The mission of the MW CTR-IN Program is to build clinical and translational research capacity and facilitate extramural funding success among investigators with faculty appointments at the 13 MW university partners. Our thematic focus is to address health disparities in regions. In the past six years, the MW CTR-IN Program has provided over $6M in pilot grant funding to over 90 investigators at our partner universities.

MULTI-SITE PILOT PROJECT (MSPP) FUNDING OPPORTUNITY

Key Dates:

Funding Opportunity Announcement Release Date	January 15, 2019
Final day for submission of Nominating Packets by institution partners*	February 28, 2019
Invitations to investigators to submit full applications will be issued by	March 4, 2019
Application Due Date	April 8, 2019
Announcement of applications selected for Intent to Fund	June 30, 2019
Earliest Start Date	July 15, 2019
Project Period**	July 15, 2019 – June 30, 2020

* 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.

Criteria. Multi-Site Pilot Projects must include at least two CTR-IN institutions. For example, the project will include the Lead Institution/Lead PI and one or more collaborating Site Institution(s)/Site PI(s).

Research Emphasis. Priority will be given to projects focused on health disparities and CTR-IN programmatic priorities (see below).

What are health disparities? Health disparities (or health inequalities) can have different meanings and interpretations depending on the setting and population being studied. In general, health disparities are considered to be differences in the incidence, prevalence, mortality, access to care and burden of diseases and other adverse health conditions that exist among specific population groups. We support a broad array of disparities research, including (1) projects focused on addressing health inequalities; and (2) projects that are focused on learning more about specific diseases or health behaviors that areknown to differentially impact particular populations in our communities. MSPPs do not support pre-clinical research.

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: (1) mental health as well as suicide prevention, substance abuse and psycho-social trauma; and (2) obesity and metabolic conditions 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 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 this funding mechanism is not limited to the programmatic priorities listed above, although applications clearly related to the above themes will receive priority consideration. 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. 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: Maximum $100,000 with up to $50,000 for the Lead Site and up to $50,000 per Collaborating Site. UNLV will administer separate subawards for each collaborating site.

Examples of Potential Multi-Site Pilot Projects. As this is a relatively new mechanism for our CTR-IN program, we offer the following examples of potential projects for this funding priority.

Expansion of existing clinical trials infrastructure. The IDeA States Pediatric Clinical Trials Network (ISPCTN) includes sites at 4 of our 13 partner institutions. Communities represented by the remaining 9 institutions provide additional opportunities for underrepresented pediatric patient populations to participate in clinical trials research. A CTR-IN Multi-Site Pilot Project would create the opportunity for existing ISPCTN sites to expand to other CTR-IN communities. A given ISPCTN site within the CTR-IN network would serve as Lead Site and partner with pediatricians, developmental neonatologists, or other appropriate clinical professionals at collaborating CTR-IN institutions not currently represented in the ISPCTN. Under this example, multi-site teams would identify a specific pediatric clinical population to pursue at the extension sites, consistent with current ISPCTN program activities.

Expansion of ongoing funded clinical research. Many of the communities served by CTR-IN are sparsely populated, representing challenges for the corresponding institutions to serve as a lead institution for a clinical study. However, these communities could contribute additional study power and generalizability for an ongoing clinical study. The PI of a current funded clinical study would serve as Lead Site PI and partner with corresponding clinical researcher(s) at collaborating CTR-IN institutions that would follow the recruitment criteria and study protocol of the parent study.

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 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 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 narrative should include listing of collaborating partner site(s) and corresponding Site Lead(s).

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, mentorship and other professional development support. With respect to preparing research strategy and budgets, the following requirements will apply:

- Cover page- use PHS Form Page 1
- 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.
- IRB approval of an existing Lead Site study must be included with application if participant enrollment is planned at Collaborating Site(s). If applicable, a timeline must be included for obtaining IRB approval (or reliance agreement) at Collaborating Site(s).
- 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.

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	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. Specifically, the four main areas of translational research are 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.

CTR-IN 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
- For assistance with study design and analysis strategy, contact your institutional CTR-IN biostatistician
- For questions on the CTR-IN pilot grant program, contact Curtis Noonan curtis.noonan@umontana.edu and Scott Seville SSeville@uwyo.edu