



Clinical & Translational Science Center Newsletter

August 2022

Letter from the Director

Dear Colleagues,



It is with great pleasure that I announce a new record of growth in our research efforts! UNM HSC was awarded \$239,787,141 in external funding in FY2022. This represents 17 out of last 18 years of record increases. I would like to congratulate all of you, since this is due to the hard work and drive that all of you have shown. I want to personally thank you and commend all of you. Without the dedication, insight, and ideas of our faculty, the important works of UNM HSC would not be possible.

As we are entering the new 2023 fiscal, I would like to highlight a recent research award and an exciting new research study.

Co-PI Alberta Kong, along with medical student Joshua Vasquez, have received a Research Supplement award to promote diversity in health-related research from ISPCTN. The project aims to better understand adolescents, caregivers, and pediatricians' perceptions of weight loss medications, as part of planning for a multicenter clinical trial on adolescent weight.

UNM CTSC has received approval to begin enrollment in the Researching COVID to Enhance Recovery (RECOVER) Initiative study "A Multi-Center Observational Study: The RECOVER Post-Acute Sequelae of SARS-CoV-2 (PASC) Pediatric Cohort Study." UNM CTSC's participation in the RECOVER initiative is led by local investigators, Drs. Hengameh Raissy, and Walter Dehority, in collaboration with University of Arkansas Medical Sciences (UAMS) ISPCTN. UNM CTSC is one of 15 pediatric enrollment sites under the UAMS Hub Site umbrella.

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

The Participation Clinical Interactions (PCI) is supporting Drs. Gulshan Parasher and Euriko Torraza Perez in their randomized, double-blind, placebo-controlled, phase 2b study to evaluate safety and efficacy of (IV) DUR-928 in subjects with alcoholic hepatitis trial. This study will evaluate the safety

and efficacy, of DUR-928 in subjects with severe alcohol-associated hepatitis, also known as severe alcoholic hepatitis (AH).

The Biostatistics, Epidemiology, and Research Design (BERD) core group is assisting Dr. Richard Gadomski with the analyses of a study entitled: Descriptive Study: A Novel Model for the Delivery of Full Spectrum Care for Persons with Opioid Use Disorder. This study investigates medical service utilization among patients with opioid use disorder. The study tracks service utilization of buprenorphine-naloxone and other services at low barrier, syringe exchange programs. This research furthers our understanding of service utilization and ultimately aids in expanding access to treatment to this vulnerable population.

The Community Engagement and Research Core (CERC) team is currently supporting the research of Dr. Kimberly Page for the project titled "A mixed methods study of methamphetamine use in the context of the opioid epidemic: identifying opportunities for intervention (AMPED Study)". The project, in collaboration with a group at the University of Nevada Reno, is examining methamphetamine (MA) use patterns in the context of the opioid use endemic to develop and adapt opportunities for prevention and intervention among communities disproportionately affected by drug-related harm. The study will do qualitative interviews, and quantitative interviewer-led surveys to examine patterns between MA use and other drugs and identify social and structural factors that influence MA use and the availability of opioids. This study will also focus on identifying prevention and harm reduction strategies to potentially reduce disparities in MA and opioid use.

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.

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

Record Year for UNM HSC Extramural Funding- \$240 Million!

UNM HSC was awarded \$239,787,141 in external funding in FY22. This represents 17 out of last 18 years of record increases.

Without the dedication, insight, and ideas of the faculty, the important works of UNM HSC would not be possible. The research conducted with these funds will have a tremendous positive impact on health care in New Mexico and the United States. This research advances the understanding, diagnosis and treatment of numerous diseases including- behavioral health, asthma, cancer, stroke, Alzheimer's disease, substance abuse, heart disease and many others. HSC researchers have

established projects in many underserved, rural areas of New Mexico that have improved their access to treatment, determining new ways to address chronic disease, and increasing access to clinical trials and state of the art technologies. In short, research brings hope.

Research is also what separates academic health centers, like UNM HSC, from other health care providers. It is the power of integrated efforts in research, education, and clinical care at academic health centers throughout the US that has led to much of the innovation in the US healthcare system. Everyone should all be proud of their contributions to the advancement of health and healthcare.

