ALZHEIMER'S DISEASE CENTER   DEPARTMENT OF NEUROLOGY
4860 Y STREET, SUITE 3900   SCHOOL OF MEDICINE
SACRAMENTO, CALIFORNIA 95817

REQUEST FOR APPLICATION

UCD ALZHEIMER'S DISEASE RESEACH CENTER DEVELOPMENT PROGRAM

DATE: November 22, 2022

TO: PROSPECTIVE APPLICANTS

SUBJECT: UC Davis Alzheimer's Disease Research Center Development Program

The University of California, Davis Alzheimer's Disease Research Center (UCD ADRC) invites applications for development projects with support from the National Institute on Aging (NIA) Alzheimer's Disease Research Center program award P30 AG072972. The center has allocated $100,000 per year to fund development projects for basic or clinical biomedical, translational, epidemiological, caregiving, educational, or behavioral research for the period July 1, 2023 – June 30, 2024. The development project term may be extended beyond 1 year in length upon successful completion of periodic reviews. This research program is available to researchers interested in studying Alzheimer's disease and Alzheimer's disease related dementias.

Inquiries about this RFA or the UCD ADRC should be directed to Charles DeCarli, M.D. at cdecarli@ucdavis.edu or (916) 734-8413, Lee-Way Jin, M.D. at lwjin@ucdavis.edu or (916) 703-0392; or Delia Roberts at daroberts@ucdavis.edu or 916-734-5728.

I. ACTION TIMETABLE	DATES
Due date and time for applications	March 6, 2023, at 5:00 p.m. (Pacific Time)
Completion date for evaluation of proposals by the Review Panel	May 1, 2023
Notification of awards	To be determined
Earliest anticipated start date	July 1, 2023

II.   BACKGROUND

The National Institute on Aging (NIA) funds 33 Alzheimer's Disease Research Centers (ADRCs) at major medical institutions across the United States. Based in the UC Davis School of Medicine, Department of Neurology, the UCD Alzheimer's Disease Research Center has been continuously funded by the NIA as an Alzheimer's Disease Research Center (ADRC) for more than 31 years. During this period, the Center has awarded over 47 Development Project Awards to clinicians and scientists totaling over $1.3 million.

NIA-designated ADRCs serve as major sources of discovery into the nature of Alzheimer's disease and Alzheimer's disease-related dementias (AD/ADRD) and in the development of more effective approaches to prevention, diagnosis, care, and therapy. They contribute significantly to the

development of shared resources that support dementia-relevant research, and they collaborate and coordinate their research efforts with other NIH funded programs and investigators.

This funding mechanism is intended to give an investigator the opportunity to develop preliminary data sufficient to provide the basis for an application for independent research support. It is designed for postdoctoral (with faculty appointment by 7/1/2023) or junior faculty level investigators but may be awarded to a more senior investigator whose research interest is primarily in areas other than AD/ADRD research and who wants to work in the dementia research field or who wants to try a new hypothesis, method, or approach that is not an extension of ongoing AD research. Investigators are eligible only once for development project support unless the additional proposed developmental project constitutes a real departure from the investigator's ongoing research. The development project term may be extended beyond one year in length upon successful completion of periodic reviews.

III.   OBJECTIVES

The UCD ADRC supports research which contributes to an improved understanding of Alzheimer's disease and Alzheimer's disease related dementias. Therefore, applicants are invited to submit research proposals with a focus on Alzheimer's disease and Alzheimer's disease related dementias directed toward basic or clinical biomedical, translational, epidemiological, caregiving, educational, or behavioral research. These awards are designed as development projects, which are aimed at generating data to support future research applications. Examples of possible development projects are:

1. A study based on data in the National Alzheimer's Coordinating Center (NACC) data set to determine the feasibility of conducting larger studies in the future.
   https://www.alz.washington.edu/WEB/researcher_home.html
2. A study proposed by a new investigator, with an interest in research in AD, before the study has developed to the point of being suitable to apply for individual grant support.
3. Functional, mechanistic, or pre-clinical activities designed to move a basic discovery towards a translational endpoint in the future.

An example of unacceptable developmental project would be clinical trials. Investigators interested in clinical trials should consider applying through the NIA Alzheimer's Disease Pilot Clinical Trials FOA.

