



Clinical & Translational Science Center Newsletter

April 2022

Letter from the Director



Dear Colleagues,

Spring is here and so is daylight savings. As we head into the beginning of the fourth quarter it's time to start planning your research projects for FY2023. New funding opportunities can now be found online at https://hsc.unm.edu/research/news/funding-opps.html.

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

With support from our clinical trials unit (PCI) Dr. Emily Altman, is conducting the BeHEARD (HS0004/0005) trial to examine the efficacy and safety of bimekizumab in study participants with moderate to severe Hidradenitis Suppurativa (HS). HS0004 is a Phase 3, randomized, double-blind, placebo-controlled, multicenter, pivotal study evaluating the efficacy and safety of bimekizumab in study participants with moderate to severe HS. Depending on the success

and efficacy of bimekizumab participants may continue into the open-label study HS0005.

Our Community Engagement Research (CERC) team are assisting Dr. David Stromberg, and his research team, who are conducting a research project titled: Satisfaction with Feedback: Resident Perceptions (SaFeR Perceptions). The purpose of this study is to examine resident perceptions related to feedback in the clinical learning environment. The findings from this project will provide information on residents' perceptions about feedback, what influences residents' response to the ACGME survey question about satisfaction with feedback and how the UNM School of Medicine and individual programs could improve their feedback efforts.

Thais Schwartz, of the CTSC BERD Core assisted Dr. Kate Meriwether in completing the analyses for her pilot study entitled: Evaluation of Centering-based group treatment visits (CBGT) in the treatment of women with interstitial cystitis/bladder pain syndrome (ICBPS): A parallel, prospective cohort study. This research will determine the effect of ICBPS Centering groups on pain relief and other outcomes amongst ICBPS patients, using an evidence-based approach to support this possible therapy shift in the field of ICBPS.

After a two-year hiatus due to the COVID-19 pandemic, the 2022 Clinical and Translational Science Center (CTSC) Health Hackathon was back in person at the Domenici Center for Health Sciences Education North Wing at The University of New Mexico the weekend of March 25-27. The CTSC Health Hackathon strives to stimulate innovation in healthcare, encourage multi-disciplinary collaboration, and foster creativity in a fun and competitive atmosphere. The event is led and organized by the CTSC as part of their NIH-funded grant. Gold sponsors were the HSC Office of Research, the UNM Office of the Vice President for Research and the School of Engineering. Silver sponsors were ASCEND HUB, UNM Rainforest Innovations, the Anderson School of Management, the College of Pharmacy and the College of Nursing.

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 (<u>RLarson@salud.unm.edu</u>) to start a dialogue.

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

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: <u>https://hsc.unm.edu/research/</u>.

All standard CTSC services are available. We encourage PIs to reach out to our Research Concierge (<u>HSC-</u> <u>CTSCResearchConcierge@salud.unm.edu</u>) 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 <u>HSC-</u> <u>CTSCResearchConcierge@salud.unm.edu</u>. If you have any issues finding the information that you need, please reach out to <u>the CTSC Newsletter Team</u> 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: 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

Featured Stories

Participation Clinical Interactions (PCI)

Dr. Emily Altman, Professor/Program Director in the SOM, Department of Dermatology, is conducting the BeHEARD (HS0004/0005) trial to examine the efficacy and safety of bimekizumab in study participants with moderate to severe Hidradenitis Suppurativa (HS).

Hidradenitis suppurativa (HS) or acne inversa is a chronic, inflammatory, recurrent, debilitating skin disease that usually presents after puberty with painful, deep-seated, inflamed lesions in the apocrine gland-bearing areas of the body, most commonly the axillaries, inguinal, and anogenital regions. Bimekizumab is an engineered, humanized full-length mAb of IgG1 subclass being developed for the treatment of patients with inflammatory diseases such as PSO, psoriatic arthritis, axial spondyloarthritis, and HS.

HS0004 is a Phase 3, randomized, double-blind, placebo-controlled, multicenter, pivotal study evaluating the efficacy and safety of bimekizumab in study participants with moderate to severe HS. Participants will be at least 18 years of age and will complete a 48-week treatment period. Depending on the success and efficacy of bimekizumab participants may continue into the open-label study HS0005.