The research mission at the UNM HSC also provides tremendous economic impact and job creation. New discoveries and patents stimulate the creation of new private companies in our state. The growth of the bioscience industry in New Mexico depends on a vibrant and growing academic health center research mission at its foundation.

The research UNM HSC has, and will continue, to improve health care in New Mexico, the US and the world.

ISPCTN Diversity Supplement

Research supplement awards to promote diversity in health-related research was recently announced as a priority in the IDeA States Pediatric Clinical Trials Network (ISPCTN) under the NIH Environmental Influences on Child Health Outcomes program. Co-PI Alberta Kong, of the New Mexico site along with UNM 4th year medical student Joshua Vasquez, took advantage of the opportunity and proposed formative research to better understand adolescents, caregivers, and pediatricians' perceptions of weight loss medications as part of planning for a multicenter clinical trial on adolescent weight management that is being considered in the ISPCTN. Their efforts paid off and their proposal was selected for a diversity supplement award. Student doctor Vasquez will be mentored by Dr. Kong, Professor and Chief of the Division of Adolescent Medicine in the Department of Pediatrics, in addition to co-mentor, Dr. Andrew Sussman, a medical anthropologist and Associate Professor in the Department of Family and Community Medicine. Their proposed study will be supported by the UNM Community Engagement & Research Core of the CTSC.

ISPCTN RECOVER Initiative

The IDeA States Pediatric Clinical Trials Network (ISPCTN) program was established to provide an opportunity for children in rural and medically underserved locations to participate in state-of-the-art clinical trials, to enhance pediatric clinical trial capacity at state and national levels, and to facilitate implementation of well-designed clinical trials in pediatric populations. UNM is one of only 17 clinical sites in the ISPCTN.

Recently, UNM CTSC received approval to begin enrollment in the Researching COVID to Enhance Recovery (RECOVER) Initiative study "A Multi-Center Observational Study: The RECOVER Post-Acute Sequelae of SARS-CoV-2 (PASC) Pediatric Cohort Study." UNM CTSC's participation in the RECOVER initiative is led by local investigators, Hengameh Raissy, PharmD and Walter Dehority, MD in collaboration with University of Arkansas Medical Sciences (UAMS) ISPCTN Principal Investigator, Jessica Snowden, MD. The New York University (NYU) Langone Health is the primary NIH grant recipient and coordinator for the RECOVER adult cohort. The University of Arkansas Medical Sciences

(UAMS) College of Medicine, is one of 10 sub-recipient hubs for the pediatric cohort study. UNM CTSC is one of 15 pediatric enrollment sites under the UAMS Hub Site umbrella.

The NIH launched the RECOVER Initiative to learn why some people have prolonged symptoms or develop new or returning symptoms after the acute phase of the infection from SARS-CoV-2, the virus that causes COVID-19. The long-lasting health effects related to COVID-19 are often referred to as Long COVID or PASC. The most common symptoms include pain, headaches, fatigue, "brain fog", shortness of breath, anxiety, depression, fever, chronic cough, and sleep problems. The longevity and severity of symptoms varies from person to person. The RECOVER Pediatric Study is a combined retrospective and prospective, longitudinal, observational meta-cohort of individuals from newborns to 25-year-olds. Individuals enter the cohort with and without SARS-CoV-2 infections at varying stages before and after infection. These individuals, with and without infection, and with or without COVID-19 symptoms, will be followed for four years to identify the risk factors and occurrence of Long COVID, or PASC. Nationally, up to 20,000 dyads, or children and young adults with and without history of SARS-CoV-2 infection and their primary caregiver, are anticipated to enroll.

For more information and to sign up go to: <https://recovercovid.org/> or call UNM CTSC 505-272-4673 (HOPE). Please encourage friends and family who have never had COVID, or who have recently tested positive for COVID, to sign up.

Participation Clinical Interactions (PCI)

Gulshan Parasher, MD MASGE FACP FACG, Division Chief of Gastroenterology and Hepatology and Euriko Torraza Perez, MD, Division of Gastroenterology are conducting a randomized, double-blind, placebo-controlled, phase 2b study to evaluate safety and efficacy of (IV) DUR-928 in subjects with alcoholic hepatitis trial. This study will evaluate the safety and efficacy, of DUR-928 in subjects with severe alcohol-associated hepatitis, also known as severe alcoholic hepatitis (AH). DUR-928, is a recently discovered endogenous sulfated oxysterol which is under development for the treatment of AH. DURECT has conducted numerous efficacy and safety pharmacology studies including PK, single and repeat dose toxicity, and genotoxicity studies, all of which have demonstrated the safety and efficacy of DUR-928.

