MULTI-SITE PILOT PROJECT (MSPP) FUNDING OPPORTUNITY ANNOUNCEMENT

The mission of the Mountain West CTR-IN Program is to increase and enhance clinical and translational research capacity and facilitate extramural funding success among investigators with faculty appointments at the 12 university partners.

Key Dates:

Final day for submission of Nominating Packets by institution partners*	December 14, 2022
Invitations to investigators to submit full applications will be issued by	December 16, 2022
Application Due Date	March 22, 2023
Announcement of applications selected for Intent to Fund	May 8, 2023
Earliest Start Date	July 15, 2023
Project Period**	July 15, 2023 – June 30, 2024

* The limited competition nomination process will be determined by each institution; earlier internal deadlines may apply.

** Actual start date will be dependent upon receipt of approval from NIGMS. . In past years, this has been as late as October.

Purpose. The purpose of this funding opportunity is to provide support for multi-site clinical and translational (CTR) research with the expectation that the project will yield key preliminary data and capacity building to facilitate a large-scale multi-site extramural grant application or other extramural grant funding opportunities.

Webinar. We will have a webinar for details about this year's funding mechanisms. The live webinar will be held on October 5th at 2:00 PM Mountain Time. The link to join the webinar is: https://umontana.zoom.us/j/94044340039?pwd=Mnd3Z3ZPVDlicDlPV1E2RTBWUEJWZz09. If you can not join the webinar live, but would like to view the webinar, you can access the recording here: https://umt.box.com/s/csemdrw0qr3diryq7ibv76fxln8dyjqo.

Multisite Training.
Kim Page will also be hosting a training about conducting multi-site trials. The information about the training session will be announced during the webinar.

Overview and Criteria. Multi-Site Pilot Projects must include CTR-IN partner institutions in at least two MW states involving at least 2 partner universities. We also recognize the complexity of conducting such a large multi-site project. Hence, the potential PI and Co-PIs should consider an initial project that first demonstrates the feasibility of conducting such a large-scale multi-site project.

Programmatic Priorities. Working in conjunction with our two Regional Community Advisory Boards (CABs) representing all six Mountain West states, we solicited input on funding priorities for the communities we serve. The following specific themes were consistently identified across all CABs:

- Childhood obesity and metabolic conditions including diabetes and other related factors of food security, food sovereignty, and healthy food access.
- Opioid and other substance abuse, mental health / suicide prevention and psycho-social trauma.
- COVID-19, including impacts to healthcare access, associated influences on mental health, and disproportionate impacts to vulnerable populations.

We recognize that the above areas of research do not capture all important health priorities in all of the communities that we serve or that the CABs identified, and our funding determinations are **not** limited to these above topics. We also anticipate that these programmatic priorities will be revised and updated in forthcoming years as we continue to receive input from our regional stakeholders. All applications will undergo the same scientific merit review per standard NIH procedures, regardless of the topic area.

Principal Investigator (PI) Eligibility. The PI must 1) have a faculty-level appointment with a minimum of 0.5 FTE support at a participating CTR-IN Institution, and 2) must be eligible to submit extramural grant applications from their institution as a PI. The PI must devote at least 20% effort (2.4 person months) to the Pilot Grant project. Prior CTR-IN awardees are eligible to apply, but they must be in good standing (i.e., submission of requested progress reports and updates). Per IDeA program policy, an awardee may not concurrently receive funding for their research program through other IDeA mechanisms (e.g., CTR, COBRE or INBRE).

Direct Cost: Direct costs are $90,000 to $150,000, although justification for higher direct costs will be considered depending on the number of states and institutions involved. UNLV will administer separate subawards for each collaborating site.

Awardee Obligations. The investigator team will be expected to work with the CTR-IN programmatic Cores [e.g., Professional Development (PD), Community Engagement and Outreach (CEO), and Biostatistics, Epidemiology, Research & Design (BERD)] that will provide mentorship and guidance on multi-site clinical study design, biostatistics, community engagement and outreach, grant writing and identification of extramural funding opportunities. In particular, the investigator team should utilize support of the multisite data coordination offered at the University of New Mexico Health Science Center through the BERD Core for funded multi-site pilot projects.

APPLICATION PROCESS

STEP ONE - Limited competition nomination of applicants from eligible institutions:

Applications for the Lead Site of a Multi-Site Project must be nominated by their institution and subsequently invited by MW CTR-IN Program to submit a full application. Potential applicants must contact their local MW CTR-IN Concierge and / or Vice President for Research (VPR) Office for instructions on the internal nominating process. Each partner institution may nominate up to one application as Lead Institution, but institutions can be collaborating sites on multiple proposals.

Nominating Packets forwarded to CTR-IN must include the following for each applicant:

- An NIH format Biographical Sketch for the proposed Lead PI.