This is a multicenter effort that plans to enroll up to 1000 participants. This study will follow participants for 48 weeks of treatment and evaluate clinical outcomes along with safety data to determine the efficacy and safety of the investigational agents. The CTSC is supporting this study on many levels, CTSC regulatory support, Participant Recruitment Service (PRS) and PCI coordination.

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

Community Engagement and Research Core (CERC)

Dr. David Stromberg, Associate Professor of Family and Community Medicine, and his research team are conducting a research project titled: Satisfaction with Feedback: Resident Perceptions (SaFeR Perceptions). The purpose of this study is to examine resident perceptions related to feedback in the clinical learning environment. This is an area of interest, as UNM has had lower survey scores regarding feedback than the residency programs would like. This will be the first study to elicit what residents feel is lacking in feedback in general, rather than simply offering solutions without knowing what are the actual concerns regarding feedback. Medical residents currently in training at UNM are invited to participate in the study.

The Accreditation Council for Graduate Medical Education (ACGME) surveys are used to monitor medical education and provide an early warning of potential non-compliance with accreditation requirements. There is limited literature on this topic and only a few studies have tried to investigate resident perceptions on the feedback process. In addition, the research has generally focused on resident programs for Internal Medicine and the Emergency Department. In this study, investigators will try to better understand resident perceptions of feedback, feedback culture and more specifically their satisfaction with feedback within the institution. The CTSC Community Engagement and Research Core is assisting in the study by conducting focus groups which consist of a diverse selection from the UNM residency program.

The findings from this project will provide information on residents' perceptions about feedback, what influences residents' response to the ACGME survey question about satisfaction with feedback and how the UNM School of Medicine and individual programs could improve their feedback efforts.

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

Biostatistics, Epidemiology, and Research Design (BERD)

Thais Schwartz, of the CTSC BERD Core assisted Dr. Kate Meriwether in completing the analyses for her pilot study entitled: Evaluation of Centering-based group treatment visits (CBGT) in the treatment of women with interstitial

cystitis/bladder pain syndrome (ICBPS): A parallel, prospective cohort study. Dr. Meriwether is an assistant professor in the Department of Obstetrics, Gynecology, & Women's Health. This study compared a cohort of women who have opted to participate in ICBPS Centering in addition to their usual care (Centering group) to women who engaged in usual care alone (UC group). This research will determine the effect of ICBPS Centering groups on pain relief and other outcomes amongst ICBPS patients, using an evidence-based approach to support this possible therapy shift in the field of ICBPS.

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

Hackathon

Student housing, oral health, anti-racist app for surgeons winning ideas at 2022 CTSC Health Hackathon

They came. They saw. They hacked.

After a two-year hiatus due to the COVID-19 pandemic, the 2022 Clinical and Translational Science Center (CTSC) Health Hackathon was back in person at the Domenici Center for Health Sciences Education North Wing at The University of New Mexico the weekend of March 25-27. The CTSC Health Hackathon strives to stimulate innovation in healthcare, encourage multi-disciplinary collaboration, and foster creativity in a fun and competitive atmosphere.

Six teams participated in the event, which brought together individuals from diverse backgrounds — including students, educators, programmers, entrepreneurs, engineers, dental hygienists and physicians — to identify pressing healthcare challenges and "hack" a solution in the form of innovative technology.

Participants formed teams on Friday evening around ideas presented by fellow 'hackers'. They spent most of Saturday analyzing the ideas and issues, brainstorming approaches, methods, and solutions, developing prototypes, business plans, and their final "Shark Tank" style pitch presentation. On Sunday, the teams pitched their ideas to panel of judges, competing for a chance to apply for grants from the CTSC of up to \$10,000 to help bring their ideas to life.

Three teams won the opportunity to continue pursuing their idea, with concepts running the gamut from addressing crises in UNM student housing and oral health to helping medical professionals embrace equity and inclusion in their practice.

One winning team developed an idea called NanoPOD, which uses nanotechnology to prevent oral disease by introducing nanoparticles into toothpaste and mouthwash. Iron oxide nanoparticles added to these products disrupt biofilms and kill harmful bacteria.

