



Clinical & Translational Science Center Newsletter

October 2021

Letter from the Director



Dear Colleagues,

Fall has finally arrived and brought with it much needed cooler temperatures. As we head into the final quarter of the year it's time to start planning your research projects for 2022. New funding opportunities can now be found online at https://hsc.unm.edu/research/news/funding-opps.html.

Our Community Health Network unit has collaborated with Dr. Carla Wilhite to help promote her data focused study about the effects of COVID-19 on New Mexicans with an emphasis on rural individuals. In addition to soon publishing her finding, Dr. Wilhite has been sharing the results with rural communities throughout the state, "bringing the data back".

The Community Engagement Research Core (CERC) is currently supporting Dr. Kate Meriwether, in her CTSC pilot study "Evaluation of a Centering-Based Group Treatment Visits (CBGT) in the treatment of women with interstitial cystitis/bladder pain syndrome (ICBPS): A parallel, prospective cohort study." The study is examining the effectiveness of CBGT in the treatment of interstitial cystitis/bladder pain syndrome (ICBPS). The CERC team has completed interviews and focus groups for the study as well as a qualitative analysis and summary of the results.

In coordination with the Participation Clinical Interactions (PCI) team, Dr. J. Pedro Teixeira, has begun a new trial "A phase 3 Randomized, Double-Blind, Placebo-Controlled, Parallel Group, Multicenter Study Evaluating the Efficacy and Safety of Remdesivir in Participants with Severely Reduced Kidney Function who are Hospitalized for COVID-19". The purpose of this study is to evaluate the possible benefits of remdesivir in COVID-19 patients with compromised kidney function.

Exciting news, former KL2 scholar Brandi Fink, PhD, has been chosen to present at The Western CTSA Education Consortium to share how they successfully transitioned into an independent researcher. The KL2 Scholars Program is now looking for two new junior faculty members for their Mentored Career Development (KL2) Scholar Program at the Assistant Professor level on either a tenure- or flex-track beginning in the Spring of 2022. Successful candidates will have 75% of their effort committed to their research, and 25% committed to other duties. If your looking to start-up or expand your research career I encourage you to apply.

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 now required indoors for all individuals at the HSC. 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 <u>Laboratories & Research Facilities</u> and <u>Clinical Trial Research Faculty & Staff</u>) and can be accessed through the following link: https://hsc.unm.edu/research/.

If you have any questions about our assets and services, please contact the CTSC Research Concierge at <a href="https://example.com/hsc-englished-nc

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: Nancy Pandhi, MD, PhD, MPH
Collaboration and Commercialization Module Lead: Eric Prossnitz, PhD
Translational Endeavors (TE) Component Director: Christopher Abbott, MD
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: Corey Ford, MD, PhD
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: Christopher Abbott, MD

Network Capacity (NC) Component Director: Hengameh Raissy, PharmD

Trial Innovation Network (TIN) Module Lead: Hengameh Raissy, PharmD

Drug Discovery & Repurposing Core Lead: TBD

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

CHN (Community Health Network)

"Bring the data back to us." This is the message we keep hearing from communities across the state when approached about participation in health research projects. In efforts to include diverse populations in our health research projects at CTSC/UNM HSC, the CTSC Community Health Specialist (CHS), Cynthia Killough, has encouraged and supported researchers to bring the findings of their studies back to communities where we promote their studies. This can be done in a myriad of ways including presentations, infographics, postcards, etc.

