	PA-20-185, PA-20-195	May 8, 2024	R01, R21
Limited Competition Emergency Awards: Shared Personal Protective Equipment Resources for COVID-19 Related Vaccine and Treatment Clinical Trials and Clinical Studies (S10 Clinical Trial Not Allowed)	PAR-21-276	NIAID	Jul 16, 2021	Reissue of PAR-20-256	Jul 16, 2022	S10

If you are interested in applying for any of the grants, please email Michelle Parra (MMParra@salud.unm.edu).

For a full listing of COVID-19 through NIH, please access the following site: https://grants.nih.gov/grants/guide/COVID-Related.cfm.

Citing the CTSC

When citing the CTSC, please be sure to include our Grant numbers:

Thank you!

HS in the News

For additional Health Sciences news, please visit:
http://hscnews.unm.edu/

News or corrections?
Please contact the Newsletter Team.

The University Of New Mexico Mailing Address:
One University of New Mexico
MSC 08 4635
Albuquerque, NM 87131