

Request for Proposals

Multi-Year Developmental Research Pilot Project

Alaska IDeA Network of Biomedical Research Excellence (Alaska INBRE)

Announcement Date: August 30, 2021
Letter of Intent Due: September 24, 2021
Full Application Submission Date & Time: November 19, 2021 at 5pm AKST
Budget total = up to \$150,000 (direct) Awards
Announced and Forwarded to NIH for Approval: ~ March 15, 2022
Funding Period: May 2022 – June 30, 2024

BACKGROUND

The Alaska IDeA Network of Biomedical Research Excellence (AK INBRE 4), supported by a grant from the National Institute of General Medical Sciences (NIGMS), provides pilot awards for developmental research projects in the biomedical and health sciences to partner institutions in Alaska to improve the competitiveness of individual researchers for winning ongoing support for research and graduate student training programs. AK INBRE 4 research themes are One Health and health disparities in Alaska Native people as opportunities for building research collaborations to address Alaska's needs for enhancing the health of individuals, families, and communities. Pilot research project awards can support any compelling topic in basic, translational, clinical, biomedical or behavioral health research; however, projects that align with our One Health theme of the well-being of people, animals, and the safety of their shared environment are given priority. Collaborative and interdisciplinary research are also encouraged.

I. LETTER OF INTENT

For investigators wishing initial feedback on their research ideas, Alaska INBRE will accept letters of intent (LOI) for this funding opportunity. Although an LOI is not required or binding and does not enter into the review of a subsequent application, AK INBRE 4 leadership and/or the INBRE External Advisory Committee (EAC) members will reply with feedback on the appropriateness of the research area for support through this mechanism.

A two-page LOI should include the following:

- Descriptive title of proposed research
- Name, address, and telephone number of the principal investigator(s)
- Names of other key personnel
- Anticipated aims and approaches
- How the work, if funded, will lead to applications for independent research support
- Participating institutions

The LOI can be sent any time prior to September 24th to <u>ua-akinbre@alaska.edu</u> with the subject "LOI Mod 22 Pilot *PI Last Name*". For more information, contact Julie Benson at jcbenson@alaska.edu.

II. ELIGIBILITY

The principal investigator (PI) must have a full-time faculty appointment (tenure-track or research) at a University of Alaska campus at the time of award OR be a researcher at SCF or ANTHC; collaborating investigators can be from any institution within an NIH IDeA state. <u>Investigators are encouraged to contact the Alaska INBRE PI, Co-I, or Program Coordinator (PC) to confirm their eligibility and to discuss their ideas for a pilot project ahead of time. PIs will need to have sufficient time to execute the funded research; NIGMS</u>

guidelines expect that at least 6 out of 12 months of each year during the award period will be available to the PI for research, graduate student training, and professional development. Therefore, the proposal applicant must include a letter from their supervisor to ensure that their workload distribution for research will be compatible with these expectations if an INBRE pilot grant is awarded. For faculty, this is typically accomplished through a full-time research plan during the three summer months and assignment of no more than three formal courses during the 9-month academic year. Pls cannot have two research projects supported at the same time from the NIGMS IDeA program (INBRE, CTR, or COBRE). Preliminary data are not required.

The INBRE EAC will advise whether previously funded investigators qualify for support using the following guidelines: recipients of prior awards should show they have disseminated the conceptual basis of the research and/or preliminary results in a poster or oral presentation at a professional meeting and have concrete plans to submit a major proposal. A major proposal is defined as that which supports biomedically relevant research and has a multi-year duration, preferably supports undergraduate, graduate students, and/or post-doctoral scientists, and is \$100,000 or more in direct costs per year. Examples include R15, R21, and R01 applications to the NIH.

A single investigator at the awardee or network institutions should supervise each research project. Applications for multi-disciplinary studies with PI and co-I or co-Is from different disciplines are allowed.

