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.

PILOT GRANT FUNDING OPPORTUNITY

Key Dates:

Final day for submission of Nominating Packets by institution partners*	January 15, 2020
Invitations to investigators to submit full applications will be issued by	January 22, 2020
Application Due Date	April 8, 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 promising early career and / or other mid-level to senior investigators with support to capture the key preliminary data that will support and inform a competitive "R-level" grant application to NIH or other extramural funding sources. Projects must involve human subjects; we do not support pre-clinical research.

Programmatic Priorities. Working in conjunction with our three regional Community Advisory Boards (CABs) representing all seven states, we have identified funding priorities for the communities we serve. The following themes were consistently identified across all CABs: (1) mental health as well as suicide prevention, opioid and other substance abuse and psycho-social trauma; and (2) obesity and metabolic conditions such as diabetes including the related factors of food security, food sovereignty, and healthy food access. We recognize that the above areas of research do not capture all important health priorities in all of the communities that we serve. 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 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 Costs: $60,000

APPLICATION PROCESS

STEP ONE - Limited competition nomination of applicants from eligible institutions:
Applicants 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 a maximum of four applicants.

Nominating Packets must include the following for each applicant:
- An NIH format Biographical Sketch for the proposed PI.
- An NIH format Other Support document for the proposed PI.
- A summary of the proposed research of not more than one page with sufficient detail to establish that the research is clinical or translational.
- A letter of support signed by an appropriate institutional official committing to provide support for half of the requested PI effort if the CTR-IN Pilot Grant is awarded.

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 where applicable. 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 the research strategy and budget, the following requirements will apply:

- Cover page- use PHS Form Page 1
- Project Summary – Form Page 2
- Specific Aims – 1 page
- Research Strategy – 4 pages. Note: in addition to Significance, Innovation and Approach sections, the Research Strategy should include timeline, interim milestones and plans for developing and submitting a subsequent extramural grant application.
- Budget details and Justification- 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 PI and the mentor 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.
- o Special requirements regarding PI support: <u>PIs must devote at least 20% effort to the proposed research (i.e., 2.4 calendar months)</u>; up to 50% effort may be proposed. While the budget narrative must reference the full amount of effort required to accomplish the proposed scope of work, the budget may request CTR-IN funds for not more than half of the PI effort. Per prior agreement with CTR-IN partner institutions, the balance of PI effort is to be covered by institutional support in the form of release from teaching, direct salary support, assignment of time provided to pursue scholarly activity, or other mechanism appropriate to the institution. This support is not a formal cost share, and no recording/reporting requirements exist. Budgets should list the full PI effort proposed as appropriate for their appointment in calendar months, or academic and summer months.
- o 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 must be included with application.
- 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

<u>Eligible Mountain West Research Consortium Institutions</u>:

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	

<u>The types of clinical or translation research we fund</u>:

Pilot 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.

<u>The MW-CTRIN Professional Development (PD) Core</u>:

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 **<u>required</u>** to attend this important GWW.

<u>CTR-IN programmatic resources are available to assist with application submissions, study design and career development</u>:

- For questions about the nomination process, contact your institutional CTR-IN concierge
- 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
- For questions on the CTR-IN pilot grant program, contact Curtis Noonan curtis.noonan@umontana.edu and Scott Seville SSeville@uwyo.edu