

2007 Sample Consent form for Alzheimer's Disease Genetics Researchs

IRB approval date_____

Approval expiration date_____

XXXXXX Medical Center

Consent to Participate in A Research Study (Proband)

The purpose of this consent is to provide you with the information you need to consider deciding whether to participate in this research study.

Study title:

IRB study number:

Contact information:

Study Purpose

You are invited to participate in a research study of risk factors, which might be associated with the development of diseases of the nervous system associated with late-onset Alzheimer's disease (AD) (late onset is defined as symptoms of AD beginning at age 60 or older), aging and other related disorders. Dr. **XXXX** and associates hope to learn about factors that might increase the risk of developing late-onset Alzheimer's disease or other related disorders and study genes that are associated with late-onset Alzheimer's disease, aging and other related disorders in extended families or in the general population.

In addition, you are being asked to take part in the National Cell Repository for Alzheimer's Disease (NCRAD), a research facility at Indiana University that is supported by the National Institute on Aging (**or another NIA approved repository**) to facilitate genetic research on Alzheimer disease, aging, and related disorders. The NCRAD is a national resource that prepares and stores DNA samples and cell lines and makes them available to scientists who would otherwise have no access to this information for them to determine whether certain differences in gene or genes within the population correlate with clinical symptoms and/or brain changes at autopsy.

Alternative to study participation

This is not a treatment study. Information being collected is for research purposes only and is to learn more about risk factors for Alzheimer's disease and other related

disorders, not about you, and will not provide information that will be medically useful for you. The alternative to participating would be simply not to participate.

Study Procedures

If you decide to participate, you will receive a neurological examination from a physician and you will also be asked to take a pencil and paper test, to assess memory and other cognitive functions including reasoning, attention and language (neuropsychological testing). Additionally, you will be asked to complete an interview of risk factors and family history. This interview may take 30-40 minutes. You will be asked to give a blood sample (2 tablespoons). You may be invited to participate in this study on a yearly basis, during which you may be asked to complete all or some of the interview, neurological exam or memory testing. In addition, you may be asked to give another blood sample. The total amount of time required for each visit will be approximately two to three hours.

The interview will consist of questions regarding habits and behavior such as smoking, alcohol intake, physical activities and your past medical history. We will ask you about the state of health of many of your first-degree relatives (mother, father, brother, sister and children). We will ask you about a number of conditions in those individuals such as whether or not they had Alzheimer's disease or other related disorders. Since we wish to study the relationship between heart disease and these neurological disorders, we will ask you about previous heart attacks and related disorders.

Additionally, we want to study the genetic factors, the inherited factors passed from parents to their children that may be associated with the risk of developing Alzheimer's disease or other related disorders. These genetic factors are called genes. To study the genes, we will obtain approximately 2 tablespoons of blood by putting a needle in one of the veins in your arm (much like a regular blood test). This blood will be used to examine some of the genetic material (DNA) from the cells and used in the research studies. We will also freeze these cells in a special way so that we can re-examine other genes that may cause or increase the risk of Alzheimer's disease or other related disorders at a later date. If another blood sample is needed, the appropriate consent will be obtained from you.

This blood sample will be shared with other researchers doing research in similar fields through the National Cell Repository for Alzheimer's Disease in Indiana (**or another NIA approved repository**). This blood sample will be made into a cell line (a family of cells grown in a laboratory) that will enable your DNA to be available indefinitely for use by qualified scientists at other research centers. All biological samples sent to National Cell Repository (NCRAD) (**or another NIA approved repository**) will be stored indefinitely and processed at NCRAD (**or another NIA approved repository**) for use by qualified scientists at other Alzheimer's Disease Centers and other research centers

(including other academic and commercial laboratories studying Alzheimer's disease, aging, and other related disorders). In addition to the blood sample, some coded demographic information about you (year of birth, family history of dementia, and diagnosis) will be sent to NCRAD **(or another NIA approved repository)**. Your identity will not be shared with NCRAD **(or another NIA approved repository)** or with any investigators.

We also ask your permission to share your coded sample and data with investigators studying the genetics of other human diseases. These investigators will not be given any of your identifying information. At the end of this consent form, you have the option of choosing whether you want to share your samples with NCRAD **(or another NIA approved repository)** or with other investigators studying the genetics of human disease.