III. AMOUNT & DURATION OF AWARD:

This Alaska INBRE Developmental Research Pilot Project Award is a multi-year award with funds provided as follows:

Year 1: May - July (up to \$30,000) Summer Kick Off

Year 2a: August – February (up to \$50,000)

Year 2b: March – July (up to \$50,000) with EAC review and approval

Year 3: August - June (up to \$50,000) Write Up Results & Publish

Total Project Support = up to \$150,000 direct costs

IV. SCIENTIFIC ADVISOR:

Each pilot award PI must identify a science advisor with expertise relevant to the proposed research, a willingness to mentor the PI, and who may be a collaborator on the project. The advisor must provide a letter of support at time of submission (Section 9) and will be confirmed by the EAC chair as having the appropriate research expertise and experience with NIH (or other federal) funding. Science advisors may be from the AK INBRE 4 network or from outside institutions and serve to help oversee the proposed research and professional development of the PI. Science advisors can aid in the development of hypotheses, research design, and methodology relevant to the investigator's research and provide technical training in their laboratory, if appropriate. Advisors will be expected to mentor PIs and review their manuscripts and proposals. Prior to award, a mentoring plan describing their scientific and developmental goals, meeting frequency, and the types of collaborative input will be generated by the PI and their advisor. Advisor costs of \$2000 each budget period (plus additional costs if needed) must be included in the submitted project budget. Advisor costs may include travel between the PI and advisor's laboratories, salary support for the science advisors, and other mentoring plan support. A report to the Alaska INBRE PI from the scientific advisor describing the project PI's scientific progress and professional development and any associated challenges must be provided in May via the Alaska INBRE reporting database.

V.APPLICATION INSTRUCTIONS:

Unless otherwise noted in this announcement, follow the instructions for the PHS 398 Grant Application. Page limits are noted by section. All previously funded Alaska INBRE investigators whose pilot projects have been

funded for 2 years or more must submit additional documents, in addition to the proposal requirements listed below, as part of the appendix. A complete application will consist of a single PDF document that includes all of the following sections:

Section 1: Form Page 1: Face Page and Form Page 2: Summary, Relevance, etc. = 3 pages.

Section 2: Specific Aims – Limited to 1 page (Continuation Format Page)

Section 3: Research Strategy – Limited to no more than 6 pages (Continuation Format Page) to include the following 3 sections:

Significance Innovation Approach

If a proposal has multiple Specific Aims, the applicant may address Significance, Innovation, and Approach for each Specific Aim individually or collectively. Regardless of the option selected, the page limit remains the same.

Section 4: Budget – Submit a detailed budget justification for the entire proposed project period (Form Page 5) AND your institutional budget spreadsheet. Please note: Do not include indirect costs on these internal awards in your budget forms. If you are in the University of Alaska System (UAF, UAA, UAS), your home department will be distributed 2.5% of your institution's F&A rate towards the overhead of administering your pilot project. At the time of award, the INBRE Fiscal Officer will set up this distribution and notify your department head of the incoming revenue to cover overhead. If you work for network partners ANTHC or SCF, F&A is based on your institution's negotiated indirect cost rate agreement.

Helpful Hints:

- a. Include how you will meet the 6-person month commitment to research, trainee mentoring, and professional development.
- b. Use only calendar months OR academic year and summer months but not both.
- c. Include costs for your scientific advisor (see IV. Scientific Advisor on page 2.)
- d. Covering tuition for a graduate student is "tuition remission" in NIH terminology; please use this terminology.
- e. Include costs for travel and publication fees to disseminate results including travel for student/trainees.
- f. Submit the budget periods required to reflect your plan for the research project. See Section III: Amount & Duration of Award. Split year 2 into 2 budget periods.
- g. Questions? Contact INBRE Fiscal Officer Matt Seymour at mjseymour@alaska.edu.

Section 5: INBRE Specific Information - Limited to 3 pages (Continuation Format Page)

- (1) Explain how your research project expands biomedical research in Alaska AND builds research capacity;
- (2) Explain how your project is NIH relevant or develops further expertise in alignment with the <u>aims of INBRE</u>, which are biomedical research focused on One Health investigating the well-being of people, animals, and their shared environment;
- (3) Explain how this project will lead to applications for extramural funding, including specific target FOAs and/or NIH ICs; include a target Study Section or SRG and explanation of how your work fits this review group (ask your mentor or INBRE leadership if you are unfamiliar with this).
- (4) Research schedule that documents the milestones of achievable objectives that can be completed for inclusion in the February progress report to the External Advisory Committee;
- (5) A summary and outcomes of progress made from prior INBRE research support, if applicable.

Section 6: Biographical Sketch – Limited to 5 pages (Biographical Sketch Format Page). Include a biosketch for PI and if applicable, co-I. Applicants must use the new NIH biosketch format for applications due on/after January 25, 2022. Please see the NIH biosketch sample for questions.

