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Consent To Participate In A Research Study
Clinical Cohort Study of the Duke/UNC Alzheimer's Disease Research Center (ADRC)

CONCISE SUMMARY

The purpose of the study, also known as the Memory & Aging Study, is to establish a Clinical Cohort (group) of research participants to examine normal cognition, mild cognitive impairment (MCI) and Alzheimer's disease and related dementias (ADRD) as people get older. We will be measuring changes in your memory and the way you process information as you age. As part of the study, you will be asked to participate in yearly evaluations of your memory and health. You will have brain imaging done by Magnetic Resonance Imaging (MRI), a lumbar puncture (LP) and blood will be drawn at some visits. Also, as part of this research you must designate a "project partner." This should be someone who is familiar with your health and will be able to provide information about your health and wellbeing as appropriate.

Samples collected as part of this research will be kept in a repository for future research related to aging and brain health by researchers from Duke University and the University of North Carolina at Chapel Hill (UNC-CH). Later, during the research, data and samples may be shared with investigators at Duke, UNC-CH, and outside locations. Your data and samples will be given a unique identifier to protect your identity.

There are risks as described in this document. Risks of blood draw include discomfort and/or bruising; infection, excess bleeding, clotting, and/or fainting. Risks of LP include headache, back pain and stiffness, pain at the site of the puncture, and neck and shoulder pain. There is also risk of low blood pressure or dizziness. MRI may cause some claustrophobia. There is also a risk of loss of confidentiality. Every effort will be made to protect your confidential information, but this cannot be guaranteed.

If you are interested in learning more about this research, please continue to read below.

You are being asked to take part in this research study because you have some impairment to your memory and/or thought processes, or because you have been identified as a control participant with normal memory and/or thought processes. Research studies are voluntary and include only people who choose to take part. Please read this consent form carefully and take your time making your decision. As your study doctor or study staff discusses this consent form with you, please

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ask them to explain any words or information that you do not clearly understand. We encourage you to talk with your family and friends before you decide to take part in this research study. The nature of the study, risks, inconveniences, discomforts, and other important information about the study are listed below.

Please tell the study doctor or study staff if you are taking part in another research study.

WHO WILL BE MY DOCTOR ON THIS STUDY?

If you decide to participate, Heather Whitson, MD will be your doctor for the study and may be in contact with your regular health care provider throughout the time that you are in the study and afterwards, if needed. A grant from the National Institutes of Health (NIH) will sponsor this study. Portions of Dr. Whitson's and the Duke/UNC ADRC research team's salaries will be paid by this grant.

WHY IS THIS STUDY BEING DONE?

The purpose of this study is to examine normal cognition, mild cognitive impairment (MCI) and Alzheimer's disease and related dementias (ADRD) as people get older. We also hope to be able to assess risk factor information, and the role of genes and environmental exposures (e.g., health conditions, diet, and medications) in ADRD and other conditions of aging.

The biological samples collected in the study will create a repository. A repository is a collection of blood and tissue samples from people with certain diseases and conditions. For the purpose of this research, we hope to help researchers learn more about ADRD and other conditions of aging.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

Approximately 100 people per year will take part in this study at Duke and UNC-CH.

WHAT IS INVOLVED IN THE STUDY?

Although this research may lead to a diagnostic test for the identification of persons at increased risk of developing Alzheimer's disease (AD), you and your relatives may not learn your status regarding AD from this project. The purpose of this study is not for the diagnosis or treatment of AD. Data and samples collected from this research will help us learn more about memory loss and changes in thought processes as we age.

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As part of this research, we will ask that you provide several samples including a blood sample, a cerebrospinal fluid sample (CSF) and a urine sample (for women of child-bearing potential). If you agree to provide these samples, a portion of these samples (without any information that links the samples to you – we call this "de-identified") may be shared with other researchers doing research in similar fields. In addition, your de-identified samples may be shared with other investigators for future research on aging or brain health. A leadership group of Alzheimer's scientists affiliated with the Duke/UNC ADRC will review any such research requests prior to sharing your samples.

This future research may involve tests of genes or gene products. Your genes are made up of DNA. DNA is short for deoxyribonucleic acid. A gene, or DNA, contains information that determines in part the traits, such as eye color, height, or disease risk, that are passed on from parent to child.

