

April 24, 2007

**National Institute on Aging  
Checklist  
Consent Form for Use of Biological Materials for Research**

This checklist is designed to aid the investigator who is preparing either a new or an amended IRB consent form for use in association with the "National Cell Repository for Alzheimer's Disease" (NCRAD <http://ncrad.iu.edu/>) at Indiana University. It is assumed that the P.I. will have included in the original consent form, or will write into the addendum, statements concerning the storage and sharing of biological materials (these may include serum, plasma, urine) at the P.I.'s institution. For collection of samples and data for the NCRAD, the consent form should include statements addressing the following points:

- The subject agrees to share a blood sample and clinical data (with code numbers only) with investigators doing research in similar fields at other research centers.
- An explanation of the "National Cell Repository for Alzheimer's Disease (NCRAD)" at Indiana University.
- A statement that researchers are working to find genes that may play a role in the occurrence of late onset AD and related disorders in extended families or in the general population. The samples could also be used for secondary study goals such as finding genes playing a role in aging.
- Explanation that an extra blood sample (coded) will be drawn. A portion of the subject's sample will be sent to NCRAD.
- The blood sample sent to NCRAD will be made into a cell line (a family of cells grown in the laboratory) that will enable the subject's DNA to be available indefinitely for use by qualified scientists at other research centers.
- If the only appropriate tissue available to do these studies is from an autopsy, then a small amount of frozen tissue (3-5 grams) will be shipped to the cell bank for preparation of DNA.
- All biological samples at NCRAD will be stored indefinitely or processed at NCRAD for use by qualified scientists at other Alzheimer's Disease Centers and other research centers.
- If a subject withdraws from the study, then the subject can request that any unused sample be destroyed.
- Samples will not be identifiable by other researchers. Samples will be de-identified (not anonymized); samples. Other researchers will NOT receive the subject's name or other identifying information.
- Some of the subject's coded data (such as demographics, family history of dementia, and diagnosis) will be sent to NCRAD. The subject's identity in these data will not be identifiable by researchers. All of this information will be used by researchers to determine whether certain differences in a gene (or genes) within the population correlate with clinical symptoms and/ or brain changes at autopsy.
- Coded data linked to the blood sample will be kept on a secure computer at the data coordinating center at NCRAD that can be accessed only by authorized investigators.
- Data will be stored on a secure password protected website,
- Summary de-identified (coded) data will be made available to researchers via a web site that will be maintained by NCRAD.
- There is no cost of the study to the subject.
- Explanation of possible follow-up interview / testing

- Possibility that research done with biological materials may be used to develop new products; sharing with companies
- Risks: There are no additional risks to the subject from participating in this study
- Benefits: there are no additional benefits to the subject from participating in this study.

NIA has established the National Institute on Aging Genetics of Alzheimer's Disease Data Storage Site (NIAGADS; <http://www.niageneticsdata.org/>) for the collection of genetic data for NIA-funded studies. The "Policies And Guidance For Sharing Of Resources And Data From Studies On The Genetics Of Alzheimer's Disease" states that NIAGADS along with other NIA approved sites will make these genetic data and associated phenotypic data available to qualified investigators in the scientific community for secondary analysis in accordance with standards established by NIA. The consent form should include statements addressing the following points:

- Language that defines NIAGADS,
- Deidentified genetics data will be stored at NIAGADS or another NIA approved site or both.
- Data are stored on a secure password protected website,
- Data are stored without identifiers,
- Only qualified investigators will have access to these data.
- Genome Wide Association Study (GWAS) language: "NIA may distribute, through NIAGADS, any and all Genetic Analysis Data and Associated Phenotypic Data to others and to use it for its own purposes. NIAGADS may also make available upon request from NIA, genetic data to be deposited at an NIH database which will continue to ensure the privacy and confidentiality of the individuals that participated in the original genetic association studies."