PILOT PROJECT GRANT (PPG) 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 its partner institutions in the Mountain West region.

Eligibility. For year 12 **(2024-2025)**, faculty who are eligible to apply are limited to the following 6 universities that are continuing their partnerships and collaboration with MW CTR-IN in the grant renewal application to be submitted to NIGMS on November 9, 2023:
1. **Montana State University**
2. **New Mexico State University**
3. **University of Alaska, Anchorage**
4. **University of Alaska, Fairbanks**
5. **University of Nevada Las Vegas**
6. **University of Nevada Reno**

Key Dates:

Final day for submission of Nominating Packets by Institution partners*	December 8, 2023
Invitations to investigators to submit full applications will be issued by	December 15, 2023
Application Due Date	**March 8, 2024**
Announcement of applications selected for Intent to Fund	**June 2024**
Earliest Start Date**	**July 2024**
Project Period**	**July 2024 – June 2025**

* The limited internal competitive nomination process will be determined by each partner institution; earlier internal deadlines may be set by each partner institution.

** Actual start date will be dependent upon receipt of approval from NIGMS.

MW CTR-IN Grant Renewal. The number of grants awarded will be dependent upon the availability of funds. The MW CTR-IN will be applying for grant renewal on November 9, 2023. The funding for this round of grants is not dependent upon receiving the grant renewal award as MW CTR-IN may be able to allocate its unobligated funds to support proposals during a no cost extension period.

Purpose. The purpose of this funding opportunity is to provide promising early career and / or other mid-level to senior investigators with support to obtain 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. This mechanism also requires that the PI have a mentor.

Webinar. We will have a webinar about this year's funding mechanisms on **Wednesday, October 18, 2023**.
Start Time: 1:00 pm, Alaska Time / 2:00 pm, Pacific Time / 3:00 pm, Mountain Time
Zoom Link: hhttps://unlv.zoom.us/j/97486423645?pwd=ak8rY2xoemQxWjhZbVZTeDNwaDlKdz09.
Meeting ID: 974 8642 3645 *Passcode:* 64842908. If you cannot join the webinar live, but would like to view the webinar, you can access the recording on the MW CTR-IN website at: https://ctrin.unlv.edu/year12-foa/.

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 health disparities research in the communities we serve. The following specific themes were consistently identified across all CABs:

- 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 and other emerging diseases / conditions, including impacts to healthcare access, associated influences on mental health, and its disproportionate impacts on populations with health disparities.

We recognize that the above areas of health disparities research do not capture all important health priorities in all of the communities that we serve, or that the CABs have identified, and our funding determinations are **not** limited only to these topics. We also anticipate that these programmatic priorities may be revised and updated in forthcoming years as we continue to receive input from our local and regional stakeholders. All applications will undergo the same scientific merit review using 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 project through other IDeA mechanisms (e.g., CTR, COBRE or INBRE).

Direct Costs: up to $90,000 (depending on the availability of funds)

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 10 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 and / 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 is encouraged*** in order to allow adequate time to prepare a replacement nomination 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 automatically have "tickets" generated to their biostatistical (BERD Core), community engagement and outreach (CEO Core), and professional development (PD Core) team members 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 <u>must</u> include costs for the PI and the mentor to attend the CTR-IN Annual Meeting in Las Vegas. This will likely be two and a half days of meetings. 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.
  - 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 include 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.
  - 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 or a timeline of how IRB will be obtained before May 4, 2024 must be included with application. If the IRB approval is not obtained by May 4, 2024 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 previously funded pilot project.

OTHER IMPORTANT INFORMATION

Eligible Mountain West Clinical & Translational Research Infrastructure Network Partner Institutions:

Montana State University	University of Alaska, Anchorage	University of Nevada, Las Vegas
New Mexico State University	University of Alaska, Fairbanks	University of Nevada, Reno

The types of clinical or translation research we fund:

Pilot projects must be clinical and / 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.

MW CTR-IN Professional Development Core (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 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 (GWW) and the Advance To Funding (ATF) 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
- For questions about the portal, contact Kathrene Conway Kathrene.Conway@unlv.edu
- For questions on the CTR-IN pilot grant program, contact Dr. Jeffrey Ebersole (jeffrey.ebersole@unlv.edu) or Dr. Jay Shen (jay.shen@unlv.edu).