



**Alzheimer's Disease Genetics Sharing Plan
Request for Transfer of Samples to the
National Cell Repository for Alzheimer's Disease (NCRAD)**

1. Overview

The National Institutes of Health (NIH) advocates making available to the public the results and accomplishments of the activities that it funds. NIH assures that research resources developed with public funds become readily available to the broader research community in a timely manner for further research, development, application, and secondary data analysis in the expectation that this will lead to products and knowledge of benefit to the public health. Resources expected to be shared include data and biological materials collected and pertinent methods of analysis.

NIA has in place a Genetics Initiative to assist in the identification of the risk factor genes for Alzheimer's disease. To this end, NIA supports the National Cell Repository for Alzheimer's Disease (NCRAD) at Indiana University as a national repository in order to facilitate access by qualified investigators to samples and Associated Phenotypic Data for the study of the genetics of late-onset Alzheimer's disease. Therefore it is the policy of the NIA that useful specimens and Associated Phenotypic Data for the genetics of late-onset Alzheimer's disease be deposited at NCRAD whenever possible. Qualified investigators will be able to use biological samples and Associated Phenotypic Data supplied by NCRAD. Application for use will be made directly to NCRAD.

Associated Phenotypic Data is defined as deidentified data on family structure, age, sex, vital status, psychopathology, diagnosis, and other clinically relevant associated phenotypic information, stripped of all personal identifiers and thus unlinkable to the individuals from whom they were obtained.

The NIA and NCRAD have created the NCRAD Executive Committee whose purpose is to review the properties of potential samples that could be acquired and distributed by NCRAD. The goal of this committee is to provide NCRAD and NIA with recommendations that will allow those samples that are most likely to be requested by researchers to be included in NCRAD.

2. Request to NCRAD for Sample Storage and Distribution.

In order to effectively review the samples that might be available for inclusion in NCRAD, it is required that a uniform set of material be provided by each researcher to NCRAD. This information must be provided electronically. The information provided by the researcher will be reviewed by the NCRAD Executive Committee which will then provide guidance to NCRAD and NIA regarding sample acquisition.

Please provide the following information in your application.

1) Grant Information

- Grant/Contract Number, Grant/Contract Title, Award dates, and Principal Investigator

2) Description of the sampling strategy/ascertainment of samples

- Please indicate whether samples have already been collected or have yet to be collected.



3) Phenotypic data collection

- Provide information regarding whether data collection is cross sectional or longitudinal
- Provide information regarding whether these data are already collected and available or are to be collected
- Provide method of diagnosis (i.e. DSM-IV, NINDCS-ADRDA criteria, other)
- Provide information regarding availability of autopsy information or autopsy planning in the samples and whether this information would be made available to other researchers
- Provide information regarding the storage of data and how it will be made available to the public. (i.e. will it be maintained at NACC, at your center etc.)

4) Race/Ethnic distribution of samples

- Provide this information using NIH definitions of race and ethnicity whenever possible

5) Numbers of samples that could be shared with NCRAD

- Specify the number of samples of various types that would be made available (i.e. demented, normal controls, MCI, etc)

6) Copy of Informed Consent to assess data sharing and type of sharing

- If more than one consent was employed during the course of the study, please provide all relevant consents
- Provide a statement regarding the type of sharing that was included in the consent (i.e. commercial, academic, AD only, broad use)
- Provide a statement indicating whether or not you have Institutional Certification for the Genomic Data Sharing Policy in place yet? (if not, NCRAD can work with you to implement)

7) Type of biological material obtained and to be transferred to NCRAD

- Provide types of available biological material that is proposed for transfer to NCRAD (i.e. DNA, cell lines, types of blood tubes)
- Provide information regarding quantity of material to be transferred (i.e. micrograms of DNA, number of blood tubes)

8) Protocol for collecting and processing of biological material

- Provide the protocol whereby the sample was collected and the protocol whereby the sample was processed
- In particular, provide details regarding all potential source of DNA (i.e. blood, buccal swab, brain)
- Provide information regarding any whole genome amplification (WGA) that might have been performed

9) Timeline for transfer of samples

- Provide information regarding when samples could be transferred to NCRAD and over what period of time the transfer will cover (i.e. samples will be sent over 3 years etc.).

10) Distribution of samples



- Specify when NCRAD can make samples available to public (should be included in NIA sharing plan)
- Specify who will review requests for samples (i.e. NCRAD's Executive Committee or your own committee)

3. Review Criteria

The goal of the NCRAD Executive Committee to help NCRAD and NIA identify those samples that are most likely to be requested by researchers and therefore would be most easily distributed through a central repository like NCRAD. Applications will be reviewed by the NCRAD Executive Committee on a quarterly basis. Applicants will be informed by NCRAD staff of the recommendations made by the NCRAD Executive Committee.

4. Transfer of Biological Samples and Associated Phenotypic Data

Once a study is approved by the NCRAD Executive Committee, NCRAD staff will work with the Principal Investigator to develop a sample and data transfer plan. Sharing of biological samples, Associated Phenotypic Data, and resources through NCRAD should be accomplished through the NIH approved Material Transfer Agreement (MTA) for transferring biological samples to NCRAD. The NIH approved template MTA is available from the NCRAD website.

5. Distribution of samples

Investigators who deposit samples in NCRAD will not be informed who has received their sample nor will they receive any information specifically about the results obtained using the samples that they provided. Data obtained from their samples will be deposited at the National Institute on Aging Genetics of Alzheimer's Disease Data Storage Site (NIAGADS) (www.niaqads.org) at the University of Pennsylvania or at the database of genotypes and phenotypes maintained by the NIH: dbGaP (<http://www.ncbi.nlm.nih.gov/gap>). These are national genetics data repositories established to facilitate access by qualified investigators to genotypic data for the study of the genetics.

If you have any questions regarding these procedures, please contact the NCRAD Staff at alzstudy@iu.edu or by calling 1-800-526-2839.