



Access to ADNI Samples Policy and Procedures - RARC

Alzheimer's Disease Neuroimaging Initiative (ADNI) Resource Allocation Review Committee (RARC) Policy and Procedures Statement (updated August 2012)
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 will be maintained on the ADNI website. Several analyses of general interest (homocysteine, species of isoprostanes, tau and A β) will be 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. 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 note it is ADNI policy that if your application to obtain ADNI samples is approved by the RARC, ADNI will send you these samples with a code number which does not permit you to link the samples to ADNI data. Once you have finished your analyses, and performed QC, it also is ADNI policy that you send the results to Michael Donohue at ADCS and he will upload the results to the ADNI database. Once these data are in the ADNI database you (and others) will be able to analyze the data and relate the results to diagnosis and other features.

A. The responsibilities of the RARC are the following:

1. REVIEW applications for add-on studies that propose to use ADNI biospecimens using the following criteria
 - a. Significance for advancing clinically useful biomarkers of AD.
 - b. Scientific quality of the proposal, including longitudinal design to fully exploit the value of biospecimens collected, and availability of preliminary data demonstrating feasibility.
 - c. The proposal does not duplicate studies already being done by the ADNI Biomarkers Core or studies approved and posted on the ADNI website.
 - d. Commitment to data sharing as specified by ADNI (see website).
 - e. The investigator(s) and environment can support high quality and timely analyses.
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 recommendation, NIA will make the final decision in directing the Biomarkers Core to release specimens to the investigator, once funding for the project is demonstrated. However, even after a positive RARC 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. Applications will follow the format of the NIH R01. Manuscripts accepted for publication, published manuscripts, unpublished relevant materials, and submitted grants will be considered as appendix material.
2. Applications will be uploaded to the ADNI website.
3. 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.
4. Decisions and comments will be communicated to the NIA and ADNI quarterly. The NIA will communicate with the applicant as to the RARC 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 will follow the COI policy as described by the NIH (Review). Reviewers must declare any COI with any application and recuse themselves from any review, discussion, or decision about that application.

