OVERVIEW OF SELECTION PROCESS:

A. Review Committee
A review committee has been established that includes individuals from both within and outside UC, representing the breadth of stakeholders involved in the overall initiative. The committee will score the projects, providing recommendations regarding all aspects of the proposals. The final decision regarding funding will be made by UC Biomedical Research Acceleration, Integration and Development (UC BRAID), a consortium of the five UC health campuses in which data and resources are shared to improve health through ambitious research and clinical initiatives. Awardees will be announced on July 25, 2016.

B. Criteria
Selection criteria will include, but not be limited to, the following:

- Study feasibility, including the potential for significant and important results to be realized within the two years.
- Depth and breadth of data available and potentially available in Alzheimer’s across the UCs and from partnering institutions/organizations (for example, the volume and scope of phenotypic and molecular data available for the patient cohort).
- Scientific innovation and uniqueness of the approach.
- Preliminary data supporting the approach and the ability to launch a study during the first year.
- Expertise of team members.
- Resources available for the project outside project funds, including the potential for leveraging dollars (internal, extramural, or other external).
- Clinical and commercial potential of the platforms.
- Strength of connections between proposal team collaborators.
- Potential to leverage expertise of the ADCS in support of the project.
- Attention to particular challenges of privacy, participant engagement, consent, security and ethical concerns and establish appropriate standards.
- Potential downstream use of tools, measurements, and data, including open public accessibility of generated data and publications.
- Impact of a successful study on Alzheimer’s disease.

DEADLINE:
Your full application is due by 5 p.m. COB PST on Monday, June 6, 2016.

SUBMISSION INSTRUCTIONS:
Please submit your final proposal to Sylvia Plummer at alzrfa@ucsd.edu.

CONTACTS:
The CTRI scientific contact is Murray B. Stein, M.D., MPH and the CTRI administrative contact for technical information about the application process or questions related to the RFA: Sylvia Plummer at alzrfa@ucsd.edu or (858) 657-5109.
ADCS CONSULTATION AND COORDINATION:
Consultations with Alzheimer’s Disease Cooperative Study (ADCS) faculty and staff regarding design, methods, and feasibility are **required and must be documented**. A description of how the ADCS will participate in study coordination should be included.

Please complete the attached ADCS Protocol Specification Template and email it to alzrfa-adcs@ucsd.edu to set up a consultation.

FULL PROPOSAL APPLICATION INSTRUCTIONS:

Concept proposals that are accepted require a formal proposal following NIH PHS 398 format. **Please complete all applicable sections of the PHS 398 forms.** In addition, include the following in your application:

1) Cover page listing key personnel and responsibilities – 1 page
2) Abstract – 1 page – no more than 500 words
3) Specific Aims – 1-page maximum
4) Proposal – 12-pages maximum, to include the following:
   a. Background, preliminary findings, innovations and impact
   b. Experimental approach
   c. In addition, in preparing the application, please pay special attention to the following:

**Use of ADCS resources:** The faculty and staff of the ADCS will help you design the experimental approach. There is expert support available for trial design, data collection and management, informatics, biostatistical analysis, neuroimaging, biomarkers, medical safety and clinical operations. The ADCS will assist in developing a plan for defining the resources required and how they could be managed.

**Project team:** Provide a description that defines the ability of the PI(s) and their team(s), as well as key collaborators in undertaking the study. Describe the nature and strength of existing external collaborations – e.g., links to study sites.

**Impact:** Address the impact of the proposed study on improving the diagnosis and treatment of Alzheimer disease. Define gaps in knowledge that will be addressed and the how the insights derived would be used to create new possibilities for improving the lives of people with this disorder within the two-year project timeframe and beyond.

**Technical and methodological innovations:** Describe novel advances and interventions that will be studied, including protocol design, endpoints, power analysis, intellectual property, infrastructure and tools that will be built, new consortia, collaborations, personnel competencies, databases, software or computational development, patient cohorts, participant communities and networks, models for responsible data sharing, etc.
**Participant engagement**: Describe strategies to attract, enroll subjects and secure their participation throughout the study (e.g., opportunities to build trust, approaches ensuring consent, approaches to data sharing, privacy, security, etc.).

**Data management and analysis**: The plans for collecting and organizing data should be outlined and the biostatistical analysis plan detailed.

**Anticipated challenges and proposed solutions**: Describe potential barriers to the project’s success, paying particular attention to barriers that could delay the launch, progress or completion, and provide potential solutions to these challenges.

5) NIH biosketches for key personnel using the most recent format, including a personal statement describing qualifications.

6) **Budget with budget justification**:

Propose a budget of up to $1 M/year for two years. Matching funds from the host institution can supplement the budget but must be clearly specified and a letter(s) of commitment from an institutional representative(s) attached. No indirect costs will be provided.

Provide a budget justification that outlines how funds will be used. Define resources that will be leveraged (e.g., experts’ time; biomedical informaticians at each medical center to obtain and structure electronic health data; molecular characterization, including DNA, RNA and genomic sequencing; computational platforms, including genome analysis, data visualization, innovative databases, data sharing, data privacy and security, or high-performance computing; mobile platforms to reach patients between medical encounters, to track their health and outcomes, etc.)

Specify what funds will flow to the ADCS to support the trial.

Attached are the following templates, for your reference:

1. NIH Biosketch Instructions
2. NIH Biosketch Form
3. NIH Biosketch Sample
4. NIH PHS 398 Instruction Guide
5. ADCS Protocol Specification Template

For additional information, view the RFA announcement here: [http://www.ctri.ucsd.edu/news/Pages/UCLaunchesNew4AlzheimersDiseaseInitiative.aspx](http://www.ctri.ucsd.edu/news/Pages/UCLaunchesNew4AlzheimersDiseaseInitiative.aspx)

*Leveraging the strength of UC San Diego Alzheimer’s Disease Cooperative Study (ADCS), Clinical Trials Research Center (CTRI), and the trans UC Experience of the UC Biomedical Research Acceleration, Integration and Development (BRAID) consortium.*