"Oral disease is a crisis," said team leader Jennifer Carranza, a student in the dental hygiene master's program. "Fortyseven percent of adults over the age of 30 have some form of periodontal disease, and it is preventable."

Team members included: Adreanna Rael, an undergraduate student in the College of Population Health; Mia Baca, an undergraduate in the Department of Chemical and Biological Engineering; Shruti Gharde, a Ph.D. student in the Optical Sciences and Engineering program; Mark Reymatias, a Ph.D. student in the Nanoscience and Microsystems Engineering program; and Marek Osinski, Ph.D., Distinguished Professor in the Department of Electrical and Computer Engineering, Computer Science, and Physics and Astronomy.

Another winning team tackled impacts on student health resulting from the lack of accessible student housing. Homeless young people experience higher rates of chronic health problems, trauma-related injuries, and nutritional problems according to Youth.gov. The Alternative Student Housing (ASH) app's mission is to connect students in need of housing to nearby affordable and available residences. According to the team, 41% of UNM students experience a housing crisis at some point during their time at UNM.

Anthony Wallace said he was inspired to create this app after experiencing homelessness as a student in another state several years ago.

"This is personal for me because as a student, I had many scholarships, but spent 11 months on the street," he said. "I now have housing security, but it took me many years. I wanted to create this app so this doesn't have to be anyone else's problem."

In addition to Wallace, members of the team are Amelia Bierle (who was on a winning Hackathon team in 2020), an MBA student in the Anderson School of Management; John Schwitz, local entrepreneur, Michael Millar, an

undergraduate in the Department of Computer Science; Marlene Brown, educator at CNM in Photovoltaics and Math; and Katrina Guinta. local businesswoman in social media marketing and management.

The third winning pitch, IDEA (Inclusion, Diversity, Equity and Anti-discrimination), was led by Ming-Li Wang, M.D., UNM surgeon and associate professor, focused on creating an engaging, game-based app to help medical professionals recognize the impacts of bias and micro-aggressions on patients and alter behaviors in the workplace.

Team-member, Mary Thelander Hill, an assistive technology professional, explained "There are documented cases of mistreatment of residents and patients. What we hope to do is gamify the training and provide a friendly competition, while also educating medical professionals on issues of inclusion, equity and diversity." Workplace discrimination is detrimental but research also shows strong correlation that micro-aggressions lead to elevated levels of depression and trauma among minorities. More effective training to recognizing symptoms and behaviors will benefit both patients and medical professionals resulting in improved patient care.

The other IDEA team members include: Joshua Benavidez, student; Tione Buranda, Ph.D., Department of Pathology; Michael McDonald, retired engineer; and Nancy Shane, UNM School of Medicine program evaluator.

Other ideas in the competition were developing an "electronic nose" to detect diseases like COVID-19, heart disease and cancer; an app to help nurture compassion in future healthcare providers; and an app that uses machine learning to detect indicators of inflammation, which is a major consequence of obesity and contributes to cardiovascular disease and diabetes.

Teams were judged on the content, impact to healthcare, quality, and clarity of their presentation, as well as the marketability and feasibility of the idea or technology.

The event is led and organized by the Clinical and Translational Science Center as part of their NIH-funded grant. Gold sponsors were the Health Sciences Center Office of Research, the UNM Office of the Vice President for Research and the School of Engineering. Silver sponsors were ASCEND HUB, UNM Rainforest Innovations, the Anderson School of Management, the College of Pharmacy and the College of Nursing.

The event was co-chaired by Eric Prossnitz, Ph.D., Distinguished professor of internal medicine and Robert G. Frank, Ph.D., professor in the College of Population Health. Christina Salas, Ph.D., an associate professor in the Department of Orthopaedics and Rehabilitation helped to organize the event and provided 3D printing assistance for teams interested in designing prototypes of their technology.

Judges for this year were Gregg Banninger, Ph.D., innovation manager for life sciences at UNM Rainforest Innovations; John Chavez, MBA, managing director of the New Mexico Start-Up Factory; Trish Lopez, founder of Teeniors; Stacy Sacco, MBA, lecturer in the Anderson School of Management and director of the UNM Small Business Institute; and Mathis Shinnick, director of corporate engagement at UNM Rainforest Innovations.