IV.   RESOURCES

The UCD ADRC provides investigators and research groups with well-characterized patients and control subjects, family information, brain tissue, biospecimens and data. Requests for brain tissue or biospecimens can be submitted to Lee-Way Jin, MD, PhD at lwjin@ucdavis.edu or Brittany Dugger, PhD at bndugger@ucdavis.edu. Available biospecimens include DNA, Plasma, serum, RNA, and postmortem CSF from select subjects.

Proposals for the analysis of data can be submitted for the center's data as well as program wide data available thru the National Alzheimer's Coordinating Center (NACC). NACC serves as a repository for data collected at approximately 33 Alzheimer's Disease Research Centers (ADRCs) throughout the U.S. NACC maintains a cumulative database including clinical evaluations, neuropathology data when available, and MRI Imaging. The NACC database comprises several standardized clinical and neuropathology data sets, all of which are freely available to the research community. Information about the available data can be found on their website under the investigator/researcher link (https://www.alz.washington.edu/).

The Center has a strong biostatistical component through its collaboration with investigators from the UC Davis Department of Public Health Sciences. Data Management Core Leader Danielle Harvey (djharvey@ucdavis.edu) is available to consult applicants on their development applications.

Investigators interested in basic research may contact Lee-Way Jin at lwjin@ucdavis.edu for assistance in evaluating the feasibility of the study protocol.

Investigators interested in clinical research may contact Martha Forloines at mrforloines@ucdavis.edu for assistance in evaluating the feasibility of the study protocol and information concerning IRB applications.

Pilot applicants may present their research proposals at ADRC Research meetings for feedback prior to submission. Meetings are scheduled for March 9th and 23rd between 9 - 11 a.m. via video conference. Please contact Anna Schmidt at agschmidt@ucdavis.edu to schedule a presentation.

V.   APPLICATION INFORMATION

A.   FUNDING SCOPE AND TIME PERIOD

During Academic Year 2023-2024 the UCD ADRC intends to award $100,000 in direct costs to be distributed for development projects for a one-year period. This allows projects flexibility to meet administrative and regulatory start up activities. Extensions may be approved beyond one year upon successful completion of periodic reviews. Indirect costs will be applied at the current U.S. Health and Human Services approved rate. The amount may be subject to change depending on availability of NIA funding awarded to the parent grant P30 AG072972 or if the applicant is from an outside institution.

Applications for development projects can range from $25,000 to $50,000 for direct funds for a one year project term. The funding mechanism is intended to give junior investigators opportunities to develop projects and generate preliminary data to support future applications for independent research support from extramural funding agencies.

The Administrative Core will conduct reviews throughout the year to determine if continued funding beyond the initial period is merited. The amount of these awards is subject to change depending on availability of NIA funding awarded to the parent grant or if the applicant is from an outside institution.

B.   APPLICANT ELIGIBILITY

Investigators of development projects must be eligible to hold Principal Investigator status on NIH funded projects at the University of California, Davis or other academic institution in the United States.

Projects may involve multiple investigators, but the maximum award as stated above still applies.

Applicants who have previously received awards from the UCD ADRC are not eligible to apply for new research projects.

VI.   APPLICATION REQUIREMENTS

The final application should use the current **PHS 398 form** (Rev. 03/2020). The research plan (i.e., sections 1 – 4) should not exceed five pages. Instructions for using the PHS 398 form should be followed except as specifically noted below. This website provides downloadable forms and instructions for the new PHS 398 forms: https://grants.nih.gov/grants/funding/phs398/phs398.html Attachments, appendices, and exhibits should be used sparingly.

A.   FACE PAGE (NIH 398 fp1)

Fill in completely. The initial project period is for one year. Indirect costs will be applied at the current U.S. Health and Human Services approved rate. If the applicant is from another institution, please contact Delia Roberts for further instructions. **UC Davis institutional approval by the Office of Research is not required for internal applications.**

B.   PROJECT ABSTRACT (Description and Personnel – NIH 398 fp2)

Provide an abstract or summary of the proposal in compliance with PHS 398.

C.   BUDGET AND BUDGET JUSTIFICATION

1.   Prepare a detailed line-item budget for the contract period (not to exceed 12 months) using the NIH format in the PHS 398 instructions and the Detailed Budget for Initial Budget Period.

