NIMHD Center of Excellence in American Indian and Alaska Native Health Disparities
Alzheimer's Disease/Related Dementias and Precision Medicine
(COE-ADRD/PM)
Investigator Development Pilot Study Information

Center Overview

Alzheimer's Disease and related dementias (ADRD) have become major health concerns in American Indian and Alaska Native (AI/AN) communities. This center partners across private, tribal, and public constituencies to create a scientifically rigorous, culturally informed, patient-centered research program for cognitive impairment and dementia. Based on a precision medicine (PM) framework this center will develop precise approaches to address such conditions in American Indian and Alaska Native populations.

The **Investigator Development Core** provides financial, logistical, and scientific resources to support innovative Pilot Studies that will generate preliminary data for subsequent grant applications. Members of the Core will use the scientific review process as a learning opportunity for interested junior investigators as well as integrate, coordinate, and centralize research services that support these investigators.

Pilot Studies

The Center will fund innovative Pilot Studies with meaningful implications for personalizing the prevention, diagnosis, and treatment of cognitive impairment, dementia, and AD in AI/AN communities. Applicants will have pertinent expertise and be well-suited to the proposed work. Two to three Center Pilot Studies will be supported each year, depending upon available resources.

The full period of support will span 18 months. The actual Pilot Study will be pursued within the first 12 months, concluding with a manuscript submitted for publication to a professionally referred journal. The remaining 6 months will be devoted to finalizing a research grant application to the National Institutes of Health (NIH) to continue the investigator's work in this area. In accordance with scientific advances and community priorities, the relative emphases of Pilot Studies may change during the 5 years of funding.

Eligibility

Proposals will be accepted from any postdoctoral research fellow or junior faculty member from an institution or organization in the United States that is eligible to receive research awards from the NIH. Applicants must meet the NIH definition of an early-stage investigator (ESI). According to the NIH, an ESI is an investigator who is within 10 years of completing her/his terminal degree (MD or PhD) or post-graduate clinical training and who has not previously received (as Principal Investigator) a substantial independent research award from NIH (e.g., R01). Additional information about the classification of ESI is provided at the following website: https://grants.nih.gov/policy/early-investigators/index.htm.

Pilot Study applicants must:

1) Plan to conduct research with American Indian (AI) or Alaska Native (AN) people. Research topics must have relevance for Alzheimer's disease and related dementias (ADRD) and/or Precision Medicine (PM).

2) Have an advanced degree in social, behavioral, or health sciences or a similar field.

3) Be a transitioning post-doctoral fellow, a junior faculty member, or a mid-career scientist newly transitioning to research on ADRD/PM

4) Be up to date with human subjects training or commit to completing training before the cohort's kickoff meeting; and

5) Obtain a letter from her/his academic supervisor guaranteeing adequate release time to conduct the Pilot Study.

6) Pilot studies that entail secondary analyses of relevant, existing data sets are **<u>strongly</u>** encouraged.

Pilot Study Program Activities

The Pilot Study Program will involve:

1) An initial 2-hour teleconference that reviews program expectations, tasks, timelines, desired products, and introduces Pilot Study Investigators to Center support staff and faculty, notably analytic resources

2) Bi-monthly interactions with mentor team

3) A brief, monthly written progress report

4) Quarterly presentation of work in progress

5) Preparation of at least 1 manuscript based on the results of the Pilot Study Investigator's work.

6) Preparation of a NIH research grant application, either a Diversity Supplement, a small grant, K-series career award, or R-series study as appropriate to the investigator's status.

Responsibilities and Expectations

Pilot Study Investigators are expected to complete the program activities listed above. Each participant will be required to complete the Duke University course in scientific writing before starting the program. In months 12 and 18 of the program, each participant will provide a brief standardized report of her/his accomplishments, including the status of the Pilot Study, publications, current plans for grant application, and plans for future career development. Because some outcomes of pilot funding will not be immediate, we will annually request and review each participant's progress in terms of all new publications, presentations, grants, and

contributions to health and health disparities research during all 5 years of funding of the parent grant. In addition, trainees will present their findings at an annual conference and will thereby stimulate new collaborations, highlight active projects, and publicize one's achievements.

Pilot Project Award Amounts

Applicants proposing a secondary data analysis project may request up to 0.2 FTE of their salary and fringe benefits. Funds related to support for acquiring a dataset, if appropriate, necessary software, data analysis, copy-editing, mentorship, and travel, though counted toward the total award, will be held at the Center and costs thereof borne directly by the Pilot Study Program. The maximum total award will be no more than $37,500 over the 18-month period ($25,000 for Months 01-12 and $12,500 for Months 13-18), including applicable Facilities and Administrative Costs.

A wide range of factors may affect the feasibility and cost of completing a primary data collection project within these limited time periods. Therefore, preference will be given to secondary data analysis projects. Budget requests for equipment (e.g., computers) and other faculty salaries will be discouraged, although they may occasionally be appropriate. Therefore, we will maintain flexibility to consider exceptions on a case-by-case basis.

Application

Pilot Study Program applicants will need to provide:

1) A completed COE-ADRD/PM Initial Application form.

2) A cover letter describing her/his goals, need for this program, and experience, if any, working with the priority populations.

3) A curriculum vitae.

4) 2 letters of recommendation.

5) A completed **Pilot Study Application** (see below)

For the **Pilot Study Application**, applicants must provide:

1) A **4-page scientific narrative** including:

   a. Specific Aims

   b. Significance

   c. Innovation and Approach (including preliminary data if they exist)

   d. Project Timeline

   e. Bibliographies (limited to 1 page, does not count towards 4-page limit)

2) A **1-page statement** of future directions and career plans.