If you agree to give your blood sample and clinical information to NCRAD **(or another NIA approved repository)**, this information will be given a code and will not be tracked by your name. The blood sample and other information will be de-identified and assigned a code number. This means that we will not send your name, address, phone number or other identifying information to NCRAD **(or another NIA approved repository)**. Coded data linked to the blood sample and clinical information will be kept on a secure computer at the data coordinating center at NCRAD **(or another NIA approved repository)** that can be accessed only by authorized investigators. Summary data (coded) will be made available to researchers via a website that will be maintained by NCRAD **(or another NIA approved repository)**. Data that has been stripped of all identifying information from genetic analysis will be kept separate from the clinical and demographic data stored at NCRAD **(or another NIA approved repository)** and can only be accessed by authorized individuals.

The coded genetic data may be stored on a secure website through a National Institute on Aging supported institution and the data may be shared for secondary analysis by other authorized investigators. **NIA has established the National Institute on Aging Genetics of Alzheimer's Disease Data Storage Site (NIAGADS), as a national genetics data repository. If you agree, then data that has been stripped of all identifying information will be stored at NIAGADS or another NIA approved site or both. Your genetics data will be stored on a secure password protected website without identifiers, and only qualified investigators will have access to these data. NIAGADS may make available genetic data that may also be deposited at an NIH database which will continue to ensure your privacy and confidentiality.**

At any time you may withdraw your consent to be in this study and for us to use your data. In addition, you have the right to have your samples destroyed or anonymized. If you withdraw from the study, you will continue to have access to health care at **XXXXX**.

If you do decide to withdraw, we ask that you contact Dr. XXXX in writing to let him know that you are withdrawing from the study. His mailing address is XXXX or if you prefer you may call the study coordinator at XXX XXXX. At this time we will ask your permission to continue using all information about you that has already been collected as part of the study prior to your withdrawal. If you withdraw and no longer wish for your tissue/cell/blood to be used at the National Cell Repository for Alzheimer's disease (or another NIA approved repository) or wish to have your sample anonymized please inform us at this time. The National Cell Repository for Alzheimer's Disease (or another NIA approved repository) will destroy/anonymize any unused samples, but it may not be possible to retrieve or destroy/anonymize samples that have already been distributed to other investigators. If the samples have already been analyzed prior to your request to withdraw, the data may still be used.

If the investigators determine that additional tests are necessary, then individuals may be offered the opportunity to complete additional brain imaging and laboratory studies in the Irving Clinical Research Center. These tests will be offered at no cost to you. The complete evaluation including the neurological examination, memory testing (neuropsychological testing), family history and risk factor interview and blood draw, should take approximately 2-3 hours to complete.

Throughout the duration of this study, we will evaluate individuals who are unaffected, who have questionable dementia or memory problems on a yearly basis by repeat neurological and medical examination and neuropsychological testing in order to detect any change in the individual's cognitive status. If you are asked to participate yearly, the appropriate consent will be obtained from you.

While brain donation is important for the study of Alzheimer's disease, this study does not include brain donation. If you are interested in brain donation, we will refer you to the coordinator of the brain donation study. If you agree, the brain donation coordinator will contact you.

Study Risks

You should be aware that there is a very small risk that participation in a genetic research study might be misunderstood by others, such as employers or health care insurers. Confidentiality is a central concern of this study of Alzheimer's disease and other related disorders. Every possible effort will be made to maintain the research information in the strictest confidence. We cannot absolutely guarantee that disclosure might not occur unintentionally. We remind all persons participating in this research that maintaining complete confidentiality is a responsibility of both the investigator and his/her staff (US), and the participant (YOU). If you are concerned about these issues, you should consider them carefully before telling anyone that you are participating in a

genetic study of Alzheimer's disease. Revealing your participation could potentially affect your ability to obtain health insurance or employment.

If you decide to participate in the NCRAD, **NIAGADS**, (or **another NIA approved repository**), there may be additional risks to your confidentiality. However, we will take all necessary steps to ensure confidentiality by removing identifying information such as your name, address and phone number.

If you have concerns about memory problems or other health related questions, the research team will refer you to appropriate medical resources (ie, your primary care physician, a memory disorders specialist).

Under some circumstances medical research, including genetic research, can lead to the association of a specific medical illness with a particular group of people. This association could be viewed as harmful to the group because of potential for group discrimination or stigma, but it may also benefit the group if such research ultimately leads to earlier detection and treatment of the condition.

