



## MOUNTAIN WEST CLINICAL TRANSLATIONAL RESEARCH - INFRASTRUCTURE NETWORK

The mission of the MW 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 13 MW university partners. In the past six years, the MW CTR-IN Program has provided more than \$7M in pilot grant funding to over 100 investigators at our partner universities.

### **MULTI-SITE PILOT PROJECT (MSPP) FUNDING OPPORTUNITY:**

#### Key Dates:

Final day for submission of Nominating Packets by institution partners*	January 22, 2020
Invitations to investigators to submit full applications will be issued by	January 29, 2020
Application Due Date	April 15, 2020
Announcement of applications selected for Intent to Fund	June 17, 2020
Earliest Start Date	July 15, 2020
Project Period**	July 15, 2020 – June 30, 2021

\* 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.

**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.

**Overview and Criteria.** Multi-Site Pilot Projects must include CTR-IN partner institutions in at least three and preferably five to seven of our MW states. For example, the project will include the Lead Institution/Lead PI from one of the seven states and at least two or more and preferably ≥4 collaborating Site Institutions / Site Co-PIs from three and preferably five to seven of our MW states. We also recognize the complexity of conducting such a large multi-site project. Hence, potential PI and Co-PIs should consider an initial project that first demonstrates the feasibility of conducting such a large scale multi-site project. Those large scale multi-site projects that can demonstrate feasibility for the initial one year of funding are then also encouraged to apply for another year of competitive funding that builds upon the results of the first year.

**Programmatic Priorities.** Working in conjunction with our three Regional Community Advisory Boards (CABs) representing all seven Mountain West states, we have identified funding priorities for the communities we serve. The following 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.

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. However, we anticipate that these programmatic priorities will be revised and updated in forthcoming years as we continue to receive input from our regional stakeholders. It is also important to note that virtually most if not all of the major diseases and health conditions [e.g., cardiovascular, metabolic (e.g., diabetes), CNS, renal, etc.] are a health disparity in the Mountain West region. 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 be eligible to submit extramural grant applications from their institution as a PI. 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 CTR-IN programmatic Cores [e.g., Professional Development, Community Engagement and Outreach, 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 multisite data coordination offered at the University of New Mexico - Health Science Center (UNM-HSC) 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 are encouraged**

in order to allow adequate time to prepare a replacement nominations 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 be provided with further guidance on obtaining biostatistical, community engagement and outreach, mentorship and other professional development support 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 E
- IRB approval of an existing Lead Site study must be included with application if participant enrollment is planned at Collaborating Sites. If applicable, a timeline must be included for obtaining IRB approval (or reliance agreement) at Collaborating Sites.
- 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, Fairbanks	University of Nevada Las Vegas
Idaho State University	University of Hawaii at Manoa	University of Nevada Reno
Montana State University	University of Idaho	University of Wyoming
New Mexico State University	University of Montana	
University of Alaska, Anchorage	University of New Mexico-HSC	

## 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 as 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 (PD) Core:

The PD Core offers [several resources to enhance your application and facilitate career advancement](#). For nominees, the PD Core can help identify an appropriate mentor for your project. For eventual awardees, the PD Core offers critical educational resources that are often required by NIH and that will enhance your project, such as Good Clinical Practice (GCP) and Responsible Conduct of Research (RCR) 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 (GWW) and the Advance to Funding (ATF) Program (a pre-review service offered for R-level applicants) are offered annually. We are also currently planning to potentially offer a GWW to funded Pilot Grant Awardees at our next Annual Meeting in *early* June 2020 to assist in the next set of critical steps in applying for extramural grant funding. Hence, funded PG Awardees will be required to attend this important GWW.

## CTR-IN programmatic resources are available to assist with application submissions, study design and career development:

- For questions about the nomination process, contact [your institutional CTR-IN concierge and / or VPR Office](#)
- For assistance with mentorship, research training and grant writing, log into the portal (<https://ctrin.health.umt.edu/public/login>) and completing an intake form at Support, Create Intake Form marking the areas with which you like the Professional Development Core to assist you.
- For assistance with study design and analysis strategy, log into the portal (<https://ctrin.health.umt.edu/public/login>) and completing an intake form at Support, Create Intake Form marking the areas with which you like the BERD Core to assist you.
- For projects that involve community engagement activities, log into the portal (<https://ctrin.health.umt.edu/public/login>) and completing an intake form at Support, Create Intake Form marking the areas with which you like the CEO Core to assist you.
- For questions about the portal, contact Kathrene Conway [kathrene.conway@umontana.edu](mailto:kathrene.conway@umontana.edu)
- For questions on the CTR-IN pilot grant program, contact Curtis Noonan [curtis.noonan@umontana.edu](mailto:curtis.noonan@umontana.edu) and Scott Seville [SSeville@uwyo.edu](mailto:SSeville@uwyo.edu)