We would like to keep your blood, CSF samples, urine samples (if obtained) and MRI images for future research studies. By signing this consent form, you agree that the data, images, and samples we collect from you can be used for future research on the topic of aging and brain health.

Project Partner
As part of the study, you must identify a "project partner" to assist you with your annual participation in the study. A project partner is a contact person who knows you well, preferably a family member, (e.g., a spouse or an adult child). Once you have obtained their permission, this person will be asked questions about your day-to-day activities and behavior, and your mood. Optimally, we would prefer this person to accompany you at all visits to meet with the project staff. If this is not possible, then this person needs to be available to answer the questions by telephone. (This phone session would take about 15 –20 minutes of their time to complete.) At the first visit, this person will be asked to sign their own consent form stating they have gained your permission to answer questions about you. Though preferred, your project partner does not need to be the same person every year and can decline participation at any time without affecting your own participation in this project. **Providing a project partner to assist with your participation in this project is required**. Important information about you is gathered from them that will enhance the information you provide about yourself.

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If you agree to be in this study, you will be asked to sign and date this consent form. You will undergo the following visits, procedures and tests as part of your participation in the study:

Baseline visits (typically up to 3 visits, conducted within 60 days of initial visit)
During these visits the following tests and procedures may be completed:

- Basic information about you and your project partner
- Family history, medical history and current medications
- General physical, neurological, and sensory exams
- Vital signs (blood pressure, heart rate, etc.)
- Blood sample (approximately 4-5 tablespoons obtained through venipuncture)
- Urine sample (for women who could possibly become pregnant)
- Testing of your memory, thought processes and cognition
- We will ask that you sign a Release for Medical Records. By signing this form, you give us permission to obtain your medical records from physicians, hospitals, or other agencies to document aspects of your medical history. All of your medical records are maintained according to Duke University Health System (DUHS) requirements.
- You may also be asked to partner with one of our other studies and complete retinal imaging (non-invasive screening of your eyes to look for potential signs of Alzheimer's or related disorders). You will review and sign an additional consent form if you agree to participate.

The above tests and procedures should take approximately 5-6 hours to complete but may take longer in some instances. Your project partner is required to attend the related visit(s) with you.

We may audio record your responses for portions of the tests of your memory, thought processes and recognition. However, you will not be identified in any of these recordings. Your voice recording will be given a unique study identification number.

Note: As deemed appropriate by the study team, portions of this visit may be conducted remotely via phone/video chat, particularly pertaining to obtaining subject demographics and project partner demographics, family history, medical history, current medications, and neuropsychological testing.

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You may also be asked to complete:

- An MRI of your brain
- A lumbar puncture to collect CSF (approximately 2 teaspoons)

The MRI and the lumbar puncture may be done on the same day, or on 2 different days within the 60-day time frame. Duke staff will schedule these appointments with you to determine what works best for your schedule.

The MRI involves entering a large room in which a magnet is present. If there is any question about potentially hazardous metal within your body, you will not undergo the MRI. This may exclude you from participation in this research study. Let the study team and/or study doctor know if you have a fear of enclosed spaces (claustrophobia).

During the lumbar puncture, you will have fluid drawn from your spine. Spinal fluid tells researchers special information about changes in the brain that occur before memory loss symptoms develop, as well as after someone has memory loss. A physician will numb an area along your spine and insert a needle to extract some spinal fluid. Following the lumbar puncture, a member of the Duke study team will call you 1-3 days after the procedure to discuss your health and confirm if you had any adverse (bad) effects from this procedure.

At the time of the MRI and/or lumbar puncture, a trained technician will explain to you more about the procedure.
You may request a mild sedative that may help reduce anxiety if you expect to be uncomfortable during the MRI or lumbar puncture. The investigator may provide a prescription for this mild sedative after they have reviewed your health information and medications that you may be taking. Health conditions such as drug allergies, narrow angle glaucoma, liver, kidney or heart conditions should be discussed with the investigator since the mild sedative may be affected by such conditions.

Either Lorazepam (0.5 to 1.0mg) or Alprazolam (0.25 to 0.5mg) may be prescribed. Both medications are taken by mouth. Both medications help relieve anxiety. Risks associated with these drugs are discussed further in this consent.

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If you request a mild sedative, you must be accompanied by your project partner or by a responsible adult to serve as a designated driver on the day of your appointment(s).

Risks associated with MRI scan and lumbar puncture are explained further in this consent.

