Year 5 of the American Indian/Alaska Native Clinical Translational Research Program (AI/AN CTRP) Request for *Pilot*, *Development*, and *Diversity* Proposals

[August 30, 2019]

The America Indian/Alaska Native Clinical and Translational Research Program (AI/AN CTRP) is soliciting proposals from investigators to support and develop research programs relevant to AI/AN health disparities in Montana and Alaska.

The AI/AN CTRP has the goal of developing the capacity of several Montana and Alaska institutions to address health disparities that Native communities in these states face. The AI/AN CTRP seeks to: 1) Strengthen Montana's and Alaska's clinical and translational research infrastructure through continued development of shared facilities, intellectual resources, research collaborations, focused working groups, and training opportunities; 2) Increase the numbers of mentors while developing the careers of clinical investigators in Native health disparities research in Montana and Alaska; and 3) Expand and support sustainable and culturally responsible community-engaged research that will mitigate health disparities in Montana's and Alaska's Native communities.

There are three types of awards:

- **Pilot awards** (up to $100,000 direct costs) are intended for ready-to-go/ongoing projects with a high likelihood of leading to independent funding.
- **Development awards** (up to $50,000 direct costs) are intended for projects that require more preparation time for activities such as securing IRB approvals, developing agreements between investigators and community groups, hosting planning meetings and travel, conducting needs assessments, or similar activities leading to a future Pilot award proposal.
- **Diversity awards** (up to $35,000 direct costs) support AI/AN mentees working with the PI or Project Leader of a funded project.

Key Dates for Pilot, Development and Diversity Proposals:

Activities	Dates
Register in portal and submit proposal idea(s)	Rolling-ASAP
Pilot & Development pre-proposals due (**required** for ALL pilot and development proposals to be submitted in this cycle)	February 6, 2020
All proposals due	March 23, 2020
All applicable IRB and IACUC approvals must be secured by investigators	May 14, 2020
Notification of proposals recommended for funding	June, 2020
Complete PHS Human Subjects and Clinical Trials Information forms and submit CITI Training certifications if human subjects are involved	Upon notification of funding recommendation
Anticipated start date	August 1, 2020
End of project award period	July 31, 2021

Year 5 of the AI/AN CTRP's awards are anticipated to start as early as August 1, 2020, and will have an end date of July 31, 2021. Approximately 1.2 million dollars will be awarded. No carryover will be allowed. Awards are contingent upon the availability of NIH funding. Facilities and Administration rates (i.e., indirect costs) will be held to 10%. Funds cannot be used to support investigators' time to write subsequent NIH proposals. Do not detail grant writing activities in the proposal.

Answers to frequently asked questions are continually updated and available on the FAQ section of the CTRP website. Additional questions and clarifications can be directed to the Pilot Projects Core. For general inquiries contact ctrp-applications@mso.umt.edu or the Project Coordinator, Chelsea Bellon at chelsea.bellon@mso.umt.edu. A detailed list of cores, their staff and administrative support can be found at the AI/AN CTRP website. To receive important updates/clarifications about this Request for Proposals by e-mail, please sign up here.

Required submission of proposal concepts/pre-proposals:

Applicants for Project Development Awards and Pilot Awards are required to engage with the CTRP cores prior to submitting an application. Pre-proposals and proposals are submitted via an electronic portal, which is designed to facilitate communication between applicants and core personnel. After registering with an e-mail address and creating a password, the portal requests preliminary information about the project idea, such as a title, what community you plan on working within, and a short summary of your ideas. You can change this information at any time. The purpose of gathering this information is to match you and your project with the most appropriate AI/AN CTRP core members and resources. **Please submit your proposal ideas immediately because early and frequent contact with the Community Engagement and Outreach (CEO) and Research Design, Epidemiology, and Biostatistics (RDEB) cores are essential for successful applications.**

Application Submission:

The electronic portal for submitting pre-proposals and applications is also available on the AI/AN CTRP website. Investigators registered in the portal who are submitting development or pilot applications are able to submit proposals after completing consultations with the RDEB and CEO cores. Investigators registered in the portal who are submitting Diversity awards can submit proposals at any time before the deadline. The Professional Development core is available for support and inquiries, but consultations with applicants is not required prior to applying.