At the end of 2020, and the start of 2021, Dr. Carla Wilhite (pictured) collaborated with Ms. Killough to promote her study about the effects of COVID-19 on New Mexicans with an emphasis on rural individuals. Now with the data analyzed and getting ready for publication, Dr. Wilhite has been presenting the results of the study back to communities through health councils. Recently Dr. Wilhite presented to the Quay Health Council with an amazing reception from members. After the presentation council members asked questions such as: What differences were there between rural and urban folks? Where will the results of your study be housed so we can have access to them? What have the findings revealed for ongoing preparedness? Dr. Wilhite also shared that the results of her study led her to submit another grant proposal that was unfortunately denied. To this Dr. Wilhite said "If I were queen for a day, I would have used the funding to make sure we got out to rural places in NM without internet or access to computers so we could really get rural insight on the pandemic." One of the council members responded, "I move to make Dr. Wilhite Queen for a year!" with those in favor saying, "I second that!" I hope you don't mind wearing a crown, Dr. Wilhite, because It sounds like you will be wearing a health council tiara for the next foreseeable year. The Quay County Health Council have been instrumental to helping promote studies like Dr. Wilhite's and it was an amazing experience to be able to share the results of the study back with their community. We hope to continue to share results back with all participants through presentations like Dr. Wilhite's.



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

CERC (Community Engagement and Research Core)

Dr. Kate Meriwether, the Director of Fellowship Research in Obstetrics and Gynecology, is conducting a CTSC pilot study entitled, "Evaluation of a Centering-Based Group Treatment Visits (CBGT) in the treatment of women with interstitial cystitis/bladder pain syndrome (ICBPS): A parallel, prospective cohort study." The study is examining the effectiveness of CBGT in the treatment of interstitial cystitis/bladder pain syndrome (ICBPS).

It is estimated that ICBPS affects at least one in 20 women, who experience symptoms of pain in the suprapubic pelvic and/or genital area, dyspareunia, urinary urgency and frequency, and nocturia. The impact of ICBPS are not only physical but also emotional in terms of patients feeling discouraged, experiencing psychosocial dysfunction and suicidal ideation. Dr. Meriwether recognized that there is little research surrounding the efficacy of group-based treatment or support systems for patient management of ICBPS.

This study examines the effectiveness of Centering-Based models compared to Routine Care Alone. Centering models are described as group medical visits which emphasize community and peer collaboration in order to increase health education and wellness. This model utilizes a credentialed provider to incorporate healthcare, interactive learning and community building into these visits. Dr. Meriwether has hypothesized that "women with ICBPS Centering included as part of their care will have improved outcomes as opposed to women without this element of care. "

The Community Engagement (CE) component of CTSC is currently supporting Dr. Meriwether with her study. The CE team has completed interviews with the control group to learn about their reasons for not participating in CBGT and what barriers they faced. The team has conducted a focus group with the CBGT participants about what they found valuable, what they would change about CBGT, and what facilitated their participation with the treatment group. The CE team is currently working to

qualitatively analyze and summarize the focus group, interviews, and open-ended survey questions and will eventually help develop a manuscript for publication to better understand these factors.

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

http://hsc.unm.edu/research/ctsc/community-engaged-research-core/index.html

Participation Clinical Interactions (PCI)

Dr. J. Pedro Teixeira, Assistant Professor in the Department of Internal Medicine, has begun a new trial "A phase 3 Randomized, Double-Blind, Placebo-Controlled, Parallel Group, Multicenter Study Evaluating the Efficacy and Safety of Remdesivir in Participants with Severely Reduced Kidney Function who are Hospitalized for COVID-19". The purpose of this study is to evaluate the possible benefits of remdesivir in COVID-19 patients with compromised kidney function.

According to the National Kidney Foundation, 37 million people in the US have chronic kidney disease and 660,000 live with end-stage kidney disease. Acute kidney injury occurs in approximately 15% of hospitalized patients with COVID-19. Patients with chronic kidney disease, and end-stage kidney disease are at higher risk of death with COVID-19. Remdesivir has been shown to be safe and effective in hospitalized patients with COVID-19 with a trend towards improved mortality. However, it is not recommended for patients with reduced kidney function. Since there is not an alternative treatment option, remdesivir is a treatment of interest to providers.

This study is a multicenter effort with 120 sites from all around the world. Of those, 80 are located in the US. The study will follow patients for 60 days and evaluate clinical outcomes along with safety data to determine the efficacy and safety of remdesivir in this specific patient population. The PCI coordination team will work with Dr. Teixeira to support this trial and to ensure that the aims of the study are fulfilled.