Menu of Services & Resources

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

Data Requests & "Using Data Courses"

The CTSC informatics is pulling data for the study lead by Dr. Chow, her research question is: Viral bronchiolitis is a leading cause of hospitalization in the first year of life. There is currently side variability in the use of high flow nasal

canula (HFNC) initiation and weaning practices. This project aims to reduce overutilization of HFNC in the treatment of infants with bronchiolitis to target HFNC initiation and weaning practices.

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

"Benefits of team science included enhanced insights from multidisciplinary perspectives, increased scholarly productivity and impact, and mentoring of newer faculty by those with greater experience". (Dana DeHart, Team science: A qualitative study of benefits, challenges, and lessons learned, The Social Science Journal, Volume 54, Issue 4, 2017, Pages 458-467, ISSN 0362-3319, https://doi.org/10.1016/i.soscij.2017.07.009. https://www.sciencedirect.com/science/article/pii/S0362331917300708)

As Team Science becomes the primary mode of operation for researchers, clinicians, and academia, the CTSC Health Hackathon is a fun approach to experience the principals of team science. This weekend event promotes diversity in collaboration across healthcare, engineering, and business with multidisciplinary teams working in intense collaboration, in the hopes of creating a viable new start-up / innovation.

CTSC invite you to participate in our Team Science focused activities:

- CTSC Translational 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. February 2022 Synergy meeting will focus on COVID-19 Research and Omicron variant updates as a joint presentation with DOIM Grand Rounds. <u>Contact Melanie Hazlett</u>, CTSC Team Strategist, to request more information about the Spring 2022 CTSC Synergy Meetings.
- The HSC CTSC office supports many Commercialization efforts by participating with <u>The ASCEND (Accelerating</u> <u>Solutions for Commercialization and Entrepreneurial Development)</u> 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: <u>https://ascendhub.org</u>.

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: <u>https://hsc.unm.edu/research/ctsc/training/index.html</u>

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,

<u>HSC-CTSCResearchConcierge@salud.unm.edu</u>, 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 <u>ChAnderson@salud.unm.edu</u>.

Reminder of the new timeline for pilot submissions in March.

November 11, 2021 Request for Applications Release Date

January 21, 2022 IRB Submission Deadline

Note: Any application without IRB submission prior to this date will be administratively disqualified

March 18, 2022 Application Deadline in Camino

 IRB Approval Deadline
 Note: Any application without IRB approval by this date will not be considered for funding.

April 11, 2022 Notice of Intend to Fund/Decline
May 13, 2022 Announce Awards
June 1, 2022 Funding Begins
May 31, 2023 Funding Ends

Pilot Award

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

Linking Clinical Trials to Drug Discovery and Repurposing Award

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

CTSC/DCI Kidney Pilot Project Award

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

Innovation & Commercialization Award

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

Wicked Problems: Target Pilot Project Award

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

- Data Sharing
- Big data to alter practice/diagnosis
- Use of multiple datasets
- Access to resources to address labor-intensive activities
- Privacy and data protection for research
- Removing institutional bottlenecks/sharing of resources
- Evaluating the impact of translational research efforts

- Implementing scientific review before studies are performed
- Dissemination and implementation Science
- EHR data integration
- Defining Impact for the CTSA Program
- Building a KL2 Scholar Community
- Addressing challenges in recruiting from rural sites
- Hub Stability

Mentored Career Development Program (KL2)

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

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

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

Research Methods (RM)

Biostatistics, Epidemiology, and Research Design (BERD)

Biostatistics Consultation Services Available at CTSC

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

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

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

Appointments are available; but do fill up quickly. To schedule an appointment, please contact

HSC-CTSCbiostats@salud.unm.edu. Services are offered Monday through Friday.