Proposal Due Dates:

- All proposals are due on March 23, 2020.

Applications must be submitted by the due date no later than 11:59 pm in the local time zone. **Late applications will not be accepted.**

Eligibility:
Projects in basic biomedical, social, and behavioral sciences focused on clinical or translational research with AI/AN people are eligible. Investigators must be affiliated with an institution in Montana or Alaska, and preference is given to AI/AN PIs or Project Leaders. Applicants cannot receive concurrent support for research from more than one NIH IDeA program (e.g., COBRE, INBRE, or CTR-IN). Investigators who receive IDeA support for research may serve as paid mentors on other IDeA-funded projects. Other than mentees, eligible investigators must have terminal degrees in their field (e.g., PhD, MD). Investigators that already hold an R01 in a related area may not serve as PI, but are eligible to serve as mentors or collaborators.

Proposal Review:

- All proposals will be administratively reviewed for completeness. Applicants will be notified of missing components and will have 48 hours from notification to amend the application.
- CEO Core personnel will review all proposals for culturally respectful research approaches and practices, including community suitability and acceptability.
- Applications for development and pilot awards will also be scored for scientific merit by external reviewers who are experts in the topic area of the application. Reviewers will use standard NIH criteria: Significance, Investigator, Innovation, Approach, and Environment. Applicants are invited to recommend external reviewers (who must have no conflict of interest per NIH guidelines).
- All proposals will then be reviewed by an internal review process using the standard NIH criteria, and will include an evaluation of the project's feasibility, suitability, and cultural acceptability for the intended community. Diversity Supplements will also be evaluated on the quality of the career development experience.
- The highest-ranking proposals will also be reviewed by the AI/AN CTRP's External Advisory Committee and recommended projects will be submitted to the NIH for final approval. Only projects with applicable IRB and/or IACUC approvals in place will be forwarded to the NIH.

Application Formatting Requirements:
When indicated in the instructions in this RFP, use the linked form page from NIH. If there is no form page indicated, then there are no special requirements for formatting that section of the proposal. Unless specified otherwise in the NIH form page, font sizes must be 11 point or larger and page margins must be at least 0.5 inches on all sides.

Reporting Requirements:
Applicants for Pilot Awards and Development Awards are required to submit a pre-proposal and engage with the cores prior to proposal submission. All grant recipients will be required to continue engagement with CTRP cores and resources. All recipients will report project and career development outcomes as part of the CTRP's reporting requirements to NIH. Investigators are required to work with the Tracking and Evaluation Core to submit progress reports during the funding cycle.

Project Development Awards

Development awards are intended for projects that require more preparation time for activities such as securing IRB approvals, developing agreements between investigators and community groups, hosting planning meetings and travel, conducting a needs assessment, and fact-finding in the early steps of Community Engagement (CE) or Community-Based Participatory Research (CBPR). Research with human participants is not expected to begin during the development award period unless an IRB is already in place. Development awards can be up to $50,000 in direct costs, but please provide a well-justified budget with realistic allowable costs. Award recipients are eligible to apply for a continuing award from the AI/AN CTRP. Applicants that are new to CE/CBPR are strongly encouraged to submit proposal ideas as *early as possible* to allow time for iterative interactions with the CEO core prior to submitting a full proposal.

Development awards are open to both new investigators in fields relevant to translational research, as well as established investigators that may have track records in basic or pre-clinical research who wish to develop translational and/or community engaged programs focused on improving the health of AI/AN in Alaska and Montana. Development award investigators must have a doctorate (or equivalent) degree and must also meet criteria for securing independent funding at their own institution. The Development Awards should result in pilot projects that have a high likelihood of leading to independent funding.