Your participation in this study might be associated with slight pain due to the blood test. For most people, drawing blood does not cause any serious problems. However, there is a risk of bruising, discomfort, dizziness, infection, and pain at the needle site. To reduce any risk, we will take every precaution using skilled individuals to obtain blood from you. If there is any difficulty in obtaining the blood or if there is some medical reason you cannot allow us to perform the blood draw, we will omit this part of the study.

You may also be slightly embarrassed, tired, or anxious about the memory testing or answering questions about your habits such as smoking and alcohol use, but we assure you that you can choose not to answer a specific question or we can stop at any time.

Study Benefits

You are not expected to benefit personally from this study. However, the greatest benefit will be to society where you will assist us in identifying important risk factors for the cause of diseases of the nervous system in the elderly.

Costs/Compensation

There will be no costs to you for participating in this study. Instead you will obtain **\$XX** in cash, at the time of the study visit, as compensation for your time. In addition, you will receive **\$XX** at follow-up study visits. Samples and data sent to NCRAD (**or another NIA approved repository**) and genetic data stored at **NIAGADS (or another NIA approved repository)** may be shared with companies and there is the possibility that the research done may be used to develop new products. You will receive no financial

compensation for the development of new products that result from the use of your biological sample (blood, cell line, autopsy tissue), clinical and demographic data, and/or genetic data.

Confidentiality

Any information obtained during this study and identified with you will remain confidential. To protect your identity, we have assigned you a unique code number. At no time will we link your name to your code number. We will analyze your sample along with many others so that your sample cannot be specifically identified and linked to you. This number will not include names or any other identifying characteristics. Likewise, the samples or cell lines will be safely stored and identified by a code number only. Access will be limited to authorized scientific investigators.

For research data shared outside of **XXXX**, you will be assigned a unique code number. The key to the code will be kept in a locked file in Dr. **XXXX**'s office and in the case of samples sent to NCRAD (**or another NIA approved repository**) they will be kept on a secure computer that can only be accessed by authorized investigators.

The data and results of these studies may not be communicated to anyone. This includes you, as well as relatives, personal physicians and insurance companies. DNA information about a relative will be released only if a genetic counselor confirms that the relative in question is deceased or cannot be found and that the information is essential for clinical counseling. Since these data will not be released to you or your family, they will not be available for genetic counseling. If you request genetic counseling, you will be referred to a genetic counselor who may then request additional blood samples to be used for that purpose.

Research records are maintained in locked paper files and secured computer files, available only to research staff and institutional personnel as part of routine audits. Information is coded and password protected. Access is restricted to the authorized scientific investigators.

We think that you should be aware that insurance companies sometimes use information from genetic testing to deny coverage to applicants. It is the opinion of the investigators that this study is not genetic testing. It is aimed at developing such testing for the future, but cannot currently provide any meaningful information about participants. Since that is the case, if you are asked, this should not be reported as genetic testing.

You do have the right to have the material and/or data destroyed or anonymized at any time. Should you choose to anonymize your samples no one, including the Principal

Investigator, will be able to link your samples back to you. This particular consent form does grant: 1) permission for future testing of samples for Alzheimer's disease and other related disorders by the **XXX** lab or other licensed outside facilities; 2) permission for other authorized scientific investigators to use these data for the study of Alzheimer's disease and related disorders; 3) permission for future contact regarding this study. At the minimum, the principal investigator intends to store these data from these samples throughout the duration of the study, approximately 5-10 years to study genes that are associated with Alzheimer's disease and other related disorders. All biological samples sent to National Cell Repository (NCRAD) **(or another NIA approved repository)** will be stored indefinitely and processed at NCRAD **(or another NIA approved repository)** for use by qualified scientists at other Alzheimer's Disease Centers and other research centers.

The researchers for this study have obtained a Confidentiality Certificate issued by the Department of Health and Human Services (DHHS) that will help them protect your privacy during this study. With this certificate, the research staff cannot be forced (for example by court subpoena) to disclose research information that may identify you as a research participant, without your written consent. However, if the researchers learn that you are in real danger of physical or serious mental harm (example, suspected or known sexual or physical abuse of a child or threatened violence to self or others) they will release study related information to protect you and the other persons. Such information must be reported to the appropriate authorities. You should also understand that this Confidentiality Certificate does not prevent you or a member of your family from voluntarily releasing information about you or your participation in this research. If an insurance company asks you to release information and you choose to do so, the Certificate of Confidentiality will not protect your privacy.

Research Standards and Rights of Participants

Participation in this research study is voluntary. If you decide not to participate, or if you later decide to stop participating, you will not lose any benefits to which you are otherwise entitled. If you agree to be in this study, you are free to change your mind. Participants will be notified of significant new findings that may relate to their willingness to continue to participate. Signing this form does not waive any of your legal rights.