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

Regulatory Knowledge & Support (RKS)

The clinical research community is supported by the Federal Regulatory Support. This no cost service at the UNM HSC provides assistance with sponsor-investigator IND or IDE applications. This includes personal consultation and helpful templates through online modules on a range of topics related to FDA regulated studies. The goal is to provide the research community with the tools, training and support needed to navigate the complex regulatory pathways that accompany translational research. As part of this support, the UNM CTSC regulatory manager, Rebecca Brito, 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. <u>ClinicalTrials.gov</u>: 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 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. 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: <u>https://hsc.unm.edu/research/ctsc/Community-Engaged-Research-Core/integrating-special-populations.html</u>

CHN (Community Health Network)

Community engagement efforts, partnerships, and relationships continue to flourish beyond the challenges posed by COVID-19. Cynthia Killough, the program Community Health Specialist (CHS), has been attending 12 community health councils virtually around the state consistently (see map) some before the start of the pandemic and some were more recently. These meetings provide a wealth of information about health priorities and concerns that are important to each county. The meetings also provide a way for Cynthia to introduce health research from UNM and help break down stigma associated with research in general. In the upcoming months there are exciting new projects in the que that include CHS involvement. Stay tuned!



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

Trial Innovation Network (TIN)

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

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

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

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

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

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

Drug Discovery & Repurposing Core (DDRC)

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

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

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

Clinical Laboratory (T-Laboratory)

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 <u>HSC-CTSCResearchConcierge@salud.unm.edu</u>.

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 (<u>MMParra@salud.unm.edu</u>) if you are interested in applying for any of the COVID-19 funding opportunities listed below.

Recent	Active	Funding	Opportu	nities Spe	ecific to (COVID-19	are listed	below:
						00110 10		

Title	Notice	Organization(Release	RFA/PA/	Expiry	Activity
	Number	s)	Date	PAR #	Date	Code(s)
Notice of Special Interest	NOT-ES-22-	NIEHS	Mar 29,		Jun 7, 2022	333
(NOSI): Promoting Health,	005		2022			
Safety, and Recovery						
Training for COVID-19						
Essential Workers and their						
Communities						
Notice of Special Interest	<u>NOT-HD-22-</u>	<u>NICHD, NID</u>	Mar 28,		Jun 6, 2024	R01,
(NOSI) - Emerging and	<u>002</u>	<u>A</u> ,	2022			R21
Existing Issues of		<u>NIEHS, NIN</u>				
Coronavirus Disease 2019		<u>DS</u> ,				
(COVID-19) Research		<u>OBSSR, OR</u>				
Related to the Health and		<u>WH</u>				
Well-Being of Women,						
Children and Individuals						
with Physical and/or						
Intellectual Disabilities						
Understanding and	<u>RFA-MD-22-</u>	<u>NIMHD, NCI</u>	Mar 22,		Nov 14,	R01
Addressing Misinformation	<u>008</u>		2022		2022	
among Populations that						
Experience Health						
Disparities (R01 - Clinical						
Trials Optional)						
Accelerating the Pace of	PAR-22-138	<u>NIMH, NIAA</u>	Mar 15,		May 8, 2025	R21
Child Health Research Using		<u>A</u> ,	2022			
Existing Data from the		<u>NIEHS</u> , <u>ORW</u>				
Adolescent Brain Cognitive		<u> 번</u>				
Development (ABCD) Study						
(R21-Clinical Trial Not						
Allowed)						

Accelerating the Pace of Child Health Research Using Existing Data from the Adolescent Brain Cognitive Development (ABCD) Study (R01-Clinical Trial Not Allowed)	<u>PAR-22-137</u>	<u>NIMH, NIAA</u> <u>A,</u> <u>NIEHS, ORW</u> <u>H</u>	Mar 15, 2022	May 8, 2025	R01
Emergency Awards: RADx- UP - Social, Ethical, and Behavioral Implications (SEBI) Research on Disparities in COVID-19 Testing among Underserved and Vulnerable Populations (U01 Clinical Trial Optional)	<u>RFA-OD-22-</u> 005	OD, NCATS, NCCIH, NCI, NEI, NHGRI, NHLBI, NIA, NIAAA, NIAID, NIAMS, NIBB, NICHD, NIDA, NIDCD, NIDCR, NIDCR, NIDCR, NIDCR, NIBHS, NIGMS, NIMH, NIMHD, NINDS, NINR	Feb 17, 2022	May 3, 2022	U01
Emergency Award: RADx-UP Community-Engaged Research on Rapid SARS- CoV-2 Testing among Underserved and Vulnerable Populations (U01 Clinical Trial Optional)	<u>RFA-OD-22-</u> <u>006</u>	OD, NCATS, NCCIH, NCI, NEI, NHGRI, NHLBI, NIA, NIAAA, NIAID, NIAMS, NIBB, NICHD, NIDA, NIDCD, NIDCR, NIDCR, NIDCR, NIDCR, NIDCK, NIBHS, NIGMS, NIMH, NIMHD, NINDS, NINR	Feb 17, 2022	May 3, 2022	U01
Notice of Special Interest (NOSI): Addressing Accessibility Inequities with COVID Home-Based Testing	<u>NOT-EY-22-</u> 010	<u>NEI</u>	Feb 4, 2022	Mar 9, 2024	R41/R4 2, R15, 333, R01,