Application for Project Development awards must include the following elements:

- ☐ NIH Face page (use PHS398 forms and instructions)
- ☐ NIH Project Summary (use Forms Page 2)
- ☐ Abstract (500 words or less)
- ☐ *Anticipated* Specific Aims of the planned Pilot Project that will result from the successful implementation of the development plan: statement of problem, hypothesis, and specific aims that will address the hypothesis. (1 page)
- ☐ Research Development Plan (2 pages) to include:
    - Significance: the importance and health relevance of the project, how it will improve our knowledge, and how it will improve the health of individuals
    - Approach: describe the developmental activities and how they will support the development of culturally responsible community-engaged research
    - Analysis: summarize (1) how activities will address the approach and (2) analysis elements needed for a subsequent pilot grant application (see Pilot Awards section of this RFA)
- ☐ Community engagement and outreach plan (1 page) must include descriptions of: (1) benefit to AI/AN people and whether the health area is a tribally-identified priority; (2) strategy for respectful engagement and collaboration with community members to include but not limited to: letters from all named community partners is required is encouraged, plans to disseminate study findings to the community, mechanisms for active engagement and oversight by community members – justify approach if a community advisory board will not be used; (3) how the study methods or approaches are appropriate for the

community including cultural adaptation approaches, potential for harm to community/tribe. Lastly, incorporation of recommendations from Community Engagement and Outreach Core pre-proposal consultation will be reviewed.

- ☐ Timeline that includes explicit plans for planning, training, community involvement, or any other needed project development activity
- ☐ Bibliography (no page limit)
- ☐ Description of the Facilities and Resources, in NIH format
- ☐ NIH-style Biographical Sketches of key personnel (required for PIs and mentors)
- ☐ Project budget (use Forms Page 4) and budget justification. Investigators must include funds to support their travel and may include travel for their mentors to the CTRP's annual meeting. The meeting is expected to be 3 days long and held in Montana.
- ☐ List of current and pending funding for all key personnel (separate from biosketches). Include proposal title, funding source, total award amount, and role on grant for each proposal or award listed. If any current or pending support is from any IDeA program, include a statement verifying that no IDeA funding will overlap based on award start/end dates or the intention to accept only one IDeA award.
- ☐ Letter of support from chair, director or supervisor verifying that the requested amount of research time and space is available to the investigator
- ☐ Contact with human participants (i.e., human subjects) is not expected to begin during the development award period, but if contact with human participants is included the following elements are required:
    - Documentation that all IRB application(s) are submitted to the applicable Human Subjects review committee(s)
    - Timeline showing the steps that will be taken to secure the following by the deadlines listed in the "Key Dates" table:
        - Applicable IRB approval(s).
        - Letter(s) of support from the appropriate tribal entity (approval notice from the appropriate tribal IRB is sufficient; due at the same time as applicable IRBs).
        - The following must be completed by the listed deadline *only* if the applicant is notified that the proposal is being recommended for funding:
            - PHS Human Subjects and Clinical Trials Information forms completed in collaboration with the applicant's IRB office or sponsored programs staff. See NIH Application Instructions for additional information.
            - Human Subject Education Certification for all key personnel via CITI training.
            - If the project meets the NIH definition of "clinical trial," Good Clinical Practice Training Certification for all involved investigators and staff to meet the NIH guidelines. A free online training is available through NIAD.
- ☐ If no human subjects are involved, please upload a statement verifying that no study activities involve human subjects. Note that projects that involve human subjects, but are Exempt from Federal regulations still require the submission of the PHS Human Subjects

and Clinical Trials Information forms. See your institution's IRB office for a determination if you are unsure if the study involves human subjects.

- ☐ Involvement with vertebrate animals is not expected to begin during the development award period, but if vertebrate animals are involved, the following elements are required:
    - IACUC approval letter, or timeline showing the steps that will be taken to secure IACUC approval by the deadline listed in the "Key Dates" table.
    - Vertebrate Animal Section addressing the following 5 points:
        - Description of Procedures. Provide a concise description of the proposed procedures to be used that involve vertebrate animals in the work outlined in the application or proposal. Identify the species, strains, ages, sex and total number of animals by species to be used in the proposed work.
        - Justifications. Provide justification that the species are appropriate for the proposed research. Explain why the research goals cannot be accomplished using an alternative model (e.g., computational, human, invertebrate, in vitro).
        - Minimization of Pain and Distress. Describe the interventions including analgesia, anesthesia, sedation, palliative care and humane endpoints to minimize discomfort, distress, pain and injury.
        - Euthanasia. State whether the method of euthanasia is consistent with the recommendations of the American Veterinary Medical Association (AVMA) Guidelines for the Euthanasia of Animals. If not, describe the method and provide a scientific justification.
- ☐ Proposals that have been funded by the AI/AN CTRP in the past must include a summary of the progress made during the AI/AN CTRP support period (1 page). This should include research progress on prior Specific Aims, progress or updates on community engagement activities, publications (submitted or accepted), presentations, dissemination to community partners, and proposals submitted (with funding status), as applicable.