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

KL2 Scholars

A previous graduate of the UNM HSC KL2 scholar program Brandi Fink, PhD, has been selected to give a presentation to The Western CTSA Education Consortium on how they successfully transitioned from the K, a career development award, to an R, an independent investigator award. It is a huge honor to be chosen as a presenter at this prestigious conference, and to be able to share their knowledge and experience with the next generation of KL2 scholars looking to apply for R funding.

If you are interested in joining the UNM CTSC Mentored Career Development (KL2) Scholar Program, please see below how to apply.

Junior Faculty Position - Mentored Career Development (KL2) Scholar Program

The University of New Mexico's Clinical and Translational Science Center seeks up to two junior faculty members for our Mentored Career Development (KL2) Scholar Program at the Assistant Professor level on either a tenure- or flex-track beginning in the Spring of 2022. Individuals engaged in all types of clinical and translational research – from molecular to community and population level investigations – relevant to the Departments of Internal Medicine, OBGYN, Emergency Medicine, Neurology, Surgery, Biochemistry and Molecular Biology, Psychiatry and Behavioral Sciences, Pediatrics, and the Colleges of Pharmacy and Population Health are encouraged to apply. The successful Scholar candidate will have 75% of their effort committed to their research and 25% committed to other duties. MD, PhD, MD/PhD, Pharm D and equivalent candidates, who are motivated and interest to become independently funded in clinical and translational research, are encouraged to apply.

The goal of the KL2 Scholar Program is to enhance the career development and training of junior faculty in multidisciplinary, team research with the overarching goal of promoting clinical and translational investigation that will improve health and prevent disease. Candidates will be expected to aggressively pursue extramural funding while in the program. The Program will train and foster the career development of junior faculty to become the next generation of researchers who will perform clinical and translational investigation in multidisciplinary, collaborative research settings.

The Scholar will be known as a Clinical and Translational Science Center Scholar. The program will include an educational component tailored to the individual scholar in order to strengthen competencies in the design, conduct, and analysis of clinical and translational research. This opportunity will use the NIH Mentored Research Scientist Development Program Award (KL2) mechanism. Awards will be made for up to five years. The earliest anticipated start date is April 2022.

The successful candidate will be able to become a faculty member in one of the following School of Medicine departments: Internal Medicine, OBGYN, Emergency Medicine, Neurology, Surgery, Biochemistry and Molecular Biology, Psychiatry and Behavioral Sciences, Pediatrics, or in the Colleges of Pharmacy and Population Health. This position is subject to criminal records screening in accordance with New Mexico law.

Eligibility (per NIH Guidelines):

- The position is open to health professionals with degrees that include MD, PhD, MD/PhD, Pharm D or equivalent.
- Applicants must have the ability to obtain the appropriate licensure in the State of New Mexico.
- Candidates for this Scholar Program must be an existing or prospective junior faculty member, with a terminal degree in their chosen field.
- A minimum of 2 years of post-terminal degree research experience (i.e. post-doc, fellowship, etc.) is required.

- Applicants may not simultaneously submit or have pending an application for any other PHS mentored career development award (e.g., K07, K08, K22, K23) that duplicates any of the provisions of the K component. Former or current PDs/PIs on any NIH research project grant (this does not include NIH Small Grants (R03), Exploratory/ Developmental (R21) or SBIR, STTR (R43, R44 grants)) or equivalent non-PHS peer reviewed research grants that are over \$100,000 direct costs per year, or project leaders on sub-projects of program project (P01) or center grants (P50) are NOT eligible to participate as scholars.
- Applicants must be US citizens or permanent residents

Preferred Qualifications:

- Quality, appropriateness and amount of previous training
- Quality, clarity, significance and innovation of the Scientific Plan
- Number and Quality of authored publications
- Likelihood of receiving external funding in 3 years
- Commitment to a career in clinical translational research
- Appropriateness of experience and education in relation to the position focus area
- A demonstrated commitment to diversity, equity, inclusion, and student success, as well as working with broadly diverse communities

UNM is an EEO/AA Employer.

