Year 3 of the American Indian-Alaska Native
Clinical Translational Research Program (AI-AN CTRP)
Request for Proposals
[Released December 21, 2017]

Pre-proposals due February 21, 2018
Application due dates:
March 21, 2018 (for new and revised proposals)
April 18, 2018 (for competitive renewals)

The American Indian-Alaska Native Clinical and Translational Research Program (AI-AN CTRP) is soliciting proposals from investigators and community groups 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.

New Special Emphasis: Priority will be given to proposals that address substance abuse, including but not limited to methamphetamine and opioid addiction. Proposals addressing all priority health issues in AI-AN communities will be considered; set aside funds are available for the special emphasis area on addiction.

Year 3 of the AI-AN CTRP's awards are anticipated to start as early as August 1, 2018, and will have an end date of July 31, 2019. 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 support investigators' time to write subsequent NIH proposals. Do not detail grant writing activities in the proposal.

Questions and clarifications can be directed to the Pilot Project Core members. Jocelyn Krebs, Co-Director: jekrebs@alaska.edu, Kari Harris, Co-Director: kari.harris@umontana.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 Pre-proposal Submission:
Applicants for Project Development Awards and Pilot Awards are required to coordinate with the CTRP cores prior to submitting an application. The electronic portal is designed to facilitate the communication. After registering with an e-mail address and creating a password, the portal requests a 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 be able to match you and your project with the most appropriate AI-AN CTRP core members and resources.   Pre-proposals for pilot and development awards are due February 21, 2018.

Application Submission:
The electronic portal for submitting pre-proposals and full applications is also available on the AI-AN CTRP website. Applicants are able to submit full proposals after consultations with the three cores —Professional Development; Research Design, Epidemiology, and Biostatistics; and Community Engagement and Outreach.

Full Proposal Due Dates:
New or revised full proposals are due on March 21, 2018. Proposals that have been funded by the AI-AN CTRP in Year 2 (competitive renewals of development or pilot awards) are due April 18, 2018. Applications must be submitted by the due date no later than 11:59 pm in the local time zone.

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. Applicants cannot receive concurrent support for research from more than one NIH IDeA program (e.g., COBRE or INBRE, or CTR-IN).   Investigators who receive IDeA support for research may serve as paid mentors on other IDeA-funded projects. Other than trainees, eligible investigators must have terminal degrees in their field (e.g., PhD, MD). Note that trainees are eligible for diversity supplements even if the sponsor's research project is funded via another IDeA award.

Types of Awards:
 Applications to support projects will be awarded in several categories. For all project categories, we encourage, but do not require:
- Collaborations between Montana and Alaska investigators or communities
- Interdisciplinary teams
- Projects led by American Indian or Alaska Native investigators

Proposal Review:
- All proposals will be administratively reviewed for completeness. Applicants will be notified of missing components and will have 24 hours from notification to amend the application.

- AI-AN CTRP Community Engagement and Outreach Core personnel will review all proposals for culturally respectful research approaches and practices, including community suitability and acceptability.
- AI-AN CTRP Research Design, Epidemiology, and Biostatistics Core personnel will review all proposals for merit of the study design and analysis plan.
- Applications for new pilot awards (not competitive renewals of prior pilot awards funded by the AI-AN CTRP) 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.
- Some applicants may be asked to respond to external reviewers concerns before their proposal is submitted to NIH.
- 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.

Formatting Requirements:
Unless specified otherwise in the NIH forms pages, font sizes must be 11 points or larger and page margins must be at least .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.

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). Contact with human participants is not expected to begin during the development award period. Development awards will be up to $50,000 in direct costs. Award recipients are eligible to apply for a continuing award from the AI-AN CTRP.

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 (Forms Page 2)
- ☐ 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, no Forms page is needed)
- ☐ Abstract (500 words or less, no Form page is needed)
- ☐ Specific Aims of the Project that will result from the successful implementation of the development plan (e.g., a pilot project proposal): statement of problem, hypothesis, and specific aims that will address the hypothesis. (1 page, no Forms page is needed)
- ☐ Research Development Plan (2 pages, no Form page is needed) to include:
  - o Significance: the importance and health relevance of the project, how it will improve our knowledge, and how it will improve the health of individuals
  - o Approach: describe the developmental activities and how they will support the development of culturally responsible community-engaged research
  - o 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, no Forms page is needed) to include: benefit to AI-AN people and whether the health area is a tribally-identified priority; strategy for respectful engagement and collaboration with community members (e.g., letters from named community partners 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); explanation of how study methods or approaches are appropriate for the community (e.g., cultural adaptation, is