Pilot Awards

Pilot awards are intended for ready-to-go/ongoing projects to provide funding to collect seed data and/or respond to prior NIH reviewer comments for extramural NIH applications (to be submitted within one year of completion of award). Pilot awards will be awarded up to a maximum of $100,000 direct costs. Award recipients are eligible to apply for continuing awards from the AI/AN CTRP.

Pilot awards are open to both new investigators in fields relevant to translational research, as well as established investigators that may have track records in basic or pre-clinical research who wish to develop translational and/or community engaged programs focused on improving the health of AI/AN in Alaska and Montana. Pilot award investigators must have a doctorate (or equivalent) degree and must also meet criteria for securing independent funding at their own institution. The Pilot award should have a high likelihood of leading to independent funding.

Application for Pilot awards must include the following elements:

- ☐ NIH Face page (use PHS398 forms and instructions)
- ☐ NIH Project Summary (use Forms Page 2)
- ☐ Abstract (500 words or less)
- ☐ Specific Aims of the Project: statement of problem, hypothesis, and specific aims that will address the hypothesis. (1 page)
- ☐ Research Plan (6 pages) to include:
    - Significance: the importance and health relevance of the project, how it will improve our knowledge, and how it will improve the health of individuals
    - Innovation: how the project is creative, unique, and innovative
    - Approach: (Design and Methods) description of preliminary data (if such data are available) that support the need for the research and how the aims will be achieved. Applicants should describe the rationale and scientific basis for the proposed research and provide a strong research plan.
    - Analysis Plan: study design (e.g., observational vs. experimental, cross sectional vs. longitudinal); target population and recruitment methods; sample size and justification; types of data to be collected (qualitative, quantitative or both) including the primary variables of interests (e.g., exposures, health measures) and covariates; methods of ascertainment of variables of interest and covariates; data analysis methods that are consistent with the design, overall research objectives, and specific questions of interest
- ☐ Community engagement and outreach plan (1 page) must include descriptions of: (1) benefit to AI/AN people and whether the health area is a tribally-identified priority; (2) strategy for respectful engagement and collaboration with community members to include but not limited to: letters from all named community partners is required is encouraged, plans to disseminate study findings to the community, mechanisms for active engagement and oversight by community members – justify approach if a community advisory board will not be used; (3) how the study methods or approaches are appropriate for the

community including cultural adaptation approaches, potential for harm to community/tribe. Lastly, incorporation of recommendations from Community Engagement and Outreach Core pre-proposal consultation will be reviewed.

- ☐ Timeline, including the project outcomes to be accomplished and detailed plans for submitting subsequent funding applications (e.g. R01 or similar)
- ☐ Bibliography (no page limit)
- ☐ Description of the Facilities and Resources, in NIH format
- ☐ NIH-style Biographical Sketches of key personnel (required for PIs and mentors)
- ☐ Project budget (use Forms Page 4) and budget justification. Investigators must include funds to support their travel and may include travel for their mentors to the CTRP's annual meeting. The meeting is expected to be 3 days long and held in Montana.
- ☐ List of current and pending funding for all key personnel (separate from biosketches). Include proposal title, funding source, total award amount, and role on grant for each proposal or award listed. If any current or pending support is from any IDeA program, include a statement verifying that no IDeA funding will overlap based on award start/end dates or the intention to accept only one IDeA award.
- ☐ Letter of support from chair, director or supervisor verifying that the requested amount of research time and space is available to the investigator.
- ☐ If contact with human participants (i.e., human subjects) is included, the following elements are required:
    - Documentation that all IRB application(s) are submitted to the applicable Human Subjects review committee(s)
    - Timeline showing the steps that will be taken to secure the following by the deadlines listed in the "Key Dates" table:
        - Applicable IRB approval(s).
        - Letter(s) of support from the appropriate tribal entity (approval notice from the appropriate tribal IRB is sufficient; due at the same time as applicable IRBs).
        - The following must be completed by the listed deadline *only* if the applicant is notified that the proposal is being recommended for funding:
            - PHS Human Subjects and Clinical Trials Information forms completed in collaboration with the applicant's IRB office or sponsored programs staff. See NIH Application Instructions for additional information.
            - Human Subject Education Certification for all key personnel via CITI training.
            - If the project meets the NIH definition of "clinical trial," Good Clinical Practice Training Certification for all involved investigators and staff to meet the NIH guidelines. A free online training is available through NIAD.
- ☐ If no human subjects are involved, please upload a statement verifying that no study activities involve human subjects. Note that projects that involve human subjects, but are Exempt from Federal regulations still require the submission of the PHS Human Subjects