If you have any questions, please ask, and we will do our best to answer them. If you have additional questions in the future, you can reach Dr. **XXXXXXXX** at **XXX XXX** and he will do his best to address your questions. If you have any questions on your rights as a research participant please call the **XXXXXXXX** at **XXXXXX** for information.

Please be aware that:

Federal regulations require that research participants be informed about our institutions' policies with regard to the provision of treatment and compensation for research related injuries. If you believe that you have sustained injury as a result of participating in a research study, you may contact the Principal Investigator, Dr. XXXXXXXX at XXXXXXXX, or the XXXXXXXX Institutional Review Board at XXXXXXXX so that you can review the matter and identify the medical resources which may be available to you.

Please be aware that:

- a. The XXXXXX will furnish that emergency medical care determined to be necessary by the medical staff of this hospital
- b. You will be responsible for the cost of such care, either personally or through your medical insurance or other form of medical coverage.
- c. No monetary compensation for wages lost as a result of injury will be paid to you by the XXXXXX .
- d. By signing this consent form, you are not waiving any of your legal rights to seek compensation through the courts.

Documentation of Consent

You do have the option of refusing to participate in the National Cell Repository (or another NIA approved repository) while continuing to participate in the XXXXXXXX research study. Please check yes or no for the statement below:

YES

NO

I give my permission to Dr. XXXXXXXX to share and to store my blood sample and other relevant clinical information at the National Cell Repository for Alzheimer's Disease in Indiana (or another NIA approved repository). I understand that my sample and other information collected as part of the research study will remain coded (my name will not be used).

NOTE: If you checked "NO" above, this does not exclude you from participating in research conducted at XXXX.

You do have the option of refusing to allow your blood sample and associated information to be shared with investigators studying the genetics of human diseases. Please check yes or no for the statement below.

YES

NO

I give my permission to Dr. XXXX and NCRAD (or another NIA approved repository) to share my blood and other relevant clinical information with investigators studying the genetics of other human diseases besides Alzheimer's disease. I understand that my sample and other information collected as part of the research study will remain coded (my name will not be used).

NOTE: If you checked "NO" above, this does not exclude you from participating in research conducted at XXXX

YES

NO

I give my permission to Dr. XXXX and NIAGADS (or another NIA approved repository) to share my genetic data with investigators studying the genetics of other human diseases besides Alzheimer's disease. I understand that my information collected as part of the research study will remain coded (my name will not be used).

NOTE: If you checked "NO" above, this does not exclude you from participating in research conducted at XXXX.

Consent by participant: I have read the above and understand the risk, benefits and alternatives (including non-participation). I voluntarily agree to participate in the research study described above.

Signature of participant

Date

Name of participant (printed)

I have discussed the proposed research with this participant, and, in my opinion, this participant understands the benefits, risks and alternatives (including non-participation) and is capable of freely consenting to participate in research.

Signature of person obtaining consent

Printed name

Date

Documentation of Assent

To be completed by research staff if participant is not able to provide consent and consent provided by surrogate.

Assent by participant:

I voluntarily agree to participate in the research study described above. I understand that _____ will provide consent for my research participation.
(name of surrogate)

Signature of participant

Date

Printed name of participant

Consent by surrogate: I was present when the proposed research study was described to the above patient and in my opinion, she or he agrees to participate, or does not object to participation.

Signature of Surrogate

Date

Name of Surrogate (printed)

Relationship to participant

I have discussed the proposed research with this participant and the participant's surrogate, and, in my opinion, the surrogate understands the benefits, risks and alternatives (including non-participation) for this participant.

Signature of person obtaining consent

Printed name

Date

Assessment of capacity by research staff

I assessed _____ (Name of subject) on _____
(Date) for the purpose of determining whether he/she is capable of understanding the purpose, nature, risks, benefits and alternatives (including non-participation) of the research, making a decisions about participation, and understanding that the decision about participation in the research will involve no penalty or loss of benefits to which the patient is otherwise entitled, for Dr. **XXXX** 's research project of Late onset Alzheimer's disease and related disorders. On the basis of this assessment I have arrived at the conclusion that:

A. This patient has this capacity at this time. _____

B. There is a question about this patient's capacity at this time. _____

C. This patient clearly lacks this capacity. _____

Print Name _____

Signature _____ Date _____