Section 7: Letter of Support from your Supervisor – Applicants must include a letter from their supervisor (typically an administrator with authority to approve workload) to ensure that their workload distribution for research will be compatible with expectations if an award of an INBRE pilot grant is made. For faculty, this is typically accomplished through a plan for full-time research during the three summer months and teaching assignments of no more than 3 formal courses during the 9-month academic year. Additionally, Pls cannot have two research projects supported at the same time from the National Institute of General Medical Sciences (NIGMS) IDeA program (INBRE, CTR, or COBRE).

Section 8: Letter of Support from your Scientific Advisor – Applicants must include a letter of support from their scientific advisor. The letter should include a statement regarding the advisors willingness to support the applicant and submit reports as requested. See **IV. Scientific Advisor** for additional information.

Section 9: Appendix – Please attach the following as needed: Bibliography & References Cited; letters from collaborators; Vertebrate Animal Section (VAS); PHS Human Subject & Clinical Trials Information and CITI certificates. If already secured, also include IACUC and/or IRB approvals. The appendix does not count against the page limits for the proposal.

If you have been previously funded as an INBRE piloted researcher, you must include at least one of the following:

- Documentation of dissemination activities of preliminary results at a professional meeting.
- Copies of drafts or submissions of articles to a peer-reviewed journal that are products of the research.
- Evidence of a major proposal submission to an extramural agency prior to when the EAC meets to consider applications.

SUBMISSION: Applicants should prepare text documents using any word processing program and then convert those files to a single PDF document before submission via the INBRE website at www.alaskainbre.org.

PDF FORMAT IS REQUIRED. Save all files as follows: "researcher(s) last name MAU/Partner Institution Mod-22 pilot app." Examples: Smith UAS Mod-22 Pilot App; Turner ANTHC Mod-22 Pilot App. If you have any questions regarding the file name or format, please contact Alaska INBRE Program Administrator Julie Benson at jcbenson@alaska.edu. Please follow your institutional requirements for departmental approvals and signatures.

SPECIFIC INSTRUCTIONS REQUIRED FOR SECTIONS 2. 3. & 5

FORMAT REQUIREMENTS

- **Font:** Use an Arial, Helvetica, Palatino Linotype, or Georgia typeface, a black font color, and a font size of 11 points or larger. (A Symbol font may be used to insert Greek letters or special characters; the font size requirement still applies.) Type density, including characters and spaces, must be no more than 15 characters per inch. Type may be no more than six lines per inch.
- ◆Paper Size and Page Margins: Use standard paper size (8 ½" x 11"). Use at least one-half inch margins (top, bottom, left, and right) for all pages. No information other than page numbers should appear in the margins, including the PI's name.
- ◆Page Formatting: Use only a standard, single-spaced, single-column format for the text. Number all pages

sequentially and centered at the bottom of each page.

- **♦Figures, Graphs, Diagrams, Charts, Tables, Figure Legends, and Footnotes:** You may use a smaller type size but it must be in a black font color, readily legible, and follow the font typeface requirement. Color can be used in figures; however, all text must be in a black font, clear and legible.
- ♦ **Grantsmanship:** Use plain English and avoid jargon. If terms are not universally known, spell out the term the first time it is used and note the appropriate abbreviation in parentheses. The abbreviation may be used thereafter.

VI. REVIEW PROCEDURES & CRITERIA

- Step 0: Early submission is encouraged. **If submitted before November 17, 2021, at 5 pm AKST**, an administrative review will be conducted, and feedback on completeness and compliance to directions will be provided no later than 5 pm November 18th so that corrections can be made in advance of the 5 pm November 19th deadline.
- Step 1: Submission final deadline is November 19, 2021, at 5 pm AKST. All submissions will receive an email confirmation of receipt within 24 hours of submission.
- Step 2: Two external reviewers review the proposal. These reviews are provided to the INBRE External Advisory Committee (EAC).
- Step 3: The INBRE EAC review and rank the proposals and make funding recommendations to the PI, PC, and Co-I.
- Step 4: The PI, PC, and Co-I will select which applications are forwarded to NIH for final review from those determined to be meritorious by the EAC.
- Step 5: NIH will review and approve the proposals for funding; this approval will require finalized IRB or IACUC approved protocols in addition to letters of community support, if relevant.
- Step 6: Upon confirmation from NIH, Alaska INBRE will fund the selected pilot projects.

