

## **National Cell Repository for Alzheimer's Disease Consent Help Form**

This section 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) at Indiana University and the Genetics Initiative. Three model consent forms are available from Jennifer Williamson Catania ([jlw61@columbia.edu](mailto:jlw61@columbia.edu)); one is an example of how to add the Genetics Initiative to an already existing protocol as an addendum; the second is an example of how to add the Genetics Initiative to an already existing protocol by incorporating it into the consent form; the third is an example of a consent form developed specifically for the Genetics Initiative.

Your consent form should be reviewed in the following manner detailed below. While this process may seem cumbersome in the beginning, after the first year we anticipate this mechanism will become routine.

1. It must be reviewed by Dr. Tatiana Foroud at the National Cell Repository for Alzheimer's Disease (NCRAD) at Indiana University, Dr. Richard Mayeux at Columbia University, and the Study Coordinator, Jennifer Williamson Catania. Please contact Jennifer Williamson Catania at [jlw61@columbia.edu](mailto:jlw61@columbia.edu) in order to initiate this process several weeks in advance of your IRB submission.
2. The first time an informed consent form for samples to be placed at NCRAD is submitted, it will be sent to NIA Program Staff after review by NCRAD and Columbia. In subsequent years this process will become routine and NIA need not see this version of the consent form.
3. Make any modifications requested by the reviewers. After NCRAD, Columbia and the NIA have approved the consent form, send the modified version to your local IRB.
4. Send the IRB approved consent form by email attachment to Jennifer at [jlw61@columbia.edu](mailto:jlw61@columbia.edu). She will forward on to NCRAD and the NIA. Columbia, NCRAD and the NIA must have an electronic version of the final approved consent form on file.
5. Send a hard copy of the IRB stamped consent form to NCRAD at the following address:  
Kelley Faber  
National Cell Repository for AD  
Department of Medical and Molecular Genetics  
975 Walnut St., IB-130  
Indianapolis, IN 46202
6. If and when you make any changes to the consent form and at each continuing review, please follow steps 4 and 5 above

Although not required at this time, we suggest that you obtain a Certificate of Confidentiality, see <http://grants1.nih.gov/grants/policy/coc/index.htm> for more information. A blanket Certificate does not exist for the Genetics Initiative; each Center is responsible for obtaining their own Certificate of Confidentiality. Please contact Jennifer at [jlw61@columbia.edu](mailto:jlw61@columbia.edu) if you have any questions.

To promote the NIA's sharing policy, we ask that each Center include a statement in the consent form that gives a subject the option of sharing his/her sample and data to other investigators studying the genetics of human disease. Sample language is included in the bulleted list below. For more information about the sharing policy, please go to the following links:

<http://www.nia.nih.gov/funding/policies/geneticpolicy.htm>

<http://www.nia.nih.gov/funding/policies/geneticguidance.doc>

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. **However, for collection of samples and data for the NCRAD, the consent form should include statements addressing the following points:**

- An explanation of the National Cell Repository for Alzheimer's Disease (NCRAD) at Indiana University. Suggested language is: "The National Cell Repository for Alzheimer's Disease (NCRAD) is a research facility at Indiana University that is supported by the National Institute on Aging (NIA) to facilitate genetic research on Alzheimer's disease and related disorders. NCRAD is a national resource that prepares and stores cell lines, DNA (genetic material), and clinical data and makes them available to researchers who would otherwise have no access to them. These researchers will study the DNA to determine whether certain differences in a gene or genes are involved in the clinical symptoms of Alzheimer's disease and related neurological disorders or changes in the brain seen at autopsy."
- A statement that researchers are working to find genes that may play a role in the occurrence of late onset AD, aging, and related neurological disorders in families or in the general population.
- A blood sample will be drawn and sent to NCRAD. The subject agrees to share a blood sample along with clinical information with investigators doing research in similar fields at other research centers. The blood sample and clinical information will be labeled with a code number.
- The blood sample sent to NCRAD will be made into a cell line (a family of cells grown in the laboratory that provides an unlimited amount of DNA) that will enable the subject's DNA to be available for use by qualified scientists at other research centers. All biological samples at NCRAD will be stored indefinitely, unless you request removal or the sample has been depleted. More specifically, cell lines will be stored indefinitely so that there will be an unlimited amount of DNA available from these cells. DNA and cell lines will be processed at NCRAD for use by qualified scientists at Alzheimer's Disease Centers and other research centers including commercial laboratories. If cell lines are currently available, they may be sent rather than a blood sample.
- 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.
- If a subject withdraws from the study, then the subject can request that any unused sample(s) be destroyed immediately upon request. However, it may not be possible to retrieve samples which have already been distributed to other investigators. Suggested language is: "You may decide to withdraw consent from the study at any time. In this

event, the Principal Investigator will destroy any unused samples at the collection site and they will notify NCRAD that consent has been withdrawn and that the sample(s) are to be destroyed. NCRAD will then notify all recipients of your research material and associated clinical data and request that the recipients destroy the samples. However, if samples have already been analyzed prior to the request for withdrawal, the analyzed data can still be used in reporting genetic data."

- Some of the subject's coded data (such as demographics, family history of dementia, and diagnostic and medical information) 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.
- Samples and data will be de-identified but not anonymized. The samples and diagnostic and demographic information for each participant will be identified by a unique code. Only the study staff at (*your ADC*) will know the link between the code and any identifying information. NCRAD and researchers that receive the samples will NOT receive the subject's name, date of birth, social security number or other identifying information.
- Coded clinical and demographic information 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.
- Summary de-identified (coded) data will be made available to researchers via a secure web site that will be maintained by NCRAD.
- De-identified (coded) data from genetic analysis will be kept separate from the clinical and demographic data on a secure computer that can be accessed only by authorized investigators. The de-identified genetic data may be stored at a secure website through an NIA supported data repository separate from NCRAD and may be shared for secondary analysis by other investigators.
- There is no cost of the study to the subject.
- Explanation of possible follow-up interview / testing. For example, the subject may be contacted annually to update medical information. There is a small possibility that we may need to obtain an additional blood sample in the future if NCRAD was not able to properly process the blood sample.
- Possibility that research done with biological materials may be used to develop new products and that samples and data will be shared with companies. Subjects will receive no financial compensation for the development of new products that result from the use of their biological sample (blood, cell lines, autopsy tissue), clinical and demographic data, and/or genetic data.
- The option for the subject to consent for their sample and data to be used in other studies of the genetics of human disease to promote the NIA's sharing policy. See below.
- Risks: Risks from blood draw, small risk that the individual may be identified (can discuss the steps taken to ensure privacy and confidentiality) There are no additional risks to the subject from participating in this study.
- Benefits: there are no additional benefits, including financial, to the subject from participating in this study.
- Alternatives to participate: The only alternative to participation is not to participate. This is a genetic research study and no treatments will be given.

- It is suggested but not required to include a statement on proxy informed consent.

It is recommended that the consent form be layered, or structured in a way that allows the subject several options for the use of his/her samples. This can be accomplished by an Options Section using check boxes. The following items should be options:

- The option for the subject to consent for their de-identified sample and data to be shared with other investigators doing other studies of the genetics of human disease.
- The option for the subject to consent for their de-identified sample and data to be shared with commercial entities.