Yearly evaluations

We will ask your permission to re-contact you and your project partner approximately every 12 months for a follow-up evaluation. At the yearly follow-up evaluation we will:

- Update your medical information and perform tests of your memory and thinking.
- You may also be asked to contribute additional blood or fluid samples. This is so that we may monitor any changes in your health.

These follow-up evaluations are ideally in person, but if an in-person visit is not possible due to cognitive decline, they can be conducted over the telephone. You will be asked to participate in yearly evaluations until the time of your death. You are free to decline continuing participation if this is not convenient for you. If you are unable to return to Duke for your annual visit, we may ask permission to come visit you at your home to do the annual assessment. We will call your project partner to discuss information over the telephone relevant to their participation in this study.

Data sharing between Duke and UNC-CH

This research is being conducted as part of the joint Duke/UNC ADRC, possibly involving subject visits to either institution. For purposes of visit scheduling, follow-up, and clinical case consultation, we would like to share identifying data such as your name, contact information and Medical Record Number (MRN) between the study team members based at Duke and UNC-CH. Once shared, this data will still be maintained in accordance with the Confidentiality section below.

_____ Please enter your initials to affirm your agreement that data regarding you can be shared between the study teams at Duke and UNC-CH, including information like your name, contact information, and MRN.

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DNA/Genetic Banking

Some of your blood samples will be used to look for certain genetic proteins. These samples are collected for research purposes only. It is not the purpose of these studies to look for or provide you with any medical information or diagnoses relating to your present condition or any other disease or illness. These studies are not being used as diagnostic tests for any disease or illness. Your participation in this research project should not be a substitute for your regular medical care or check-ups.

Through this research, we may find that you have an abnormal gene or gene product (i.e., RNA or protein) which indicates a risk for developing a disease at some time in the future. It is also possible that the research results may indirectly provide unexpected personal information about you or your family, such as ethnic/racial background or an unknown genetic relationship between family members. Please talk with the study doctor if you have any questions or concerns about the genetic testing being done in this research study. Dr. Whitson may also refer you to a genetic counselor for further information.

We would like to keep your blood and CSF samples for future research projects.

NCRAD – De-Identified National Sample Repository

Biological samples will be sent to the National Centralized Repository for Alzheimer's Disease and Related Dementias (NCRAD) for sharing with other investigators. NCRAD is a national resource supported by the National Institute on Aging (NIA) that prepares and stores biological specimens from all over the world and makes them available to approved scientists who would not otherwise be able to access this material.

Your biological samples will be maintained in the laboratory for many years. These samples will be coded and not identified by your name. The samples are necessary for long-term research and will be stored indefinitely.

Results of the analysis of the biological samples you have provided may be shared with other researchers. This information will be de-identified, meaning it will not contain any traditional identifiers (i.e. name, date of birth, address, telephone number).

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The biological samples may be provided to researchers at academic institutions, hospitals, and private companies. Specimens collected from you for this research may be used to develop products which could be sold in the future. The researchers do not plan to share any profits or losses from the sale of those products with you.

Incidental Findings

Incidental findings refer to findings that we were not expecting to find, and we were not looking for, but that we happen to observe in your brain images or other tests. Many so-called "incidental findings" have no health consequences (similar to observing freckles on your skin) and such findings are not reported. However, sometimes we encounter an incidental finding that may have health consequences or merits additional follow-up. In that case, we will attempt to notify you using the contact information you have provided, so that you can speak with Dr. Whitson at Duke University Health System (DUHS). DUHS staff will not provide this information in a voice mail, email, or otherwise prior to contacting you. Please notify us of any change in your contact information. Please initial your choice below:

_____ Please notify me of any incidental findings obtained from this research.

_____ Please do not notify me of any incidental findings obtained from this research.

_____ Please ask me at the time of notification whether or not I want to receive incidental findings information.

If at any time during or after the study you change your mind about whether or not you would like to be notified, you can contact the study team at (919) 660-2340.

After providing the information to you, Dr. Whitson may arrange for you to meet with her and/or a genetic counselor or refer you to another appropriate health care provider to review the incidental findings information with you or your health care provider.

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HOW LONG WILL I BE IN THIS STUDY?

Participation in a clinical cohort is for the rest of your life unless you choose to stop participation.

Your biological samples will be maintained indefinitely or until the samples are exhausted. You may be asked to provide another sample of blood or fluid for this study in the future. At that time, we will remind you of your participation in the study and make sure you are still willing to provide new samples.