Applications that are complete will be evaluated for scientific and technical merit by independent scientific expert reviewers in accordance with and by the EAC using NIH peer review procedures and the following review criteria:

Overall Impact. Reviewers will provide an overall impact/priority score to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration of the following five core review criteria, and additional review criteria (as applicable for the project proposed).

Score Review Criteria. Reviewers will consider each of the five review criteria below in the determination of scientific and technical merit, and give a separate score for each. An application does not need to be strong in all categories to be judged likely to have major scientific impact. For example, a project that by its nature is not innovative may be essential to advance a field.

Significance. Does the project address an important problem or a critical barrier to progress in the field? If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

Investigator(s). Are the PD/PIs, collaborators, and other researchers well suited to the project? If Early Stage

Investigators or New Investigators, do they have appropriate experience and training? If established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project?

Innovation. Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?

Approach. Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed? If the project involves clinical research, are the plans for 1) protection of human subjects from research risks, and 2) inclusion of minorities and members of both sexes/genders, as well as the inclusion of children, justified in terms of the scientific goals and research strategy proposed?

Environment. Will the scientific environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?

Relevance. How does the proposed research develop further expertise in alignment with the aims and initiatives of INBRE which are biomedical and health research and the interface of the environment, health and disease in people and animals?

Budget and Period of Support. Reviewers will consider whether the budget and the requested period of support are fully justified and reasonable in relation to the proposed research.

VII. SELECTION PROCESS

Applications submitted in response to this funding opportunity will compete for available funds with all other submitted applications. Priority will be to fund highly-ranked proposals that will expand the professional development of the project PI, are in alignment with INBRE's aims, demonstrate collaboration, lack funding from other sources, and most likely will lead to extramural funding. Preference will be given to those engaged in One Health research, those who present findings at national meetings, and those who plan publications in peer reviewed journals. All proposals will be reviewed externally by subject experts and their comments will be made available to applicants.

Only highly-ranked applications that are complete (see Section V. Application Instructions) and contain all required information including, if applicable, IACUC approval letter and Vertebrate Animal Section, or IRB approval letter, PHS Human Subject and Clinical Trials Information, and CITI certificates can be submitted to NIH for approval. Applications that include animal or human subjects research per the face page (section 4 or 5) must provide IACUC and/or IRB approval letters by March 1, 2022. If a highly-ranked application is incomplete, it may not be eligible for full funding and may be recommended for bridge funding.

Bridge awards of up to \$30,000 are determined by the External Advisory Committee (EAC) (see VI. Review Procedures and Criteria, Step 3). The EAC or INBRE leadership can recommend applications for bridge funding to support revising the application for submission in the next funding cycle based on the following scenarios:

- Require additional time to obtain IACUC, IRB approvals or community letters of support.
- Need additional effort related to study design

Other criteria identified during the review

Bridge awards will require revision of the application materials prior to submission to the NIH for approval. The INBRE program administrator and fiscal officer will work with the researcher on these revisions based on the recommendations of the EAC and INBRE PI, PC, and co-I. Bridge awardees will be expected to submit a new full pilot application in response to the next pilot FOA.

VIII. CONFLICT OF INTEREST

Alaska INBRE follows the NIH Guidelines for Conflict of Interests.

IX. AWARD CONDITIONS

To maintain an active award, pilot recipients will provide a substantive report of research progress in February that will be reviewed by the INBRE EAC for scientific progress to determine continued funding. Reports are due in April each year for submission in the annual progress report. Additional reporting details will be provided in the award notification.

Pilot awardees will participate in Alaska INBRE professional development opportunities, all required compliance trainings, and will be expected to attend and participate in the annual INBRE retreat and local seminar series. All safety training required at your institution must be completed in the first month of work performed.

Presentations (oral or poster) and publications must include the following acknowledgement and disclaimer:

"Research reported (on this poster/in this publication) was supported by an Institutional Development Award (IDeA) from the National Institute of General Medical Sciences of the National Institutes of Health under Award Number 2P20GM103395. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health."

Pilot recipients must implement the planned activities outlined in the budget section of the application. The expenditures and activities must adhere to applicable NIH rules and regulations that will be listed in the award letter and adhere to institutional policies. Overruns, unliquidated encumbrances, and unallowable costs will be moved to the pilot recipient's department funding. Failure to progress reasonably throughout the year of funding could result in dollar reallocation or reduction. All funds must be appropriately expended within the requested time frame. **No carryover is allowed each year.**

Failure to comply with prior or current award conditions will render researchers ineligible for one year to apply for future INBRE funding.

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