Appendix 1. Research Strategy

This information must be complete for the BRC to consider the application.
Research strategy should be no more than 4 pages.

1. **Rationale:** Briefly describe the studies proposed and the rationale for the proposed analyses.

2. **Background:** Provide the relevant background to justify the request. Be sure to include:
   a. Importance of the project, including the significance of both the study question and of the specific project.
   b. Justification for requesting these specific samples. This section should explain how the proposed use relates to the design and outcomes of the study that produced the requested samples. The question being posed by the investigator must be appropriate to the source of the biospecimens, how they were collected, prepared, analyzed and stored; their age; and the phenotypic and other accompanying data.
   c. Relevant preliminary data demonstrating the applicant's experience with the assay or technique that will be used with the requested samples.

3. **Sample Information:** If you will be combining the results from the proposed study with those obtained from other samples, be sure to explain how the requested samples will fit in with your overall study design (e.g. from which study and stage of the study the specimens are requested, whether random samples or specific selection of those with subjects with or without specified clinical events and laboratory or imaging findings are sought, etc.). Include a clear justification for the amount of sample being requested. In all cases, applicants should only request the minimum volume needed for the study. Finally, please note that reference pools are available for plasma, serum, and CSF. NCRAD encourages the use of these when requesting those specimen types.

4. **Project Details:**
   a. *Hypothesis:* There should be at least one clear hypothesis that can be tested using the proposed methods and non-renewable samples provided by the repository, or a strong justification for carrying out discovery research.
   b. *Methodology:* Describe how the requested samples will be used, including a description of the specific procedures by which the samples will be tested and analyzed and the quality control and robustness of the assay. Is this a discovery, optimization or replication study?
   c. *Power and effect size:* Describe the power of the project and the anticipated size of a detectable effect.
   d. *Data analysis:* Provide a detailed plan for data analysis. Include a brief summary of the team's expertise and experience and evidence that they can handle the analysis proposed.
   e. *Sample management:* Explicitly address how the samples will be held, managed, and processed. For example, who will have the main responsibility for storing and testing the samples?

f. *Plans for the next phase:* Describe plans for follow-up studies and, if relevant, further biomarker or assay development. If collaborations have been established for follow-up, include these letters of collaboration.

Table 3. Template of table to be submitted by investigators listing biofluid request.

In a table, the applicant needs to outline the number, type, and amount of biospecimens/tissue requested, including subject type (e.g. AD, control, any specific clinical parameters), visit number (if applicable), biosample type (i.e. CSF, plasma, serum etc.), volume of sample required, and the cohort or study through which the biosamples are currently available. In addition, the applicant should determine if the samples required are available through the repository prior to submitting an application. For applicants requesting access to data at another data repository, they would need to outline what data is required and how the data will be used.

Name of Cohort Sample and Data Set	**Number of Samples**	**Biosample Type**	**Volume or concentration requested** *(in # of aliquots, e.g. 2x 200µl, see Table 3a)*	**Any other criteria to be considered e.g. quality control data**	**Longitudinal samples, visit types and number of samples per visit**	**Sample Availability****
GEMS-Controls (specify criteria e.g. age and gender matched, if any	100	Plasma	1x 1000 µl		Visit 1 - 50 samples Visit 2 - 50 samples	e.g. 50 samples of 1x1000 µl plasma per visit

**Investigators should consult with the catalog or repository representative to obtain this information.

Table 3a: Standard Aliquots

Study	DNA	DNA, cell line	Plasma	Serum	LCL	PBMC	CSF	RNA	RBC	iPSC	Fibroblasts
4RTNI-2	5 µg		200 µl	200 µl		1 vial	200 µl	2 µg			
90+	5 µg										
ADNI	5 µg	10 µg			1 vial	1 vial		2 µg	1000 µl		
AA Genetics		10 µg									
ABC-DS	5 µg		250 µl	250 µl				1µg			
ADCs	5 µg		200 µl	200 µl		1 vial		2 µg			
ANGI	5 µg										
ARTFL	5 µg		200 µl	200 µl		1 vial	200 µl	2 µg			
DIAN		5 µg									
GEMS	5 µg		200 µl	200 µl							
GIFT		10 µg			1 vial						
Indianapolis Ibadan	1-5 µg	10 µg			1 vial						
iPSC Initiative										1 vial	1 vial
LEFFTDS	5 µg		200 µl	200 µl		1 vial	200 µl	2 µg			
NCRAD Family Study	5 µg	10 µg			1 vial						
NIA-LOAD Study	5 µg	10 µg			1 vial	1 vial					