You can choose to stop participating at any time without penalty or loss of any benefits to which you or your study partner are entitled. However, if you decide to stop participating in the project, we encourage you to talk to your health care provider and/or the study team first.

WHAT ARE THE RISKS OF THE STUDY?

As a result of your participation in this study, you are at risk for the following side effects. You should discuss these with the study doctor and your regular health care provider if you choose.

Lumbar Puncture (LP) - For most people, lumbar puncture or insertion of a spinal catheter does not cause any serious problems. Headache is the most commonly reported side effect and is reported by as many as half of the people who have the procedure. If the headache does not go away after 1 or 2 days, it may be due to a leak of the CSF. A CSF leak can be treated with a blood "patch". This is a procedure in which your blood is injected into the area where the leak is occurring. Back pain or stiffness, pain at the site of the catheter, and neck or shoulder pain are less common effects. Rare or very uncommon effects include low blood pressure and dizziness, bleeding into the spinal cord, or an infection of the spinal fluid (known as meningitis). These very rare complications may be serious and could require hospitalization for urgent care such as antibiotic therapy, brain surgery, or a breathing machine (known as a ventilator). If you experience complications from your LP, please contact the study team. If the study doctors believe that a blood patch is necessary, we can arrange for this to be done for you by a study physician.

Local Anesthetic - The medication that numbs your skin during a lumbar puncture may sting or burn while it is being injected, and there is also a small risk of an allergic reaction.

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Blood Draw - Risks associated with drawing blood from your arm include momentary discomfort and/or bruising. Infection, excess bleeding, clotting or fainting are also possible, although unlikely.

MRI - Magnetic resonance imaging (MRI) uses radio waves and a strong magnet to make diagnostic medical images of the body. There have been no ill effects reported from exposure to the magnetism or radio waves used in this test. However, it is possible that harmful effects could be recognized in the future. A known risk is that the magnet will attract certain kinds of metal. Therefore, we will carefully ask you about metal within your body, including medical implants, devices such as pacemakers and internal defibrillators, or certain dyes found in tattoos. Protocols are in place in the brain imaging center to ensure that no one carrying metal objects can enter while you are in the scanner.

If there is any question about potentially hazardous metal within your body, you will not undergo the MRI. This may exclude you from participation in this research study. The MRI involves entering a large room in which a magnet is present. You will be placed on a narrow bed and then slid into a small tunnel approximately 6 feet in length and a little over 2 feet in diameter. You will be asked to lie still for about one hour on this bed. You will hear a loud machine-like noise. You may be asked to have a harmless monitoring device applied during the MRI. During the MRI, you can have voice contact with MRI staff. Let the study team and/or study doctor know if you have a fear of enclosed spaces (claustrophobia).

You may have a number of MRI scans that are part of the regular care for your condition, and you would have them whether or not you participate in this research. These scans will not add to the risk of the research. As with any procedure, there may also be unforeseeable risks. If you have concerns about the MRI safety issues, you should discuss them with your regular health care provider.

Mild sedative (lorazepam and alprazolam) - If you request a mild sedative to help reduce the potential anxiety of completing an MRI or lumbar puncture, you may experience the following most common side effects of lorazepam and alprazolam: drowsiness, dizziness, weakness, and/or unsteadiness. Less frequent side effects of lorazepam and alprazolam include: confusion, nausea, and/or headache.

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Pregnancy – Some of the research procedures in this study (the LP and MRI) are not done in pregnant women unless absolutely necessary for their care. If you are a woman who could possibly become pregnant (you have not completed menopause, or you have not had a hysterectomy and/or both tubes and/or both ovaries removed) and you have a partner who is able to father children, a urine pregnancy test will be performed at the start of the study. Depending on when the procedures are performed, a urine pregnancy test may be repeated the day of the procedure.

Confidentiality - There is also the potential risk of loss of confidentiality. Every effort will be made to keep your information confidential; however, this cannot be guaranteed. Some of the questions we will ask you as part of this study may make you feel uncomfortable. You may refuse to answer any of the questions, and you may take a break at any time during the study. You may stop your participation in this study at any time.

You should also be aware that there is a very small risk that participation in a genetic research project might be misunderstood by others, such as employers or health care insurers. Confidentiality is a central concern of this project on 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 project of Alzheimer's disease. Revealing your participation could potentially affect your ability to obtain health insurance or employment. 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 project 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.