there a potential for harm, incorporation of recommendations from Community Engagement and Outreach Core members).
☐ Description of the Facilities and Resources, in NIH format
☐ Timeline that includes explicit plans for planning, training, community involvement, or any other needed project development activity
☐ NIH-style Biographical Sketches of key personnel (required for PIs and mentors)
☐ Listing of all current funding, past IDeA funding, and all pending funding. Include all past and current IDeA funding and a short paragraph describing the outcomes that resulted from the funding, including manuscripts and the grants submitted, grant score(s), and grants received.
☐ Project budget 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 Alaska
☐ Letter of support from chair, director or supervisor verifying that the requested amount of research time and space is available to the investigator
☐ Bibliography (no page limit)
☐ Contact with human participants is not expected to begin during the development award period, but if contact with human participants is included the following elements are required:
  o NIH Protection of Human Subjects section (all sections are required, including a description of "Inclusion of Women and Minorities," "Inclusion of Children")
  o Documentation that all IRB application(s) are submitted to the Human Subjects review committee(s) (if the proposal is recommended for funding, all IRB approvals must be obtained by June 22, 2018)
  o Human Subject Education Certification for all key personnel via CITI training (if the proposal is recommended for funding, all certifications must be obtained by June 22, 2018)
  o PHS Inclusion Enrollment Report (NIH fillable PDF form)
  o Letter of support from the appropriate tribal entity (approval notice from the appropriate tribal IRB is sufficient)
☐ If the project meets the NIH definition of "clinical trial, the following elements are required:
  o Good Clinical Practice Training Certification for all involved investigators and staff to meet the new NIH guidelines (Free online Good Clinical Practice Training is available through NIAID)
  o Please plan to register your study and submit your summary results to clinicaltrials.gov (no documentation is required)
☐ 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:
  o IACUC approval letter or plan to secure IACUC approval (if the proposal is recommended for funding, all approvals must be obtained by June 22, 2018)
  o 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.

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 up to $80,000 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 (Forms Page 2)
- ☐ 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, no Forms page is needed)
- ☐ Abstract (500 words or less, no Form page is needed)
- ☐ Specific Aims of the Project: statement of problem, hypothesis, and specific aims that will address the hypothesis. (1 page, no Forms page is needed)
- ☐ Research Plan (7 pages, no Form page is needed) to include:
    - o Significance: the importance and health relevance of the project, how it will improve our knowledge, and how it will improve the health of individuals
    - o Innovation: how the project is creative, unique, and innovative
    - o Approach: (Design and Methods) description of preliminary data (if such data are available) that support the hypothesis or aims 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
    - o 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 will test the hypothesis or fill a gap in knowledge.
- ☐ Community engagement and outreach plan (1 page, no Forms page is needed) to include: benefit to AI-AN people and whether the health area is a tribally-identified priority; strategies for respectful engagement and collaboration with community members (e.g., letters from named community partners, plans to disseminate study findings to the community, community collaboration in project development, mechanisms for active engagement and oversight by community members – justify approach if a community advisory board is not being used); explanation of how study methods or approaches are

appropriate for the community (e.g., prior cultural adaptation, is there a potential for harm, incorporation of recommendations from Community Engagement and Outreach Core members).

☐ Description of the Facilities and Resources, in NIH format
☐ Timeline, including the project outcomes to be accomplished and detailed plans for submitting subsequent funding applications (e.g. R01 or similar)
☐ NIH-style Biographical Sketches of key personnel (required for PIs and mentors)
☐ Listing of all current funding, past IDeA funding, and all pending funding. Include all past and current IDeA funding and a short paragraph describing the outcomes that resulted from the funding, including the grants submitted, score(s), and grants received.
☐ Project budget 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 Alaska
☐ Letter of support from chair, director or supervisor verifying that the requested amount of research time and space is available to the investigator
☐ Bibliography (no page limit)
☐ If contact with human participants is included, the following elements are required:
  o NIH Protection of Human Subjects section (all sections are required, including a description of "Inclusion of Women and Minorities," "Inclusion of Children")
  o Documentation that all IRB application(s) are submitted to the Human Subjects review committee(s) (if the proposal is recommended for funding, all IRB approvals must be obtained by June 22, 2018)
  o Human Subject Education Certification for all key personnel via CITI training
  o PHS Inclusion Enrollment Report (NIH fillable PDF form)
  o Letter of support from the appropriate tribal entity (approval notice from the appropriate tribal IRB is sufficient)
☐ If the project meets the NIH definition of "clinical trial, the following elements are required:
  o Good Clinical Practice Training Certification for all involved investigators and staff to meet the new NIH guidelines (Free online Good Clinical Practice Training is available through NIAID)
  o Please plan to register your study and submit your summary results to clinicaltrials.gov (no documentation is required)
☐ If vertebrate animals are involved, the following elements are required:
  o IACUC approval letter or plan to secure IACUC approval (if the proposal is recommended for funding, all approvals must be obtained by June 22, 2018)
  o 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.