AH is an acute form of alcoholic liver disease (ALD), a syndrome of progressive inflammatory liver injury associated with long-term heavy alcohol consumption. AH is characterized histologically by intracellular fat accumulation, neutrophilic infiltration, and hepatocellular injury. Patients with severe AH may present with fever, malaise, tender hepatomegaly, leukocytosis, marked impairment of liver function (e.g., jaundice, coagulopathy), and often have manifestations of portal hypertension (e.g., ascites, hepatic encephalopathy, and variceal hemorrhage). The traditional treatment focus for patients with AH was management of alcohol withdrawal while maintaining hydration and nutrition. The hope was that recovering liver function would help to avoid infection, acute kidney injury, acute-on-chronic liver failure, and death. Patients with moderate AH have a mortality risk of 6% within 3 months whereas severe AH is associated with a mortality risk of 15–20% at 1 month and 30% at 3 months (Mathurin, 2019). Patients who progress to multiorgan failure have a mortality risk of 20–50%. Standard medical therapy for AH consists of abstinence from alcohol, sedation, hydration, nutrition, and management of sepsis. Corticosteroids have been recommended for patients with severe AH, but with caveats that exclude many patients (Mathurin, 2002).

Liver transplantation was traditionally not offered to patients with AH until they had proven abstinence, usually for six months. This meant that patients usually died or recovered by the time they were eligible for liver transplantation. This has led to a major shift in care – many liver centers now transplant patients with severe AH if the patient is not improving, with calls for early rather than later intervention (Lee, 2019). As a result, 90-day mortality is no longer a valid endpoint unless liver transplantation is considered equivalent to death. The criteria for liver transplantation are related to, but not absolutely correlated with high MELD score and clinical deterioration. It is for this reason that we have changed our primary endpoint to death or liver transplantation.

This is a multi-site study enrolling 300 subjects. Dr. Parasher is teaming up with CTSC using regulatory and PCI service cores.

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>

Biostatistics, Epidemiology, and Research Design (BERD)

Dr. Richard Gadomski is a clinician and professor in the Department of Psychiatry. He is the principal investigator of a study entitled: *Descriptive Study: A Novel Model for the Delivery of Full Spectrum Care for Persons with Opioid Use Disorder*. This study investigates medical service utilization among patients with opioid use disorder. Dr. Jessica Gross, of the CTSC BERD Core, is assisting Dr. Gadomski with the analyses for this study.

Heroin, fentanyl, and other prescription opioids were the leading cause of death under age 50 in 2019, and were responsible for over 70% of deaths due to drug overdose in 2020. Given its high prevalence and severe consequences, it is important to provide timely and effective intervention. Traditional intervention consists of methadone administered in designated opioid treatment programs. However, a large subset of the population in need of intervention does not have access to such programs. Studies have shown buprenorphine-naloxone to be an effective treatment, and, unlike methadone, this medication can be prescribed at any location where a medical provider practices. Dr. Gadomski's study tracks service utilization of buprenorphine-naloxone and other services at low barrier, syringe exchange programs. This research furthers our understanding of service utilization and ultimately aids in expanding access to treatment to this vulnerable population.

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

Community Engagement and Research Core (CERC)

Dr. Kimberly Page, an Infectious Disease Epidemiologist and Professor in the Department of Internal Medicine, is a co-principal investigator of the project titled “A mixed methods study of methamphetamine use in the context of the opioid epidemic: identifying opportunities for intervention (AMPED Study)”. The project, in collaboration with a group at the University of Nevada Reno, is examining methamphetamine (MA) use patterns in the context of the opioid use endemic to

develop and adapt opportunities for prevention and intervention among communities disproportionately affected by drug-related harm. Drs. Page and Wagner are funded by the CDC for this project, after completing a multi-site pilot project funded by the Mountain West CTR-IN.