and Clinical Trials Information forms. See your institution's IRB office for a determination if you are unsure if the study involves human subjects.

- ☐ Involvement with vertebrate animals is not expected to begin during the development award period, but if vertebrate animals are involved, the following elements are required:
    - IACUC approval letter, or timeline showing the steps that will be taken to secure IACUC approval by the deadline listed in the "Key Dates" table.
    - Vertebrate Animal Section addressing the following 5 points:
        - Description of Procedures. Provide a concise description of the proposed procedures to be used that involve vertebrate animals in the work outlined in the application or proposal. Identify the species, strains, ages, sex and total number of animals by species to be used in the proposed work.
        - Justifications. Provide justification that the species are appropriate for the proposed research. Explain why the research goals cannot be accomplished using an alternative model (e.g., computational, human, invertebrate, in vitro).
        - Minimization of Pain and Distress. Describe the interventions including analgesia, anesthesia, sedation, palliative care and humane endpoints to minimize discomfort, distress, pain and injury.
        - Euthanasia. State whether the method of euthanasia is consistent with the recommendations of the American Veterinary Medical Association (AVMA) Guidelines for the Euthanasia of Animals. If not, describe the method and provide a scientific justification.
- ☐ Proposals that have been funded by the AI/AN CTRP in the past must include a summary of the progress made during the AI/AN CTRP support period (1 page). This should include research progress on prior Specific Aims, progress or updates on community engagement activities, publications (submitted or accepted), presentations, dissemination to community partners, and proposals submitted (with funding status), as applicable.

Diversity Awards

The PI or Project Leader of AI/AN CTRP funded projects can request an award to support an AI/AN mentee. Project Leaders who serve as mentors must have funding to support the research project through the AI/AN CTRP or other sources, but must not have concurrent funding from another NIH IDeA program (e.g., COBRE, INBRE, or CTR-IN). Awards will be made to the Project Leader (not to the mentee) for up to $35,000 direct costs to support the mentee and these awards may be renewable for support in subsequent years. To comply with the NIH Grants Policy Statement, CTRP Diversity Awards cannot be used to support stipends. The support for mentees should be budgeted and paid as salaries and benefits. If tuition remission for the mentee is also provided, the total compensation package including tuition remission cannot exceed the $35,000 in annual direct costs (for example: salaries + benefits + health insurance + tuition remission = the compensation package).