The genetic information obtained as a result of your participation in this research will not be included in your medical record. Information from which you may be personally identified will be maintained in a confidential, secure location at DUHS, accessible only by authorized members of the study team, and will not be

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disclosed to third parties except as described in this consent form, with your permission, or as may be required by law.

If you decide to participate in other biorepositories 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.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

There will not be any direct benefits to you if you decide to participate in the research study. You may receive some of your study information as a result of your participation. This information is discussed later in this document. Research conducted on these samples may help researchers to better understand dementias and related diseases in the future.

WILL MY INFORMATION BE KEPT CONFIDENTIAL?

Participation in research involves some loss of privacy. We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total confidentiality. Your personal information may be viewed by individuals involved in this research and may be seen by people including those collaborating, funding, and regulating the study. We will share only the minimum necessary information in order to conduct the research. Your personal information may also be given out if required by law.

As part of this study, you will be asked to have certain tests and/or procedures performed. Some of these tests and/or procedures may have been done as part of your regular care. These test results will be recorded in your medical record and will be included in your research data. Results of tests and studies done solely for this research study and not as part of your regular care will not be included in your medical record.

Memory testing data collected on an electronic tablet or through secure web portal are linked to a unique identification number, not to your name or other personal information. This data is stored in a secure database managed by WCG Clinical Endpoints/VeraSci. If collected on an electronic tablet, the data is temporarily stored on the device and then uploaded to the secure database. Data collected through the secure web portal is also stored directly in this secure database. Duke

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University has an agreement with WCG Clinical Endpoints/VeraSci to export the data from their secure database to a secure server at Duke for analysis.

The study results will be retained in your research record for at least six years after the study is completed. At that time either the research information not already in your medical record may be destroyed or information identifying you will be removed from such study results at DUHS. Any research information in your medical record will be kept indefinitely.

This information may be further disclosed by the sponsor of this study. If disclosed by the sponsor, the information is no longer covered by federal privacy regulations.

If this information is disclosed to outside reviewers for audit purposes, it may be further disclosed by them and may not be covered by federal privacy regulations.

While the information and data resulting from this study may be presented at scientific meetings or published in a scientific journal, your name or other personal information will not be revealed.

Some people or groups who receive your health information might not have to follow the same privacy rules. Once your information is shared outside of DUHS or UNC Healthcare System (UNCHS), we cannot guarantee that it will remain private. If you decide to share private information with anyone not involved in the study, the federal law designed to protect your health information privacy may no longer apply to the information you have shared. Other laws may or may not protect sharing of private health information.

Genetic Information Nondiscrimination Act (GINA):
A federal law, called The Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:

- Health insurance companies and group plans may not request genetic information from this research,
- Health insurance companies and group plans may not use your genetic information when making decisions regarding your eligibility or premiums,

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- Employers with 15 or more employees may not use your genetic information when making a decision to hire, promote, or fire you or when setting the terms of your employment.

GINA does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. GINA also does not protect you against discrimination based on an already-diagnosed genetic condition or disease.

We will protect your privacy and confidentiality information by labeling your samples with a code number. Researchers who obtain your sample for their research will not be given a link between the code number and your name or any other identifying information. While we hope this will prevent any potential loss of privacy or confidentiality, we cannot make any guarantees.

Certificate of Confidentiality
The Department of Health and Human Services (DHHS) has issued a Certificate of Confidentiality to further protect your privacy. With this Certificate, the investigators may not disclose research information that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings, unless you have consented for this use. Research information protected by this Certificate cannot be disclosed to anyone else who is not connected with the research unless:

1) there is a law that requires disclosure (such as to report child abuse or communicable diseases but not for legal proceedings);
2) you have consented to the disclosure, including for your medical treatment; or
3) the research information is used for other scientific research, as allowed by federal regulations protecting research subjects.

Disclosure is required, however, for audit or program evaluation requested by the agency that is funding this project or for information that is required by the Food and Drug Administration (FDA).

You should understand that a Confidentiality Certificate does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released

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to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it. This means that you and your family must also actively protect your own privacy.

Finally, you should understand that the investigator is not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others.

WHAT ARE THE COSTS TO YOU?

The Duke/UNC ADRC will be responsible for all costs associated with tests and procedures that are done solely for the purpose of this research.