MA use and MA-involved deaths have increased since 2015. Furthermore, opioid-related deaths frequently involve MA use (Rhed et al., 2012). To identify patterns of MA use amidst an opioid endemic, this study will focus on northern New Mexico and northern Nevada, two regions with significant heroin and opioid use rates. Qualitative interviews, and quantitative interviewer-led surveys will be used to examine patterns between MA use and other drugs and identify social and structural factors that influence MA use and the availability of opioids. This study will also focus on identifying prevention and harm reduction strategies to potentially reduce disparities in MA and opioid use. Another objective is to assess potential cardiac injury associated with MA use using a biomarker, the high-sensitivity cardiac troponin test. The CTSC Community Engagement and Research Core (CERC) is pleased to support this important research that addresses the urgent need to examine underlying issues associated with drug use-related harms.

Rhed, B. D., Harding, R. W., Marks, C., Wagner, K. T., Fiuty, P., Page, K., & Wagner, K. D. (2022). Patterns of and Rationale for the Co-use of Methamphetamine and Opioids: Findings From Qualitative Interviews in New Mexico and Nevada. *Frontiers in Psychiatry*, 13, 824940.

<https://doi.org/10.3389/fpsyg.2022.824940>

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

Menu of Services & Resources

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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

CTSC Informatics will work with Dr. Marianne Berwick, and medical student Eunice Choi, on their chart review study "Melanoma in Women of Color". This study aims to compare Hispanic and Native American female melanoma patients with Hispanic and Native American male melanoma patients and with non-Hispanic white patients using chart review data from the UNMH. They will be studying other skin cancers in addition to melanoma and comparing women to men. Data from the Tumor Registry (for mortality) and Cancer Center will also be used.

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

CTSC Team Science Activities

SAVE THE DATE! CTSC Annual BioVenture Partnership Event will be held Friday, November 11, 2022 2pm-6:30 pm at the UNM SUB Ballrooms.

Participation is open to all UNM faculty, fellows, students, and BioTech Companies. BioVenture aims to create important connections between UNM HSC Research and local biotech business to build long-term interorganizational relationships. The event activities will include a Scientific Poster session and Pitch Competition. More information will be forthcoming, bookmark the [CTSC BioVenture webpage](#) for 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.

CTSC Education and Training. CTSC courses focus on building a strong foundation and skill set in research through special training seminars specific to 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](#).

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.

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 <i>Note: Any application without IRB submission prior to this date will be administratively disqualified</i>
March 18, 2022 Application Deadline in Camino	
	IRB Approval Deadline <i>Note: Any application without IRB approval by this date will not be considered for funding.</i>
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 biostatistical 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)

New Mexico health councils are one of the best resources in the state for community engagement. Health councils are state mandated and there are approximately 40 of them; one in each county (33) and 7 tribal councils as well. Most are open to the public and have representation from the local community. For health researchers, New Mexico health councils provide opportunities to discuss future and current studies in efforts to make the work more meaningful and impactful for all involved (researchers & community members).

Over the past several years, Cynthia Killough, the Community Health Specialist and program manager of the Community Health Network, has been attending multiple health councils around the state in efforts to build relationships and engage communities with the various research projects that come through CTSC. Ms. Killough has learned a lot about engaging communities through health councils and with the support of CTSC faculty leads, Drs. Robert Rhyne and Nancy Pandhi, and the director of the New Mexico Alliance of Health Councils, Sharon Finarelli, Ms. Killough has put together a resource geared towards fellow academics, researchers, principle investigators, etc. so that they too can engage in meaningful and impactful ways with health councils. A great way to engage with health councils is to present on current projects to keep communities in the loop about research happening in their county. Below are some tips for presenters shared on the *Engaging with New Mexico Health Councils* resource.



CONNECT YOUR WORK



02

In your presentation, describe how your work relates to the health council's interests & priorities.

FOR DATA REQUESTS

03

Avoid over-surveying the health council. If you are conducting a survey, can you collaborate with others or does the info you want already exist?



04

BRING RESULTS BACK



This is your opportunity to say thanks: present your findings back to the health council.

