



APPLYING FOR ADNI BIOFLUIDS

CSF, plasma, and serum were collected at ADNI baseline and follow-up visits. The schedule of visits and sample collection differed between subject groups, as well as changing somewhat in the transitions between ADNI-1, ADNI-GO, ADNI-2, and ADNI-3. See (LINK NEEDED) for the exact schedule of events. Urine was collected in ADNI-1, but not thereafter. All biofluids are curated by the Biomarker Core, and stored at -70o C at the University of Pennsylvania. Details of lumbar puncture and venipuncture methodology, as well as collection of CSF and blood are available.

APPLICATION FORM INSTRUCTIONS

Applications can be submitted electronically to NIA, and are reviewed on a continuing basis. Please provide all information requested in the form, including an estimate of when study data should be available on the ADNI database.

- Abstract limited to 1 page
- Research Strategy limited to 5 pages: The research strategy should be no more than 5 pages (excluding figures, tables, and references) and should be in the style of an NIH grant application with sections addressing Specific Aims, Significance, Innovation, Approach, and Preliminary Data. Detailed methods and preliminary data may refer to material in the Appendices, but a summary should be included in Research Strategy
- Data & Power Analysis Plans limited to 1 page
- Justification for the number of subject-timepoints requested is required. A data analysis plan including power analysis must be included
- Appendices limited to 4 files: No more than 4 files can be uploaded, and all files must be in a standard digital format (e.g., Adobe PDF, Microsoft Office or Google Docs). These can include presentations (including posters), published articles, manuscripts in review or accepted for publication, or grant research plans. Extraneous and non-germane information, not necessary for RARC review, should be removed. Confidential information or data should not be included.
- Sample Selection Form: An inventory of CSF aliquots by subject-time point is included in the Sample Selection Form. Applicants must choose the specific subject-timepoints desired.

REVIEW PROCESS

Investigators will receive an email confirming receipt of their electronic application. Applications will be reviewed by ADNI's Biofluid RARC, which will provide its recommendation to the NIA. The RARC reviews applications based on several criteria:

- Scientific quality and potential impact on our understanding of AD and related dementias; and

potential for advancing treatment development and clinical trials

- Duplication of existing studies and data already available from ADNI; including Biomarker Core and RARC approved studies, in progress
- Evidence that the investigator(s) and environment can carry out the proposed work
- Impact on ADNI inventory of biofluids, especially CSF. Access to ADNI 1 baseline CSF is limited to high priority research.

The RARC may recommend changes and ask for revisions in the research plan. The Committee may recommend conditional access: demonstration of feasibility in a subset of samples before granting access to a larger set.

NIA Review/Approval

The NIA will notify investigators about its decision on sample access. The RARC and NIA work as quickly as possible, and aim to provide a response within 8-10 weeks. However, no specific timeline for review or decision is possible. NIA may provide reviewer comments to the investigator, but will not provide a summary statement. Resubmissions will not be considered unless invited by the RARC or approved by NIA. There is no appeal process.

Sample and Data Transfer

NIA will notify the Biomarker Core when a biofluid RARC application is approved. The Biomarker Core will work with approved investigators to finalize details about sample transfer, but will not transfer samples until investigators are ready to begin work, and have provided a target date for uploading their results. When samples are transferred, the application abstract and target date for results will be added as 'work in progress' on the ADNI RARC page. Samples sent to investigators will be identified by code numbers that cannot be linked to ADNI clinical data. Once analyses and QC are completed, investigators will provide their results with any associated data dictionary or method files to ADNI. These data and files will be added to the ADNI database with the correct subject ID codes to permit correlation of results to other ADNI data. Investigators will use the ADNI database to access their (now) unblinded data.

Residual Samples and Additional Studies

The investigator should notify NIA if there are residual samples left after completion of the RARC approved study. Investigators should ask for NIA approval (and RARC concurrence) before using residual samples in a new study. Investigators should not dispose of unused ADNI biofluid. Investigators may return residual samples to the Biomarker Core, where they will be pooled and used for assay standardization.

There is no charge for RARC or NIA review or for sample preparation, processing, and transfer by the Biomarker Core. No Material Transfer Agreement (MTA) is required.

Questions about ADNI biofluids and the RARC application and review process can be directed to xxxxx@nih.gov