



ACCESS TO ADNI SAMPLES POLICY AND PROCEDURES – RARC

Alzheimer's Disease Neuroimaging Initiative (ADNI) Resource Allocation Review Committee (RARC) Policy and Procedures Statement (updated October 2020). The Policy and Procedures of RARC are subject to change as ADNI progresses and further experience is gained.

One of the goals of ADNI is the collection of biospecimens, including blood, urine, and cerebrospinal fluid (CSF) from participants. An accounting of the biospecimens available through ADNI can be found in the ADNI database. Several analyses of general interest (homocysteine, species of isoprostanes, tau and A β) have been performed by the ADNI Biomarkers Core, with results made available on the ADNI web site as soon as the laboratory analyses are complete.

Interested investigators, whether associated with an ADNI site or not, are encouraged to apply for use of this limited resource in add-on studies. 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. See RARC BACKGROUND for details.), which will provide its recommendation to the National Institute on Aging (NIA). However, use of ADNI samples for technology development or comparisons among different technologies is not recommended for well established analytes unless there is preliminary data showing clearly superior performance.

Please see [ADNI Biosample Policies](#) for our process of blinded sample distribution and unblinding for analyses.

A. The responsibilities of the RARC and BRC are the following:

1. Review applications for add-on studies (rather than studies performed by ADNI's Biomarkers Core) that propose to use ADNI biospecimens using the following criteria:
 - a. Significance for advancing clinically useful biomarkers of AD and potential impact on our understanding of AD and related dementias.
 - b. 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.
 - c. The proposal does not duplicate studies already being done by the ADNI Biomarkers Core or RARC approved studies, in progress.
 - d. The investigator(s) and environment can support the proposed work and high quality and timely analyses.
 - e. Impact on ADNI inventory of biofluids, especially CSF. Access to ADNI 1 baseline CSF is limited to high priority research.
2. Make recommendations to the National Institute on Aging (NIA) with regard to sample allocation.

These recommendations are as follows:

- a. Approval of the application. After a positive RARC/BRC recommendation, NIA will make the final decision in directing the Biomarkers or Genetics Core to release specimens to the investigator, once funding for the project is demonstrated. However, even after a positive RARC/BRC recommendation, the NIA may choose to withhold the release of biospecimens for programmatic considerations.
- b. Hold application for future re-evaluation. This intermediate category reflects applications thought to be meritorious but of unclear significance with respect to expected future applications for these limited resources. Applications in this category will be re-evaluated in each session and possibly moved to category a or c.
- c. Disapproval of the application.

B. Procedure for applying for access to biospecimens:

1. Interested parties must submit an initial request summary statement. Approved requestors will be invited to submit an ADNI Biospecimens Full Application.
2. Once approved, see instructions for [Full Applications](#)
3. Applications will be reviewed by at least 2 members of the RARC/BRC 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.
4. The NIA will communicate with the applicant as to the RARC/BRC and NIA recommendations.
5. Applications approved for biospecimen allocation by the NIA will be posted on the ADNI website.

C. Conflict of interest policy:

The RARC/BRC will follow the COI policy as described by the NIH (see: <https://ethics.od.nih.gov/topics/coi.htm>). Reviewers must declare any COI with any application and recuse themselves from any review, discussion, or decision about that application.