ADNI BIOSAMPLE POLICIES

One of the goals of ADNI is the collection of biospecimens, including blood, urine, and cerebrospinal fluid (CSF) from participants. Interested investigators, whether associated with an ADNI site or not, are encouraged to apply for use of this limited resource. Applications are managed by the RARC, which is overseen by NIA and the ADNI Executive Committee.

NIA and the ADNI Executive Committee have formulated certain policies governing access to ADNI biosamples:

PURPOSE: ADNI biosamples are not usually provided for exploratory studies or methods development. Preliminary data, establishing the validity and reliability of all proposed methods, must be provided in RARC reviewed applications. Since ADNI works in a non-commercial, pre-competitive space, development of commercial products cannot be a priority. NIA will request input from the PPSB, as well as the RARCs, in those (rare) instances when NIH policy or public health impact support using ADNI biosamples in development of commercial products (for instance, an FDA or CLIA approved diagnostic).

APPROVAL FOR BIOSAMPLE REQUESTS: Interested parties must submit an initial request summary statement to catherine.conti@ucsf.edu, and approved requestors will be invited to submit a full application. For full instructions, see How to Apply. There are 3 RARCs advising NIA on applications for biofluids (CSF and plasma), genetics material (NCRAD's BRC), and postmortem tissue. RARC review is required for all access to ADNI biosamples, except for studies that are part of the ADNI cooperative agreement, itself. Any qualified scientist – whether domestic or foreign, in government, academia, or industry - may apply for biosamples collected by ADNI. No special preference is given to applications by ADNI investigators, or from sponsors of the Public Private Scientific Board (PPSB) that co-funds ADNI.

FUNDING & GRANT APPLICATIONS: Neither ADNI nor the RARC provide funding to applicants. Investigators should have funding and all necessary resources in hand before applying. Investigators needing proof of access to ADNI biosamples to prepare grant applications, should contact and ask for a letter of support from either ADNI's Principal Investigator (Dr. Michael Weiner, Michael.Weiner@ucsf.edu), or the Project Leader(s) of the relevant ADNI Core: Biomarkers, Drs John Trojanowski, trojanow@upenn.edu and Leslie Shaw, Leslie.Shaw2@uphs.upenn.edu; Genetics, Dr. Andrew Saykin, asaykin@iupui.edu; or Neuropathology, Drs John Morris, jcmorris@wustl.edu and Rick Perrin, rperrin@wustl.edu. In your request, please provide the grant title and submission date. A letter of support does not substitute for RARC/BRC review, and should explain that access to ADNI biosamples is controlled by NIA, advised by an RARC/BRC.

DATA SHARING: All data from studies using ADNI biosamples must be shared and included in the ADNI

database. Instructions for accessing the ADNI database can be found here (http://adni.loni.usc.edu/data-samples/access-data/). A list of previously completed, and currently active RARC-approved studies can be found here (http://adni.loni.usc.edu/methods/). Data from completed studies can be downloaded from the ADNI database.

BLINDING & INTELLECTUAL PROPERTY: All analyses on ADNI biosamples must be carried out blind to clinical data. Samples sent to investigators will be identified by code numbers not linked to ADNI clinical data. The relevant ADNI Core will work with investigators to ensure methodological reliability and rigor (e.g., technical replicates, sample assay sequence, plating, etc.). Once analyses and QC are completed, investigators will send their completed data submission form, methods, results (.csv data file), and data dictionary to be uploaded to the ADNI database. ADNI will then add associated subject ID codes to the data file which will permit correlation of results to ADNI clinical data. Investigators will use the ADNI database to access their (now) unblinded data. ADNI does not allow an embargo period, and as with all ADNI data, all users will have access to results as soon as data are uploaded.

NIA and the RARC/BRCs will not disseminate or release investigator applications for access to ADNI biosamples, but non-disclosure and confidentiality agreements cannot be honored by ADNI, the RARCs, BRC or NIA.

MTA FOR SENDING SAMPLES: Genetic materials are managed by NCRAD and subject to additional policies including signing of a Master Agreement for Transfer of Materials to NCRAD (MTA).
See https://ncrad.org/mta_in.html

CONFLICT OF INTEREST POLICY: The RARC and BRC will follow the COI policy as described by the NIH (review here: 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. Access to ADNI Samples Policy and Procedures - RARC