- An NIH format "Other Support" document for the proposed PI.
- A summary of the proposed research strategy of not more than two pages with sufficient detail to establish that the research is clinical or translational.
- The list of collaborating partner sites and corresponding Site Leads.

STEP TWO - Invitation to submit pilot grant application: Nominating Packets will undergo administrative review by MW CTR-IN Program to ensure that they are responsive to the respective funding opportunity. OSP representatives will be notified of any nominations that are found to be non-responsive. A Nominating Packet that is determined to be non-responsive may be replaced with another while the Nomination phase is open. ***Thus, early submission of Nominating Packets is encouraged*** in order to allow adequate time to prepare a replacement nomination when necessary. Applicants with approved Nominating Packets will be invited to submit a full application.

STEP THREE - Full application: Detailed application instructions will be provided to applicants that are invited to submit full applications. At that time, applicants will also automatically have "tickets" generated to their biostatistical, community engagement and outreach, professional development team members from the CTR-IN Program. With respect to preparing research strategy and budgets, the following requirements will apply:

- Cover page- use PHS Form Page 1 (for each site)
- Project Summary – Form Page 2 (for each site)
- Specific Aims – 1 page
- Research Strategy – 6 pages. Note: in addition to Significance, Innovation and Approach sections, the Research Strategy should include timeline, interim milestones, approach for coordinating across multiple sites and plans for developing and submitting a subsequent extramural grant application. Of particular importance is describing the benefit of a multi-site collaboration for achieving the team's long-term goals. Please note that the project must include data gathering from human subjects at each site.
- Budget details- PHS Form Page 4
    - Facilities and Administration Costs are limited to the federal/NIH de minimus rate of 10%.
    - All expenses must be allowable under NIH guidelines.
    - Travel expenses are allowed, including expenses for conducting field work as part of the project, or accessing experts or other resources such as meeting with a formal mentor. Budgets must include costs for the Lead PI to attend the CTR-IN Annual Meeting in Las Vegas. Travel expenses may be requested for the PI to present this work at one national or regional meeting, providing the meeting date is within the project period and far enough into the project for data to be available.
    - Subcontracts to institutions located in non-IDeA states are not allowable. However, services provided in non-IDeA states can be purchased on a fee-for-service basis.
- Human Subjects – Forms H
- IRB approval for all sites, or Collaborating Site only if utilizing an inter-institution reliance agreement, must be included with application. If the IRB approval is not obtained by May 4th, the application will not be considered for funding -- regardless of the Overall Impact Score.
- Other Support for PI
- If the PI has received prior MW CTR-IN funding, include a 1-page summary of the results of that funding.

OTHER IMPORTANT INFORMATION

Eligible Mountain West CTR-IN Institutions:

Boise State University	University of Alaska, Anchorage	University of New Mexico HSC
Idaho State University	University of Alaska, Fairbanks	University of Nevada Las Vegas
Montana State University	University of Idaho	University of Nevada Reno
New Mexico State University	University of Montana	University of Wyoming

The types of clinical or translation research we fund:

Projects must be clinical or translational research (CTR). Clinical research, as defined by NIH, is research with human subjects that is:

(1) patient-oriented research;
(2) epidemiological or behavioral studies; or
(3) outcomes or health services research.

Translational research has been interpreted in a variety of ways in recent years, and CTR-IN characterizes translational research according to the recent review on this topic. For this funding mechanism, we do not support pre-clinical research, sometimes referred to at T0 research. CTR-IN supports four main areas of translational research, defined as follows:

T1: Translation of basic science to early testing in humans;
T2: Early phase clinical trial; efficacy; establishment of clinical guidelines;
T3: Implementation and dissemination research; and
T4: Outcomes and effectiveness research.

The MW-CTRIN Professional Development Core (PDC):

The PDC offers several resources to enhance your application and facilitate career advancement. For nominees, the PDC can help identify an appropriate mentor for your project. For eventual awardees, the PDC offers critical educational resources that are often required by NIH and that will enhance your project, such as Good Clinical Practice and Responsible Conduct of Research training. These resources are available to MW-CTR-IN investigators regardless of whether or not their project is selected for funding. Finally, Grant Writing Workshops and the Advance to Funding program (a pre-review study section service offered for first time R-level applicants) are offered annually.

CTR-IN programmatic resources are available to assist with application submissions:

- For questions about the nomination process, contact your institutional CTR-IN concierge and / or VPR Office
- For questions about the portal, contact Kathrene Conway mailto:kathrene.conway@umontana.edu
- For questions on the CTR-IN pilot grant program, contact Curtis Noonan curtis.noonan@umontana.edu and Scott Seville SSeville@uwyo.edu