<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 important 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 HSC-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 Number	Organization(s)	Release Date	RFA/PA / PAR #	Expiry Date	Activity Code(s)
Understanding the Pathophysiology and Clinical Course of New-Onset Diabetes Following COVID-19 (U01 Clinical Trial Not Allowed)	RFA-DK-22-016	NIDDK	Jul 13, 2022		Dec 21, 2022	U01
Point-of-Care Technologies Research Network: Technology Research and Development Centers (TRDC) (U54 Clinical Trial Optional)	PAR-22-203	NIBIB , FIC , NCCIH , NCI , NHLBI , NIAID , NIDA	Jul 13, 2022		Jan 8, 2023	U54

Notice of Special Interest (NOSI): Studies of Cellular/Molecular Pathobiological Mechanisms of Lung Diseases Using Human 3-Dimensional Cellular Systems (R01)	NOT-HL-22-030	NHLBI	Jul 5, 2022		Sep 8, 2025	R01	
Notice of Special Interest (NOSI): COVID-19 Related Revisions to NINDS ADRD Human Subjects Cooperative Agreement Programs	NOT-NS-23-001	NINDS, NIA	Jun 21, 2022		Aug 12, 2022	333	
Notice of Special Interest (NOSI): Stimulating Research to Understand and Address Hunger, Food and Nutrition Insecurity	NOT-OD-22-135	ONR, FIC, NCI, NHLBI, NIAMS, NICHD, NIDCR, NIDDK, NIMH, NIMHD, NINR, OAR, OBSSR, ODP, ODS, PN, ORWH	Jun 21, 2022		Nov 29, 2024	R01, 333, R21, K01, R34, R33, R61/R33, UG3/UH3 , K43	
Coordinating Center for the HIV/AIDS and Substance Use Cohorts Program (U24 Clinical Trial Not Allowed)	RFA-DA-23-052	NIDA	Jun 13, 2022		Aug 11, 2022	U24	
NICHD Program Project Grants for HIV Research (P01 Clinical Trial Optional)	RFA-HD-23-026	NICHD	May 23, 2022		Aug 11, 2022	P01	
Limited Competition: Clinical and Translational	PAR-22-167	NCATS, NIAMS, NICHD, NIDCR, NIGMS, NIMHD, OBSSR, ORWH	May 9, 2022		Oct 18, 2024	UG3/UH3	

Science Award (CTSA) Program: Collaborative and Innovative Acceleration Award (UG3/UH3 Clinical Trial Optional)						
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: 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	NOT-HD-22-003	NICHD , NIAAA , NIDA , NINDS , OBSSR , ORWH	Apr 19, 2022		Jun 6, 2024	333

to the Health and Well-Being of Women, Children and Individuals with Physical and/or Intellectual Disabilities						
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	<u>NOT-HD-22-002</u>	<u>NICHD</u> , <u>NIDA</u> , <u>NIEHS</u> , <u>NINDS</u> , <u>OBSSR</u> , <u>ORWH</u>	Mar 28, 2022		Jun 6, 2024	R01, R21
Understanding and Addressing Misinformation among Populations that Experience Health Disparities (R01 - Clinical Trials Optional)	<u>RFA-MD-22-008</u>	<u>NIMHD</u> , <u>NCI</u>	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)	<u>PAR-22-138</u>	<u>NIMH</u> , <u>NIAAA</u> , <u>NIEHS</u> , <u>ORWH</u>	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): COVID-19	NOT-MH-22-100	NIMH	Jan 19, 2022		Jan 8, 2025	R21, R34, R01	

Pandemic Mental Health Research						
Notice of Special Interest: Administrative Supplements and Urgent Competitive Revisions on Coronavirus Disease 2019 (COVID-19) within the Mission of NIAAA	NOT-AA-22-002	NIAAA	Dec 2, 2021		May 8, 2024	333
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	NOT-DA-21-017	NIDA	Feb 4, 2021	PA-20-184 PA-20-183 PA-20-200	Sep 8, 2024	R01, R02, R03

Abuse in Individuals with HIV and COVID-19				PA-20-195 PA-20-194 PA-20-196		
Notice of Special Interest (NOSI): Complement in Basic Immunology (CIBI)	NOT-AI-21-008	NIAID	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	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	NOT-DE-21-001	NIDCR	Jan 26, 2021	PA-20-185 PA-20-195	May 28, 2023	R01, R21

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

COVID-19 Impacted NIMH Research						
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): Promoting	NOT-HD-21-038	NICHD	June 28, 2021	PA-20-200 , PA-21-	May 8, 2024	R03, R21

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 , NID A	June 25, 2021	PA-20-185, PA-20-195	May 8, 2024	R01, R21

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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