For complete details or to apply, visit https://unmjobs.unm.edu. Reference Req17126. For best consideration, apply by: November 15, 2021. This position will remain open until filled. UNM's confidentiality policy, which includes information about public disclosure of documents submitted by applicants, is located at https://www.unm.edu/~brpm

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

Menu of Services & Resources

- Biostatistics Support
- Brain & Behavioral Disorders
- <u>Citing the Clinical & Translational Science Center</u>
- 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
- <u>Team Science & Commercialization</u>
- 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 Informatics Core will be working with Dr. Pilar Sanjuan, and her team, with data collection for the UNM site of the "The Maternal and Infant Network to Understand Outcomes Associated with Treatment for Opioid Use Disorder During Pregnancy (MAT-LINK)", a national public health surveillance project funded by the CDC.

The purpose of this project is to establish a health outcomes surveillance network that spans multiple geographic regions and clinical sites across the United States to collect data and monitor the maternal, infant, and child health outcomes associated with treatment regimens for opioid use disorder (OUD) among pregnant women.

MAT-LINK will improve the understanding of maternal, infant, and child health outcomes associated with specific treatment regimens for OUD among pregnant women and the complex prenatal and postnatal factors (medical and environmental) that may contribute to specific outcomes. Data collected through this surveillance network will inform national policy and recommendations for "best practices" for clinical management to improve outcomes for pregnant patients with OUD, and infants and children prenatally exposed to opioids.

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

Community & Collaboration (C&C)

Team Science & Commercialization

What is Team Science?

Team science is defined by research in which individuals from various fields join together to work collaboratively toward the resolution of major health and social issues. The ultimate goal of such team-based research is to generate a deeper understanding of important issues and, in doing so, efficiently produce scientific discoveries that are more readily applicable.

Collaborative groups conducting team science research may include a wide range of individuals each offering their own unique expertise. They may include not only researchers, but also community members and policy makers. [By Casey D. Calhoun | Psychological Science Agenda | April 2013]

CTSC Team Science & Commercialization programs aim to strengthen team science opportunities and encourage interdisciplinary partnerships across UNM and our greater community with the goal of advancing better healthcare for New Mexico. These CTSC hosted programs include:

- Synergy Meetings: These forums highlight research, ongoing studies, clinical and translational
 methods, and collaboration opportunities on a specific topic and includes presentations from
 invited speakers. Upcoming Synergy meetings will focus on Data Sciences. <u>Contact Melanie</u>
 <u>Hazlett</u>, CTSC Team Strategist, to request more information about the Fall 2021 CTSC Synergy
 Meetings
- CTSC Health Hackathon: This multi-day event invites academic & community participants to innovate, create and advance products to address problems in healthcare. It starts with anyone 'pitching' an idea, individuals then form teams to 'hack' a solution, culminating in a final competition where winning teams can be awarded \$10,000 in grant funding. CTSC is planning for a Spring 2022 Hackathon, send an email to hsc-hackathon@salud.unm.edu to get more information.
- CTSC BioVenture Partnership Event: This one-day event is designed to create important
 connections between UNM HSC Research and local biotech business, interested in developing
 partnerships, to build long-term interorganizational relationships while boosting the state's
 biotech economy and expanding health care innovation in our state. Plans are starting for a
 Fall 2022 BioVenture Partnership event, bookmark the CTSC events webpage to get the latest
 event news. https://hsc.unm.edu/ctsc/events/

The CTSC supports many Commercialization efforts by participating with The ASCEND (Accelerating Solutions for Commercialization and Entrepreneurial Development) Hub. The focus of this program is to increase entrepreneurship and commercialization of basic medical science in the mountain west states. Visit the ASCEND Hub website to learn more about what resources are available to you: https://ascendhub.org.

