DATE: January 2, 2021

TO: PROSPECTIVE APPLICANTS

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

The University of California, Davis Alzheimer's Disease Center (UCD ADC) invites applications for development projects with support from the National Institute on Aging (NIA) Alzheimer's Disease Research Center program. It is anticipated the center will have $100,000 per year to fund 1-3 development projects for basic or clinical biomedical, translational and epidemiological caregiving, educational, or behavioral research for the period July 1, 2021 – June 30, 2026. The development project term may be 1 to 3 years in length. This funding is contingent on receipt of an NIH/NIA Notice of Award funding the center’s P30 Alzheimer's Disease Research Center application in Spring 2021. 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 Jayne La Grande at jmlagrande@ucdavis.edu or 916-734-5728.

REQUEST FOR APPLICATION

UCD ALZHEIMER'S DISEASE CENTER PILOT RESEARCH FUNDS

I. ACTION TIMETABLE

<table>
<thead>
<tr>
<th>ACTION</th>
<th>DATE</th>
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<tbody>
<tr>
<td>Due date and time for applications</td>
<td>April 5, 2021 at 5:00 p.m. (Pacific Time)</td>
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<tr>
<td>Completion date for evaluation of proposals by the Review Panel</td>
<td>June 1, 2021</td>
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<td>Notification of awards</td>
<td>To be determined</td>
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<tr>
<td>Earliest anticipated start date</td>
<td>July 1, 2021</td>
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II. BACKGROUND

The National Institute on Aging (NIA) funds 31 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 Center has been continuously funded by the NIA as an Alzheimer's Disease Core Center (ADCC) for 30 years. During this period, the Center has awarded 23 pilots to clinicians and scientists across seven UC Davis colleges and schools totaling over $927,000.
On September 15, 2020, the Center submitted an application for Funding Opportunity Announcement RFA-AG-21-019 titled P30 Alzheimer’s Disease Research Center (ADRC).

While this application is still in the review process, the center is soliciting development projects for NIA approval in anticipation of the application being funded for the first year of the project period July 1, 2021 – June 30, 2022. If the center is funded, one to three development projects will be submitted to the NIA for funding approval after receipt of the request for Just in Time.

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 into 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 7/1/2021) or junior faculty level investigators, but may be awarded to a more senior investigator whose research 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 1 to 3 years in length.

III. OBJECTIVES

The UCD ADC 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 in the area of Alzheimer's disease and Alzheimer's disease related dementias directed toward basic or clinical biomedical, translational and epidemiological caregiving, educational, or behavioral research. These awards are designed as pilot research projects, which are aimed at generating data to support future research applications. Examples of possible pilot 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 ADC provides investigators and research groups with well-characterized patients and control subjects, family information, brain tissue, biospecimens and data. Requests for brain tissue can be submitted to Lee-Way Jin, MD, PhD at hwjin@ucdavis.edu.

Requests for biospecimens and data can be obtained from the National Centralized Repository for Alzheimer’s Disease and Related Dementias (NCRAD) https://ncrad.iu.edu/accessing_data.html.
Available biospecimens include DNA (genomic or cell line), Plasma, serum, RNA, PBMCs from select subjects.

Proposals for the analysis of data can be submitted. Center data as well as program wide data is available thru the National Alzheimer’s Coordinating Center (NACC). NACC serves as a repository for data collected at approximately 31 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. Faculty member Danielle Harvey (djharvey@ucdavis.edu) is available to consult with pilot applicants.

Investigators interested in basic research may contact Lee-Way Jin at lwjin@ucdavis.edu or 916-703-0392 for assistance in evaluating the feasibility of the study protocol.

Investigators interested in clinical research may contact Martha Forloines at mrforloines@ucdavis.edu or 916-734-5223 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 January 21 and 28, February 18, March 11, 18, and 25 between 9 - 11 a.m. via video conference. Please contact Shelly Allocco at saallocco@ucdavis.edu or 916-734-6279 to schedule a presentation.

V. APPLICATION INFORMATION

A. FUNDING SCOPE AND TIME PERIOD

During Academic Year 2021-2022 the UCD ADRC intends to award $100,000 in direct costs to be distributed among one to three development projects for a 1-3 year period. This allows projects to be extended beyond one year. Indirect costs will be applied at the rate of 57%. The amount may be subject to change depending on availability of NIH funding awarded to the parent grant or if the pilot 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. Renewals of existing projects will not be considered.

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 contract period shall be for one year (July 1, 2021 through June 30, 2022). The indirect cost rate is limited to 57% of the direct costs. If the applicant is from another institution, please contact Jayne La Grande for further instructions. **UC Davis institutional approval is not required.**

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 36 months) using the NIH format in the PHS 398 instructions and the Detailed Budget for Initial Budget Period.

2. The contract term shall be from July 1, 2021 through June 30, 2022.

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

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

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

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 Jayne La Grande at jmlagrande@ucdavis.edu
C. Proposals should include the names and contact information for six reviewers who have expertise in the application’s subject matter.
D. Proposals must be received no later than 5:00 p.m. (PT), April 5, 2021.
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 the 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 administration with a progress report, due by April 1, 2022, 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.
2. Grantees are expected to participate in site visits and conferences as deemed necessary by the UCD ADC for monitoring and evaluating projects.

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.