There will be no additional costs to you for participation in the study.

However, routine medical care for your condition (care you would have received whether or not you were in this study) will be charged to you or your insurance company, including co-payments and deductibles. You may wish to contact your insurance company to discuss this further. Not all services are covered by insurance. Some procedures or scans may require pre-authorization by your insurance plan. We will notify you if we learn that a service is not covered by your insurance plan as part of the pre-authorization process. The amount of your out-of-pocket expense will depend on your insurance plan. For beneficiaries with Medicare Advantage Plans, traditional Medicare is billed for the routine cost of a research study. You may have more or higher co-pays than with a Medicare Advantage plan.

In order to make sure that tests and studies done solely for research purposes are charged correctly, we will carefully monitor your Duke and/or UNC Hospitals and Clinics charges as long as you are participating in this study. These tests and studies are not a part of routine care, and people who are not part of the study do not usually have them performed. Please ask Dr. Whitson and the study team if you would like to know more about which tests and studies are being done solely for research purposes.

WHAT ABOUT COMPENSATION?

You will receive the following compensation for your participation in this research:

- $50 upon completion of the baseline assessments, examinations, blood

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draw, etc.

- $50 upon completion of each annual (yearly) follow-up
- $100 upon completion of the MRI brain scan
- $100 upon completion of the LP

The study team will discuss the payment increments and details with you.

Additional travel compensation, via mileage, may be provided for those traveling distances of greater than 15 miles each way. We can provide reimbursement up to $250 for round-trip mileage from your home to each study visit at our facility at the current IRS rate ($0.70 per mile as of February 2025). Please inform the study staff if you are requesting these funds. In the unlikely situation that an overnight stay near the research site is needed, we will provide accommodation at a local hotel and will reimburse meal expenses up to the Federal per diem rate, with receipts. Study staff will review the procedures for making accommodations and submitting receipts.

PARTICIPATION IN THE PROJECT AND OBTAINING RESULTS OF GENETIC AND OTHER TESTING

The results of ApoE genotype and other genetic testing, CSF amyloid and tau levels will be determined by a research lab and interpreted by a study team member. ApoE genotype and other genetic testing are done to assess for possible genetic risk for developing cognitive decline. Amyloid and tau are two proteins that can be measured in CSF and are involved in Alzheimer's disease and related dementias. As mentioned in the section titled "**DNA/Genetic Banking,**" these studies are not being used as diagnostic tests for any disease or illness. These tests are performed in a research lab and are used for research purposes only. The test results do not replace results found in a clinically approved lab.

Through this research, we may find that you have an abnormal gene or gene product (RNA or protein) which indicates a risk for developing a disease at some time in the future. It is also possible that the research results may indirectly provide unexpected personal information about you or your family (such as ethnic/racial background or an unknown genetic relationship between family members). If you wish, you can be made aware of the research results as part of the study. If you decide to receive your research results, you will be required to meet with a study clinician. A member of the ADRC team will schedule a meeting with them according to your schedule, and at that time the study clinician will

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review your results with you and provide you with resources as needed. Please initial your choice below:

_____ Please notify me of any research results obtained from this research.

_____ Please do not notify me of any research results obtained from this research.

_____ Please ask me at the time of notification whether or not I want to receive research results information.

If at any time during or after the study you change your mind about whether or not you would like to be notified, you can contact the study team at (919) 660-2340.

After providing the information to you, Dr. Whitson may arrange for you to meet with her and/or a genetic counselor or refer you to another appropriate health care provider to review the research genetic and other test findings with you or your regular health care provider.

WHAT ABOUT RESEARCH RELATED INJURIES?
Immediate necessary medical care is available at Duke University Medical Center in the event that you are injured as a result of your participation in this research study. However, there is no commitment by Duke University, Duke University Health System, Inc., or your Duke physicians to provide monetary compensation or free medical care to you in the event of a study-related injury.

For questions about the study or research-related injury, contact Dr. Whitson at (919) 660-7500 during regular business hours and the Duke paging operator at (919) 684-8111, after hours and on weekends and holidays. At the end of the menu please press "0" and this will connect you to the Duke operator. Ask the operator to page Dr. Heather Whitson.

FUTURE RESEARCH
During this project, we will collect and store biological samples for future research about Alzheimer's disease and related conditions. The samples that are collected will be kept in this repository for future research about aging and brain health by

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investigators from Duke and UNC-CH, and may possibly be shared with other researchers at a later date. Any personal information that could identify you will be removed or changed before the samples are stored.

