

RESOURCE ALLOCATION REVIEW COMMITTEE (RARC) POLICY AND PROCEDURES

Alzheimer's Disease Neuroimaging Initiative (ADNI) Resource Allocation Review Committee (RARC) Policy and Procedures Statement (updated July 2024). 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, cerebrospinal fluid (CSF), genetics (DNA, RNA, etc.), and postmortem brain tissue from participants. Interested investigators 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 which will provide its recommendation to the National Institute on Aging (NIA). Please see <u>ADNI Biosample Policies</u> for appropriate use of samples and conditions of use.

| RARCs | Samples | Sample Locations | Core Leaders |
|--------------------------------------|--|------------------------------------|-------------------------------------|
| Biofluid RARC | Plasma, serum, CSF, and urine | University of Pennsylvania | Drs. Leslie Shaw and Edward Lee |
| Genetic RARC / NCRAD BRC | Genetic material (Genomic DNA, Cell Line DNA, Lymphoblastoid Cell Lines, PBMC, RNA, RBC) | NCRAD at Indiana University | Drs. Andrew Saykin and Kwangsik Nho |
| Neuropathology RARC (NPC RARC) | Postmortem tissue (frozen, 'wet' formalin-fixed, or formalin-fixed paraffin-embedded [FFPE]) | Washington University in St. Louis | Dr. Richard Perrin |

A. The responsibilities of the RARCs are the following:

- 1. Review applications for add-on studies (rather than studies performed by ADNI's Cores) 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.
 - The proposal does not duplicate studies already being done by the ADNI
 Biomarker/Genetics/Neuropathology Cores 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, plasma, PBMCs, and postmortem brain tissue. Access to ADNI1 genomic DNA and baseline CSF is limited to high priority research. PBMCs are a highly limited resource banked for iPSC development. iPSCs will be available and are a renewable resource. Blood plasma is of increasing interest and sample requests are being closely monitored; samples collected at baseline visits are limited to high priority research. Brain tissue samples from brain areas that are relatively small and/or commonly requested are limited and require a strong justification for why those areas are requested.
- 2. Make recommendations to the National Institute on Aging (NIA) about 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 Biofluids, Genetics, and/or Neuropathology Core(s) 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: See Apply For Access to Samples
- C. Conflict of interest policy:

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