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

Translational Endeavors (TE)i

Translational Workforce Development (TWD)

Translational Workforce Development has numerous <u>course offerings</u> and can even provide consultations as requested to assist you in your goals! Please request a <u>consultation</u> or additional

information on any courses offered. The TWD team may be reached via <u>HSC-CTSCTWDTraining@salud.unm.edu</u>.

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 HS faculty members— senior as well as junior investigators— in response to the following pilot Request For Application.

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

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)

UNM in collaboration with the Western Institutional Review Board (WIRB), will allow CTSC Investigators to streamline study start up activities for new clinical trials through the Clinical Research and Regulatory Support Services, as well as initiate studies in a prompt and efficient manner. WIRB has been at the forefront of protecting the rights and welfare of human subjects. They provide indepth regulatory expertise to support the development of research protocols and documentation.

WIRB is an independent IRB that has maintained full accreditation from the Association for the Accreditation of Human Research Protection Programs (AAHRPP) since 2003. If you are interested in exploring the possibility of using WIRB in conjunction with our Regulatory Management and/or Study Coordinator services, please complete the Request for Resources Form and submit to CTSC Research Concierge at https://dx.doi.org/10.1001/jcsc.2003.16 (AAHRPP) since 2003. If you are interested in exploring the possibility of using WIRB in conjunction with our Regulatory Management and/or Study Coordinator services, please complete the Request for Resources Form and submit to CTSC Research Concierge at https://dx.doi.org/10.1001/jcsc.2003.16 (AAHRPP) since 2003. If you are interested in exploring the possibility of using WIRB in conjunction with our Regulatory Management and/or Study Coordinator services, please complete the Request for Resources Form and submit to CTSC Research Concierge at https://dx.doi.org/10.1001/jcsc.2003.16 (AAHRPP) since 2003. If you are interested in exploring the possibility of using WIRB in conjunction with our Regulatory Management and/or Study Coordinator services, please complete the Request for Resources Form and submit to CTSC Research Concierge @salud.unm.edu.

To qualify for this service, you must obtain Departmental Review and Approval, provide a fully industry sponsored Phase II, III, or IV clinical trial, and utilize our CTSC Regulatory Support Service in addition to other CTSC Resources.

For more information please contact Rebecca Brito at rbrito@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. A recent example of this is the Moderna-COVID Pediatric Vaccine Trial for 6-12-year olds. UNM and New Mexico were specifically chosen for this trial due to our diverse population. Trial participation was so successful we were requested to increase our target enrollment because we had met all enrollment goals early, this included adding populations not originally part of our initial goals. Including all populations is paramount to correctly dose as well as account for possible reactions. UNM Pediatrics conducted news interviews and special releases to advertise the study. CTSC Participant Clinical Interaction (PCI) conducted recruitment screening to ensure we met the expected target enrollment. PCI was successful in meeting the target enrollment including covering for screen failures and increase goals.

If you would like to request a consultation, please fill out the intake form at the following link.

https://ctsctrials.health.unm.edu/redcap/surveys/?s=NNH84CWCAK

For more information, please contact Jesus Fuentes at JEFuentes@salud.unm.edu

For more information about the Integrated Special Population team, please contact Dr. Nancy Pandhi, MD, PhD, MPH at NPandhi@salud.unm.edu.

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

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 costefficiently 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)

Using CTSC Lab Services

The CTSC Translational Laboratory (T-Laboratory) is comprised of 6,000 square feet of wet-lab space, located in the newly renovated CTSC Building. The T-Laboratory offers state-of-the-art equipment and technical assistance with laboratory techniques for UNM HS investigators. The experienced staff of the T-Laboratory provide specialized laboratory support, customized to meet the needs of the investigators in all aspects of research including protocol/assay development, budget preparation, and testing of patient samples for various assays. The T-Laboratory provides sample preparation and technical support for other non-CTSC resources such as UNM Shared Flow Cytometry and High Throughput Screening Resource, and KUSAIR Small Animal Imaging. In addition, our staff will provide training to UNM HS investigators staff on molecular techniques, clinical techniques, or equipment. There are three options for utilization of CTSC T-Laboratory Services:

- Option A: Full Service Sample Testing
- Option B: Equipment Utilization by Investigator
- Option C: Preparation of Investigator's Experiments or Train Investigator's Staff to Perform Assays and Equipment.