for Individuals with Visual Impairment					R43/R4 4, R21
Urgent Award: COVID-19 Mental Health Research (R01 Clinical Trial Required)	PAR-22-112	<u>NIMH</u>	Jan 31, 2022	Dec 24, 2022	R01
Urgent Award: COVID-19 Mental Health Research (R01 Clinical Trial Optional)	PAR-22-113	<u>NIMH</u>	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	<u>NOT-HL-22-</u> 010	<u>NHLBI</u>	Jan 31, 2022	May 8, 2025	R01
Evaluation groups Evaluating the Impact of COVID-19 Pandemic-related Food and Housing Policies and Programs on Health Outcomes in Health Disparity Populations (R01 Clinical Trial Optional)	<u>RFA-NR-22-</u> 001	NINR, NIDA, NIMH, NIMHD, OBSSR, ODP	Jan 25, 2022	Apr 8, 2022	R01
Notice of Special Interest (NOSI): Enhancing Research on Deciphering Mechanisms of COVID-19-Associated Coagulopathy	<u>NOT-HL-23-</u> 003	<u>NHLBI</u>	Jan 21, 2022	Jul 6, 2022	R01
Notice of Special Interest (NOSI): COVID-19 Pandemic Mental Health Research	<u>NOT-MH-</u> 22-100	<u>NIMH</u>	Jan 19, 2022	Jan 8, 2025	R21, R34, R01
Notice of Special Interest: Administrative Supplements and Urgent Competitive Revisions on Coronavirus Disease 2019 (COVID-19) within the Mission of NIAAA	<u>NOT-AA-22-</u> <u>002</u>	<u>NIAAA</u>	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)	<u>NOT-OD-22-</u> 030	ORWH, NIDA, NEI, NIDCD, NIEHS, NHGRI, NIMH, NIAID, NINR, NICHD, NHLBI, NCCIH, NIAAA, SGMRO,	Dec 2, 2021	Jan 27, 2023	333

		NCATS, NIDCR, NIAMS, ORIP,				
		NIDDK, NIBIB, NIA				
Notice of Special Interest (NOSI): Telehealth Strategies for Individuals with HIV and Substance Use Disorders	<u>NOT-DA-21-</u> 019		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
(NOSI): Medical Consequences of Smoking and Vaping Drugs of Abuse in Individuals with HIV and COVID-19	<u>017</u>		reb 4, 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>	Sep 8, 2024	R01, R02, R03
Notice of Special Interest (NOSI): Complement in Basic Immunology (CIBI)	<u>NOT-AI-21-</u> 008	NIAID	Feb 4, 2021	<u>PA-20-185</u> <u>PA-20-195</u>	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	<u>NOT-DA-21-</u> 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	<u>NOT-TR-21-</u> 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 Involvement of Oral Cavity in Coronavirus Disease 2019 (COVID-19)	<u>NOT-DE-21-</u> <u>001</u>	<u>NIDCR</u>	Jan 26, 2021	<u>PA-20-185</u> <u>PA-20-195</u>	May 28, 2023	R01, R21
Notice of Special Interest (NOSI): Aging-Relevant Behavioral and Social Research on Coronavirus Disease 2019 (COVID-19)	<u>NOT-AG-21-</u> 015	NIA	Jan 26, 2021	PA-20-183 PA-20-184 PA-20-185 PA-20-200 PA-20-194 PA-20-196	May 28, 2023	R01, R03, R21, U19, P01,