- ☐ NIH Face page (use PHS398 forms and instructions)
- ☐ NIH Project Summary (use Forms Page 2)
- ☐ Abstract (500 words or less)
- ☐ Overview of the research project or specific aims of the project (statement of problem, hypothesis, and specific aims that will address the hypothesis). (1 page)
- ☐ A summary or abstract of the funded project the mentee will be involved in (if applicable)
- ☐ Plan for the research and/or career development experiences proposed for the AI/AN mentee, including how the mentor will support the mentee's success working in AI/AN communities (2 pages)
- ☐ Description of how the research and career development experiences will expand and foster the capability of the AI/AN mentee (2 pages)
- ☐ Community engagement and outreach plan (1 page) must include descriptions of: (1) benefit to AI/AN people and whether the health area is a tribally-identified priority; (2) strategy for respectful engagement and collaboration with community members to include but not limited to: letters from all named community partners is required is encouraged, plans to disseminate study findings to the community, mechanisms for active engagement and oversight by community members – justify approach if a community advisory board will not be used; (3) how the study methods or approaches are appropriate for the community including cultural adaptation approaches, potential for harm to community/tribe.
- ☐ Timeline, including the outcomes to be accomplished.
- ☐ Bibliography (no page limit).
- ☐ Description of the Facilities and Resources, in NIH format.
- ☐ NIH-style Biographical Sketches of key personnel (required for mentees and mentors)
- ☐ Project budget (use Forms Page 4) and budget justification. Investigators must include funds to support their travel and may include travel for their mentors to the CTRP's annual meeting. The meeting is expected to be 3 days long and held in Montana.
- ☐ List of current and pending funding for mentor and mentee, including proposal title, funding source, total award amount, and role on grant for each proposal or award listed. If any current or pending support is from any IDeA program, include a statement verifying that no

IDeA funding will overlap based on award start/end dates or the intention to accept only one IDeA award.

- ☐ Letter from the PI or Project Leader of the funded project explaining how the diversity supplement will achieve the goals of the mentee.
- ☐ Letter of support from the hosting institution verifying that resources, including research space, are available to the mentee (if necessary).
- ☐ Letter of support from chair, director or supervisor verifying that the requested amount of research time and space is available to the mentee. Indicate any additional institutional support (including funds) that will be allocated to support the mentee.
- ☐ If contact with human participants (i.e., human subjects) is included, the following elements are required:
    - Documentation that all IRB application(s) are submitted to the applicable Human Subjects review committee(s)
    - Timeline showing the steps that will be taken to secure the following by the deadlines listed in the "Key Dates" table:
        - Applicable IRB approval(s).
        - Letter(s) of support from the appropriate tribal entity (approval notice from the appropriate tribal IRB is sufficient; due at the same time as applicable IRBs).
        - The following must be completed by the listed deadline *only* if the applicant is notified that the proposal is being recommended for funding:
            - PHS Human Subjects and Clinical Trials Information forms completed in collaboration with the applicant's IRB office or sponsored programs staff. See NIH Application Instructions for additional information.
            - Human Subject Education Certification for all key personnel via CITI training.
            - If the project meets the NIH definition of "clinical trial," Good Clinical Practice Training Certification for all involved investigators and staff to meet the NIH guidelines. A free online training is available through NIAD.
- ☐ If no human subjects are involved, please upload a statement verifying that no study activities involve human subjects. Note that projects that involve human subjects, but are Exempt from Federal regulations still require the submission of the PHS Human Subjects and Clinical Trials Information forms. See your institution's IRB office for a determination if you are unsure if the study involves human subjects.
- ☐ Involvement with vertebrate animals is not expected to begin during the development award period, but if vertebrate animals are involved, the following elements are required:
    - IACUC approval letter, or timeline showing the steps that will be taken to secure IACUC approval by the deadline listed in the "Key Dates" table.
    - Vertebrate Animal Section addressing the following 5 points:
        - Description of Procedures. Provide a concise description of the proposed procedures to be used that involve vertebrate animals in the work outlined in the application or proposal. Identify the species, strains, ages,

sex and total number of animals by species to be used in the proposed work.

- Justifications. Provide justification that the species are appropriate for the proposed research. Explain why the research goals cannot be accomplished using an alternative model (e.g., computational, human, invertebrate, in vitro).
- Minimization of Pain and Distress. Describe the interventions including analgesia, anesthesia, sedation, palliative care and humane endpoints to minimize discomfort, distress, pain and injury.
- Euthanasia. State whether the method of euthanasia is consistent with the recommendations of the American Veterinary Medical Association (AVMA) Guidelines for the Euthanasia of Animals. If not, describe the method and provide a scientific justification.

☐ Proposals that have been funded by the AI/AN CTRP in the past must include a summary of the progress made during the AI/AN CTRP support period (1 page). This should include research progress on prior Specific Aims, progress or updates on community engagement activities, publications (submitted or accepted), presentations, dissemination to community partners, and proposals submitted (with funding status), as applicable.