Additionally, the CTSC Clinical Laboratory develops and carries out research-related sample analyses for UNM HS investigators, researchers throughout the United States and world, as well as corporate funded research projects.

For questions, please contact $\underline{\mathsf{HSC\text{-}CTSCResearchConcierge@salud.unm.edu}}.$

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 Numbe r	Organization(s)	Release Date	RFA/PA/ PAR #	Expiry Date	Activity Code(s)
Impact of	RFA-	<u>NICHD</u>	Aug 25, 2021		Nov	P01
Technology and	HD-22-				30,	
Digital Media	<u>009</u>				2021	
(TDM)						
Exposure/Usag						
e on Child and						

Adolescent Development (P01 Clinical Trial Optional)						
Notice of Special Interest (NOSI) Announcing the Availability of Administrative Supplements and Urgent Competitive Revisions for Research on the 2019 Novel Coronavirus	NOT- DA-21- 041	<u>NIDA</u>	Apr 15, 2021	PA-20-272 PA-18-935 (Urgent Supplement)	Mar 31, 2022	333
Notice of Special Interest (NOSI): Availability of Urgent Competitive Revisions for Modeling Research on Coronavirus Disease 2019 (COVID-19) and the Causative Virus SARS- CoV-2	NOT- GM- 21-019	NIGMS	Feb 25, 2021	PA-18-935	Dec 16, 2021	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	NOT- DA-21- 017	NIDA	Feb 4, 2021	PA-20-184 PA-20-183 PA-20-200 PA-20-195	Sep 8, 2024	R01, R02, R03

of Smoking and Vaping Drugs of Abuse in Individuals with HIV and COVID- 19				PA-20-194 PA-20-196		
Notice of Special Interest (NOSI): Complement in Basic Immunology (CIBI)	NOT- AI-21- 008	<u>NIAID</u>	Feb 4, 2021	PA-20-185 PA-20-195	Jan 8, 2023	R01, R21
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	<u>NIDA</u>	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	<u>NCATS</u>	Feb 3, 2021	<u>PA-20-272</u>	Aug 17, 2024	333
Notice of Special Interest (NOSI): NIDCR Support for Research on the Physiological	NOT- DE-21- 001	<u>NIDCR</u>	Jan 26, 2021	PA-20-185 PA-20-195	May 28, 2023	R01, R21

Involvement of Oral Cavity in Coronavirus Disease 2019 (COVID-19) Notice of Special Interest (NOSI): Aging- Relevant Behavioral and Social Research on Coronavirus Disease 2019 (COVID-19)	NOT- AG-21- 015	<u>NIA</u>	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	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	PAR-19-071 PAR-20-070 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: Promoting Research on COVID-19 and Rheumatic, Musculoskeleta I and Skin Diseases	NOT- AR-21- 012	NIAMS	Jan 5, 2021	PA-20-185 PA-20-195 PAR-21-055 PAR-21-054 PAR-21-053	Nov 19, 2021	R01, R02
Notice of Special Interest: Administrative Supplements for COVID-19 Impacted NIMH Research	NOT- MH- 21-120	<u>NIMH</u>	Dec 23, 2020	PA-20-272	Jun 2, 2023	333

Notice of Special Interest (NOSI): Research to Address Vaccine Hesitancy, Uptake, and Implementatio n among Populations that Experience Health Disparities	NOT- MD- 21-008	NIMHD, NIAID, NIAMS, NCI, ORWH, NIMH, NINR, OBSSR, ODP, NHLBI, NIDCR, SGMRO	Dec 17, 2020	PA-20-183 PA-20-185	Jan 8, 2022	R01
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	<u>PA-20-185</u>	May 8, 2023	R01
Notice of Special Interest (NOSI): Competitive Revision and Administrative Supplements to Existing NICHD HIV Grants and Cooperative Agreements to Understand HIV	NOT- HD-21- 037	NICHD	Jul 2, 2021	PA-20-272 PA-18-935 NOT-OD-20- 128 NOT- OD-20-118 NOT-OD-20- 018	May 8, 2022	333

