



APPLYING FOR ADNI BIOSPECIMENS

INITIAL REQUEST STATEMENTS

Interested parties must submit an initial request summary statement to cat.conti@ncire.org. Initial requests must include the following:

- Subject line format: “Initial ADNI Biospecimen Request: [Investigator name] – [Study topic/name]”
- Abstract (up to one page) including:
 - One sentence description of the desired study
 - One sentence explanation of the importance
 - Description of biospecimens and subjects requested
 - 1-2 references

Approved requestors will be invited to submit an ADNI Biospecimens Full Application. See below for details.

ADNI BIOSPECIMENS FULL APPLICATION INSTRUCTIONS

To make the most of the rich and complex ADNI data and biosamples available, please review the following documents before submitting a full application.

- [Complexity of the ADNI biobank and RARCs](#)
- [Access to ADNI samples policies and procedures](#)
- [ADNI biosample RARCs policies](#)

Please provide all information requested in the ADNI Biospecimens Full Application found here: [ADNI Full Application](#)

REVIEW PROCESS

Investigators will receive an email confirming receipt of their electronic application. Applications will be reviewed by the appropriate ADNI Resource Allocation Review Committee(s) or RARCs (for genetic materials, this is called the Biospecimen Review Committee/BRC), which will provide its recommendation to the National Institute on Aging (NIA). The RARC reviews applications based on several criteria:

- Significance for advancing clinically useful biomarkers of AD and potential impact on our understanding of AD and related dementias.
- Scientific quality of the proposal, including longitudinal design to fully exploit the value of biospecimens collected, and availability of preliminary data demonstrating feasibility. 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.
- Commitment to data sharing as specified by ADNI (see http://adni.loni.usc.edu/wp-content/uploads/how_to_apply/ADNI_DSP_Policy.pdf).
- Evidence that the investigator(s) and environment can carry out the proposed work and high quality, timely analyses.
- Impact on ADNI inventory of biofluids, especially CSF. Access to ADNI 1 baseline CSF is limited to high priority research.

The RARC or BRC 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.

The RARC will use the calendar below for their review cycles. Applications will be reviewed by at least 2 members of the RARC and discussed in conference. Ad hoc reviewers will be added to the review panel as necessary. They will submit guidance to the NIA, which has the final decision on application approvals/denials. Within 2-3 weeks of the review, the NIA will notify the applicant of the review decision.

Date Submitted	Approximate Date of Review
July 1-August 31	October 1
September 1-October 31	December 1
November 1-December 31	February 1
January 1-February 28	April 1
March 1-April 30	June 1
May 1-June 30	August 1

NIA REVIEW/APPROVAL

The NIA will notify investigators about its decision on sample access. 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/Genetics/Neuropath Core when a RARC application is approved. The 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. Please see [ADNI Biosample Policies](#) for our process of blinded sample distribution and unblinding for analyses.

For plasma, serum, and CSF requests: There is no charge to the investigator for RARC or NIA review or for sample preparation, processing, and transfer by the Biomarker Core. No Material Transfer Agreement (MTA) is required.

For requests for genetic materials: These samples are housed by the National Centralized Repository for Alzheimer's Disease and Related Dementias (NCRAD). There is no charge to the investigator but NCRAD requires an MTA be signed.

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.

Questions about ADNI biofluids and the RARC application and review process can be directed to cat.conti@ncire.org