Regarding potentially identifiable categories of data, where your identity cannot be completely removed (such as voice recordings and retinal images), we will remove identification as much as is possible. Please initial below whether we have your permission to use or share such data for future research purposes, assuming that we have removed your identity from all labelling and description of such data as much as possible. Please initial your choice below:

_____ I give permission for potentially identifiable information such as voice recordings and retinal images to be included in my data that is used or shared for future research purposes.

_____ I DO NOT give permission for potentially identifiable information such as voice recordings and retinal images to be included in my data that is used or shared for future research purposes.

The use of your data and samples may result in commercial profit. You will not be compensated for the use of your data and samples other than what is described in this consent form.

If you wish to withdraw your samples you may do so at any time. Please read the information contained in the following section.

WHAT ABOUT MY RIGHTS TO DECLINE PARTICIPATION OR WITHDRAW FROM THE STUDY?

You may choose not to be in the study, or, if you agree to be in the study, you may withdraw from the study at any time. If you withdraw from the study, no new data about you will be collected for study purposes other than data needed to keep track of your withdrawal.

Your decision not to participate in, or to withdraw, from the study will not involve any penalty or loss of benefits to which you are entitled, and will not affect your access to health care at DUHS or UNCHS. If you do decide to withdraw, we ask that you contact Dr. Whitson in writing and let her know that you are withdrawing from the study. Her mailing address is:

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Dr. Heather Whitson
DUMC Box 3003
Durham, NC 27710

We will tell you about new information that may affect your health, welfare, or willingness to stay in this study.

Dr. Whitson may remove you from this study if she determines that it is no longer in your best interest to continue. The study team and/or Dr. Whitson will discuss this with you. The DUHS, UNCHS, or regulatory agencies may stop this study at any time without your consent.

If you agree now to allow your blood and/or spinal fluid samples to be kept for future research with identifying information that could link your sample to you, you are free to change your mind at any time in the future. We ask that you contact Dr. Whitson in writing and let her know you are withdrawing your permission for your identifiable samples to be used for future research. Her mailing address is:

Dr. Heather Whitson
DUMC Box 3003
Durham, NC 27710

At that time, we will ask you to indicate in writing if you want the unused identifiable samples destroyed, or if your samples (having all identifying information removed that would link the sample to you) could be used for other research.

Your samples and data may be stored and shared for future research without additional informed consent if identifiable private information, such as your name and MRN, are removed. If your identifying information is removed from your samples or data, we will no longer be able to identify and destroy them.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?
For questions about the study or a research-related injury, or if you have problems, concerns, questions or suggestions about the research, contact Dr. Whitson at (919) 660-7500 during regular business hours. For assistance after

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hours, and on weekends and holidays, please call the Duke paging operator at (919) 684-8111. Ask the operator to page Dr. Heather Whitson.

For questions about your rights as a research participant, or to discuss problems, concerns or suggestions related to the research, or to obtain information or offer input about the research, contact the Duke University Health System Institutional Review Board (IRB) Office at (919) 668-5111.

Contact for Future Research –
We would like to contact you about other studies related to Alzheimer's Disease and related dementias for which you may qualify. Each of these studies will have their own informed consent which will be reviewed with you as it describes in detail the procedures required. Your signature will also be required indicating that you want to participate in the study. Participation is optional and you can choose not to participate. Please initial your choice below:

_____Yes, I agree to be contacted for future studies.

_____ No, I do not agree to be contacted for future studies.

[Consent continues on the following page.]

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STATEMENT OF CONSENT
"The purpose of this study, procedures to be followed, risks and benefits have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have questions, to discuss problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research. I have read this consent form and agree to be in this study, with the understanding that I may withdraw at any time. I have been told that I will be given a signed and dated copy of this consent form."

_____	_____	_____
Signature of Participant	Date	Time
_____	_____	_____
Signature of Person Obtaining Consent	Date	Time

If applicable, LAR Statement: "I am the representative of the participant and am acting on behalf of the participant. I am not aware of any factor that might create a conflicting interest for me in this role (for example, something that might bring me personal benefit). I consent to the participant's participation in this study."

_____	_____	_____
Signature of Legal Representative	Date	Time

_____
Relationship to Participant