2.   Funds may be used for the costs of personnel, equipment, subcontracts/ consultants, and general expense.

3.   The budget should include effort and personnel costs for the principal investigator.

4.   Prepare a brief budget justification explaining the proposed costs.

5.   The initial contract period shall be for one year. Extensions may be granted upon successful completion of periodic reviews.

D.   BIOGRAPHICAL SKETCH

Include a biographical sketch of all key personnel. Please use the NIH Biographical Sketch form *(Rev. 3/2020 Approved Through 02/28/2023).*

E.   RESOURCES AND ENVIRONMENT

Provide a statement of the resources and facilities of the applicant using PHS 398 forms.

F.   RESEARCH PLAN

The proposal should contain a narrative limited to the PHS 398 format. Instructions given with this form, including the sections on 1) Specific Aims; 2) Background and Significance; 3) Preliminary Studies; and 4) Research Design and Methods should be followed. Sections 1 through 4 should not exceed 5 pages. PHS 398 instructions for the remainder of the proposal, including section on human and animal subjects, should be followed, as applicable.

G.   PHS INCLUSION ENROLLMENT REPORT

If the project proposal includes human subjects, the proposal must include the PHS Human Subjects and Clinical Trials Information form.

H.   LITERATURE
Please limit the literature cited to 2 pages.

I.   LETTERS OF SUPPORT
At a minimum, the application should include a letter of support from the investigator's Department Chair. Additional letters of support may be included and will be considered in evaluating the application.

VII.   SUBMISSION REQUIREMENTS

A.   Submit a proposal as specified in Section VI guidelines above.
B.   Submit the proposal in PDF format to Delia Roberts at daroberts@ucdavis.edu
C.   Proposals should include the names and contact information for eight reviewers who have expertise in the application's subject matter.
D.   Proposals must be received no later than 5:00 p.m. (PT), March 6, 2023.
E.   Proposals do not require institutional approval from the UC Davis Office of Research.

VIII.   REVIEW PROCESS

Applications satisfying the conditions in the RFA will be forwarded to the Review Panel, which includes members of the Alzheimer Disease Research Center Executive Committee**.** Additionally, external reviewers with expertise in the subject matter of the proposals submitted will be sent applications for external written review.

Each proposal will be evaluated using the following criteria:

1.   The purpose of this program is to stimulate research and provide new funding to new investigators in the direction of studies of Alzheimer's disease and Alzheimer's disease related dementias. Thus, factors which will be important include: (a) the likelihood that the proposal will successfully compete for further funding (b) the quality of data generated by the project which could be used for publication (c) the potential for follow-up studies to be performed if the work is accomplished successfully (d) the investigator's interest and commitment to the field of Alzheimer's disease research and (e) the ability of the investigator to achieve successful outcomes in bringing the project to fruition as documented in letters of support for the investigators by their department, mentors and peers. Thus, it is very important for the investigator to clearly state where the results of the work will lead, and what sort of subsequent work will be performed on a larger scale project to follow up on the developmental project results.

2.   The overall scientific merit of the proposal. Applications will be appraised by a panel of three or more reviewers who have technical expertise in the field of applicant's research.

3.   The goal of this program is to bring new investigators into the field of dementia research, not to support well funded existing laboratories already studying Alzheimer's disease and Alzheimer's disease related dementias. The principal investigator must meet the criteria for a new investigator. For purposes of this application, a new investigator is defined as one who has not previously received federal research support or who has not received support for research related to Alzheimer's disease and Alzheimer's disease related dementias. The budget should include effort and personnel costs for the principal investigator.

VIII.   REPORTING REQUIREMENTS

1.   Grantees will be expected to provide the UCD ADRC with a progress report, due by April 1, 2024, including a description and assessment of the work accomplished as well as subjects enrolled, if appropriate. An Inclusion Enrollment Report is also required indicating gender and ethnicity of those enrolled if applicable.

2.	Grantees are expected to participate in site visits and conferences as deemed necessary by the UCD ADRC for monitoring, evaluating or promoting the development program.

3.	Research utilizing human or animal subjects must be reviewed and approved by the relevant Institutional Review Board committees prior to the project start date. This can be done after the review is completed.