3) A **1-page Mentorship Plan** and Letter of Support from the Senior Mentor.

4) A 1-**page table and narrative** briefly outlining the timeline for major project milestones.

5) **Biosketches** (NIH format) for the pilot Principal Investigators and key personnel, as applicable.

6) A **budget and a budget justification** (including personnel, travel, and equipment requests).

7) **Letters of support** from collaborators or community partners.

8) **Tribal resolutions and letters from community organizations** might also be required for some applications.

The narrative should describe the study's specific aims and research strategy. Investigators should provide an overview of the data to be examined, summarize their methodologic approach, highlight the significance of the proposed project for Native health and diabetes translation research, and identify the ways in which the proposed research is innovative. Applicants should describe the quality of the research environment in which the work will be completed and highlight the unique and complementary expertise of key personnel. It is important to clarify how the proposed project will lead to a continuing program addressing ADRD research in AI/AN communities.

Project Timeline. Each application should include a table and narrative briefly outlining the timeline for major project milestones. The timeline should include at least the following tasks:

- Receipt of approval from all relevant institutional review boards (IRBs),

- Completion of study analyses, and

- Submission of manuscript to peer-reviewed journal.

Mentorship Plan. Applicants must identify a Senior Mentor, who will collaborate with the Principal Investigator and provide guidance throughout the course of the project. The mentor must be an experienced researcher, with expertise relevant to the content or methods of the proposed project. In the application, the applicant should describe the mentorship plan, including the methods through which the mentor will provide guidance and the frequency of project-related contacts between the investigator and the mentor. The application should include a Letter of Support from the Senior Mentor, committing to the provision of professional guidance and routine oversight of project progress.

Protection of Human Subjects and Inclusion Enrollment Report. Although proposed projects will involve analysis of existing data, proposals should describe risks and methods for protecting human subjects (e.g., confidentiality) and plans for obtaining approval from relevant IRBs. The following website can help investigators determine what sort of review their proposed project is likely to require: https://www.hhs.gov/ohrp/regulations-and-policy/decision-charts/index.html#c5.

Investigators should describe the data set to be used as part of the proposed secondary-analysis project, including information about measures included and the participant sample. Investigators should complete the Cumulative Inclusion Enrollment Report, which can be found at the following link: https://archives.nih.gov/asites/grants/04-13-2016/grants/forms/phs-inclusion-enrollment-report.htm.

Biosketches. Biosketches are required for the Principal Investigator, Senior Mentor, and all key personnel. Key personnel include all individuals who will contribute in a substantive way to scientific development or execution of the proposed project (whether or not they are paid members of the project staff). Applicants should prepare biosketches using the latest NIH biosketch format: https://grants.nih.gov/grants/forms/biosketch.htm.

Budget and Institutional F&A Agreement. A detailed budget should be provided using PHS 398 Form Page 4 – Detailed Budget for Initial Budget Period: https://grants.nih.gov/grants/funding/phs398/fp4.pdf. Instructions for completing the form are available at the following NIH website: https://grants.nih.gov/grants/funding/phs398/phs398.pdf.

The award budget should not exceed $37,500 in total costs ($25,000 for Months 01-12 and $12,500 for Months 13-18). Institutional indirect costs are allowable and should be calculated and accounted for in the budget. For external, non-University of Colorado applicants, an 8% training indirect cost rate or waiver of indirect costs in their entirety is **strongly** suggested. If an external applicant is able to obtain the 8% indirect cost rate or a complete waiver of indirect costs through an approved institutional process, the difference can be converted into direct costs, thus increasing the project Scope of Work, but remaining with the total $37,500 available funds. For example:

Sample 18 Month Budget without Waiver or Reduced F&A Rate		Sample 18 Month Budget with Waiver or Reduced F&A Rate	
Salary	$15,716	Salary	$20,132
Benefits	$4,715	Benefits	$6,040
Travel	$2,000	Travel	$2,000
Research Supplies	$1,000	Research Supplies	$2,000
Other	$685	Other	$2,000
		Hourly Student Analysis	$2,550
Total Direct Costs	$24,116	Total Direct Costs	$34,722
Institutional Research F&A Rate	55.5%	NIH Training F&A Rate	8%
Indirect Costs	$13,384	Indirect Costs	$2,778

| TOTAL Request | $37,500 | TOTAL Request | $37,500 |

A copy of the institution's F&A Agreement should be included in the application.

Budget Justification. A narrative budget justification should describe project costs using the categories identified in the PHS 398 budget form. Allowable expenses include salary support, travel to present study findings, and project-specific research supplies. Although salary support is allowable for the Principal Investigator, key personnel, and other project staff, salary support cannot be requested for the Senior Mentor. Other unallowable expenses include (but are not limited to) computer equipment, food, furniture, telecommunications (i.e., monthly line charges), administrative support, and professional society dues.

Please contact Sarah Trimmer with budget-related questions (sarah.trimmer@cuanschutz.edu).

Formatting. Applications should use Arial 11-point font, be single-spaced, and use ½-inch margins.

Application Submission. Letters of Intent and formal applications should be submitted as a single PDF file to Erin Poole (erin.poole@cuanschutz.edu). **The deadline for submission of applications is September 30, 2020.**

Investigators planning to submit an application should send a letter of intent including the following information about the ESI: Name, degree (and year of completion), title, institution, address, email address, and phone number. The letter should also include the name and title of the Senior Mentor as well as an abstract (≤ 250 words) describing the proposed project.