Diversity Awards

The PI or Project Leader of any funded project (through the AI-AN CTRP or other sources) or any AI-AN CTRP partner institution can request an award to provide trainee salary support, tuition, research or dissertation support, and conference travel for an AI-AN trainee. Awards will be made to the PI or Project Leader for up to $35,000 direct costs to support the trainee and these awards may be renewable for support in subsequent years. Requested salary must not exceed the NIH stipend levels for Ruth L. Kirschstein National Research Service Award.

- ☐ NIH Face page (use PHS398 forms and instructions)
- ☐ NIH Project Summary (Forms Page 2)
- ☐ Abstract (500 words or less, no Form page is needed)
- ☐ 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, no Forms page is needed)
- ☐ A summary or abstract of the funded project the trainee will be involved in (if applicable)
- ☐ Plan for the research and/or career development experiences proposed for the AI-AN trainee, including how the mentor will support the trainee'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 trainee (2 pages, font size must be 11 points or larger)
- ☐ Community Engagement or planned community engagement (1 page, no Forms page is needed) to include: how the study addresses a priority health area and benefits AI-AN people; how the project respectfully engages and collaborates with community members (e.g., letters from named community partners, plans to disseminate study findings to the community, community involvement in the development of the proposal, methods to obtain on-going advice from community members); and how the study methods or approaches are appropriate for the community (e.g., prior cultural adaptation, recommendations from Community Engagement and Outreach Core members).
- ☐ Description of the Facilities and Resources, in NIH format
- ☐ Timeline, including the outcomes to be accomplished
- ☐ NIH-style Biographical Sketches of key personnel (required for PIs and mentors)
- ☐ Listing of all current funding, past IDeA funding, and all pending funding. Include all past and current IDeA funding and a short paragraph describing the outcomes that resulted from the funding, including the grants submitted, score(s), and grants received.
- ☐ Project budget 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 Alaska
- ☐ Letter from the PI or Project Leader of the funded project explaining how the diversity supplement will achieve the goals of the trainee
- ☐ Letter of support from the hosting institution verifying that resources, including research space, are available to the trainee (if necessary)

☐ Letter of support from chair, director or supervisor verifying that the requested amount of research time and space is available to the trainee. Indicate additional institutional support (including funds) that will be allocated to support the trainee

☐ Bibliography (no page limit)

☐ If contact with human participants is included, the following elements are required:
  o NIH Protection of Human Subjects section (all sections are required, including a description of "Inclusion of Women and Minorities," "Inclusion of Children")
  o IRB approvals (must be current and list the grant recipient as an investigator)
  o Human Subject Education Certification for all key personnel via CITI training
  o PHS Inclusion Enrollment Report (NIH fillable PDF form)
  o Letter of support from the appropriate tribal entity (approval notice from the appropriate tribal IRB is sufficient)

☐ If the project meets the NIH definition of "clinical trial, the following elements are required:
  o Good Clinical Practice Training Certification for all involved investigators and staff to meet the new NIH guidelines (Free online Good Clinical Practice Training is available through NIAID)
  o Please plan to register your study and submit your summary results to clinicaltrials.gov (no documentation is required)

☐ If vertebrate animals are involved, the following elements are required:
  o IACUC approval letter or plan to secure IACUC approval (if the proposal is recommended for funding, all approvals must be obtained by June 22, 2018)
  o 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.

Travel Awards

Travel grants are available for prospective pilot project leaders to allow them to visit potential collaborators, mentors, or training sites with the goal of developing a pilot proposal for submission. Travel to professional conferences will only be considered if the intention is to network with mentors/collaborators or to receive specific training relevant to a planned pilot grant submission. Applicants for travel awards may not currently hold CTRP awards. Travel support is awarded up to $2000.

CTRP will accept applications for travel awards anytime. Funding will be based on merit and availability of funds.

- ☐ Specific Aims of the Project under development: statement of problem, hypothesis, and specific aims that will address the hypothesis. (1 page, no Forms page is needed)
- ☐ A plan for the visit and a description of how the visit will help develop a pilot or mini-sabbatical proposal (2 pages)
- ☐ NIH-style Biographical Sketches of key personnel (required for PIs and mentors)
- ☐ Listing of all current funding, past IDeA funding, and all pending funding. Include all past and current IDeA funding and a short paragraph describing the outcomes that resulted from the funding, including the grants submitted, score(s), and grants received.
- ☐ Project budget and budget justification.
- ☐ Letter of support from the host mentor/collaborator specifying the resources available to the investigator (if applicable)
- ☐ Bibliography (no page limit)