Health Impacts						
of COVID-19						
	NOT-	<u>NIDCD</u>	Jun 4, 2020	PA-18-334	Sep 8,	R01,
Special Interest	DC-20-			PA-20-185	2022	R21,
(NOSI): NIDCD	<u>008</u>			PA-20-184		R41/R42
is Interested in				PA-20-196		,
Supporting				PA-20-195		R43/R44
Research on				PA-19-270		
the Impact of				PA-19-271		
COVID-19 on				PA-19-273		
Mission				PA-19-272		
Specific Sensor						
y and						
Communication						
Disorders						
Notice of	NOT-	NCATS	Apr 9, 2020	PA-20-135	Jan	333
Special Interest	TR-20-				26,	
(NOSI)	017				2022	
regarding the						
Availability of						
Emergency						
Competitive						
Revisions to						
Existing NIH						
Grants and						
Cooperative						
Agreements for						
Tissue Chips						
Research on						
the 2019 Novel						
Coronavirus						
Notice of	NOT-	NCATS NCATS	Apr 9, 2020	PA-18-591	Jan	333
	TR-20-		,		26,	
	016				2022	
regarding the						
Availability of						
Administrative						
Supplements						
for Tissue Chips						
Research on						
the 2019 Novel						
Coronavirus						
	PA-20-	NIH, NCATS,	Mar 10,	PA-20-135	Sep 8,	333
I I	135	NCCIH, NCI,	2020		2025	
		NHGRI, NIA,				

Existing NIH Awards (Emergency Supplement - Clinical Trial Optional) The Intersection of Sex and Gender Influences on Health and Disease (R01 Clinical Trial Optional)	RFA- OD-19- 029	NIAAA, NIAID, NIAMS, NIBIB, NICHD, NIDCD, NIDDK, NIEHS, NIGMS, NIMH, NIMHD, NINR, NLM, ORWH, OSC ORWH, NCCIH, NHGRI, NHLBI, NIA, NIAAA, NIAID, NIDA, NIDCR, NIEHS, NIMH, NINR	Sep 27, 2019	PA-20-272	Nov 27, 2021	R01
Emergency Award: Social, Behavioral, and Economic Research on COVID-19 Consortium (U01 Clinical Trial Not Allowed)	PAR- 21-213	NIA, NIDA, ORWH, NIMH, NIAA, NIMHD, OBSSR, NEI	April 6, 2021	U01 Research Project (Cooperativ e Agreements	Nov 9, 2021	U01
Notice of Special Interest (NOSI): Promoting Vaccine Access, Acceptance and Uptake among Children, Adolescents, Pregnant and Lactating Women, and Persons with Disabilities	NOT- HD-21- 038	NICHD	June 28, 2021	PA-20-200, PA-21-221, PA-20-195, PA-20-194	May 8, 2024	R03, R21
Notice of Special Interest (NOSI) HIV/AIDS in the Era of COVID- 19: When	NOT- AI-21- 057	NIAID, NIMH, NID A	June 25, 2021	PA-20-185, PA-20-195	May 8, 2024	R01, R21

Pandemics						
Collide						
Limited	PAR-	<u>NIAID</u>	Jul 16, 2021	Reissue	Jul	S10
Competition	<u>21-276</u>			of <u>PAR-20-</u>	16,	
Emergency				<u>256</u>	2022	
Awards: Shared						
Personal						
Protective						
Equipment						
Resources for						
COVID-19						
Related Vaccine						
and Treatment						
Clinical Trials						
and Clinical						
Studies (S10						
Clinical Trial						
Not Allowed)						

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.

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