Notice of Special Interest (NOSI): Effects of smoking and vaping on the risk and outcome of COVID-19 infection	<u>NOT-DA-21-</u> 011	NIDA	Jan 26, 2021	PA-20-195 PAR-19-374 PAR-19-314 PAR-19-070 PAR-20-070 PAR-20-184 PA-20-183 PA-20-195 PA-20-194 PA-20-196	Sep 8, 2024	R21/R3 3 R01, R03, R21
Notice of Special Interest: Administrative Supplements for COVID-19 Impacted NIMH Research	<u>NOT-MH-</u> 21-120	<u>NIMH</u>	Dec 23, 2020	<u>PA-20-146</u> <u>PA-20-272</u>	Jun 2, 2023	333
Notice of Special Interest (NOSI): Effects of smoking and vaping on the risk and outcome of COVID-19 infection	<u>NOT-DA-20-</u> <u>084</u>	<u>NIDA</u>	Oct 27, 2020	<u>PA-20-183</u> <u>PA-20-200</u> <u>PA-20-195</u>	Sep 8, 2024	R01, R03, R21
Notice of Special Interest (NOSI): Simulation Modeling and Systems Science to Address Health Disparities	<u>NOT-MD-</u> <u>20-025</u>	<u>NIMHD</u> , <u>NCI</u> , <u>NIDA</u> , <u>NLM</u> , <u>ODP</u> , <u>OBSSR</u> , <u>NIMH</u> , <u>NIAMS</u>	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 Health Impacts of COVID-19	<u>NOT-HD-21-</u> 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
Notice of Special Interest (NOSI): NIDCD is Interested in Supporting Research on the Impact of COVID-19 on Mission Specific Sensory and Communication Disorders	<u>NOT-DC-20-</u> <u>008</u>	NIDCD	Jun 4, 2020	PA-18-334 PA-20-185 PA-20-184 PA-20-196 PA-20-195 PA-20-195 PA-19-270 PA-19-271 PA-19-273 PA-19-272	Sep 8, 2022	R01, R21, R41/R4 2, R43/R4 4
Emergency Competitive Revision to Existing NIH Awards (Emergency Supplement - Clinical Trial Optional)	<u>PA-20-135</u>	<u>NIH, NCATS,</u> <u>NCCIH, NCI,</u> <u>NHGRI, NIA,</u> <u>NIAAA</u> , <u>NIAID</u> ,	Mar 10, 2020	<u>PA-20-135</u>	Sep 8, 2025	333

		NIAMS, NIBIB, NICHD, NIDCD, NIDDK, NIEHS, NIGMS, NIMH, NIMHD, NIMHD, NINR, NLM, ORWH, OSC				
Notice of Special Interest	<u>NOT-HD-21-</u>	<u>NICHD</u>	June 28,	<u>PA-20-200</u> ,	May 8, 2024	R03,
(NOSI): Promoting Vaccine	<u>038</u>		2021	<u>PA-21-221</u> ,		R21
Access, Acceptance and				<u>PA-20-195</u> ,		
Uptake among Children,				<u>PA-20-194</u>		
Adolescents, Pregnant and						
Lactating women, and						
Notice of Special Interest	NOT-AI-21-		lune 25	PA-20-185	May 8, 2024	R01
(NOSI) HIV/AIDS in the Fra	057		Julie 23,	PA-20-105	ividy 0, 2024	R01, R21
of COVID-19: When	<u>057</u>	, <u>NDA</u>	2021	<u>1 A-20-155</u>		NZI
Pandemics Collide						
Limited Competition	PAR-21-276	NIAID	Jul 16, 2021	Reissue	Jul 16, 2022	S10
Emergency Awards: Shared				of <u>PAR-20-</u>		
Personal Protective				<u>256</u>		
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: <u>https://grants.nih.gov/grants/guide/COVID-Related.cfm</u>.

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: <u>http://hscnews.unm.edu/</u>

News or corrections?

Please contact <u>the Newsletter Team</u>. The University Of New Mexico Mailing Address: One University of New Mexico MSC 08 4635 Albuquerque, NM 87131