INFORMED CONSENT
TO ACT AS A RESEARCH PARTICIPANT IN:

THE COMPREHENSIVE ASSESSMENT OF NEURODEGENERATION & DEMENTIA (COMPASS-ND) STUDY

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Location: McGill University-Jewish General Hospital Memory Clinic

This consent form describes a research study called the Comprehensive Assessment of Neurodegeneration & Dementia (COMPASS-ND) and what you may expect if you decide to participate. You are encouraged to read this consent form carefully and to ask the person who presents it any further questions you may have before making your decision whether or not to participate. This study is being sponsored by the Canadian Consortium on Neurodegeneration and Aging (CCNA), through a grant organized by the Canadian Institutes of Health Research (CIHR) and funded by multiple partners (CIHR, Alzheimer's Society of Canada, Sanofi, the New Brunswick Health Research Fund, the Robin and Barry Picov Family Foundation, the Saskatchewan Health Research Foundation, the Women's Brain Health Initiative, the Michael Smith Foundation for Health research, Alzheimer's Research UK, the Alberta Prion Institute, the Nova Scotia Health Research Foundation, and the Canadian Nurses Foundation).

PURPOSE AND GENERAL PLAN OF THIS STUDY

You (the research participant) are being asked to participate in a research study designed to assess individuals with different sorts of cognitive and movement changes seen in older adults. We (the study sponsor) will look at the usefulness of imaging studies, clinical assessments and biomarker tests (blood, saliva, urine, cerebrospinal fluid (optional), and feces (optional)) together with measurements of memory, thinking and daily functioning, for distinguishing these changes from each other and from healthy aging. You have been asked to participate because there are concerns about your memory, thinking or speaking ability, your behaviour, abnormal movements or problems walking. In order to participate, you must have an individual (spouse, friend, or relative), called a "study partner," who is willing to:

- Accompany you to all of the study visits
- Communicate to the study staff of changes in your health status over the period of this study.

DESCRIPTION OF STUDY PROCEDURES

This study will be conducted at approximately 35 sites in Canada. Approximately 50 participants from the Jewish General Hospital will participate in this study. Your participation may involve up to 5 visits

of 1 to 3 hours duration over the course of 3 months now as well as up to 5 similar visits 2 years from now. There will also be annual telephone contacts over the next 48 months (4 years). Over the course of the study you will be asked to:

- Give blood, saliva and urine samples;
- Provide information on your health, social engagement, nutrition, sleep, and physical activity;
- Have a physical and neurological examination done by a physician;
- Take tests of your sensory capacity (hearing, vision, and smell), of walking speed, and of memory, thinking skills, daily functioning and behaviour;
- Have Magnetic Resonance Imaging (MRI) scans of your brain;
- Consider being audio-recorded while you have a conversation with your study partner – this is optional
- Consider providing a fecal sample – this is optional
- Consider undergoing a Lumbar Puncture (LP) – this is optional;
- Consider Brain Donation at the time of death – this is optional.

During this study, Dr. Vaitekunas and her staff will be monitoring your condition.

DESCRIPTION OF STUDY EVALUATIONS

Visit 1 - Screening Evaluation & Demographic Information Gathering During this visit, we will determine your eligibility for the study. You will not be considered enrolled for the study until you and/or your authorized representative and your study partner have signed this consent form. You will be given cognitive tests (tests of memory and thinking). You may be asked if these tests can be observed by a neuropsychologist for the purposes of assessing and providing feedback to the site staff on the administration of these tests. It may be the case that the observation will be occurring by secure, encrypted video link. If you do not wish to have this session observed either by someone in the room or by someone observing via video link, you have the option to decline the observation. You will be asked about your daily functioning. You will be asked about your age, handedness, living circumstances, education, reproductive history, employment history, household income, driving history, nutrition and oral health. You will also be asked about symptoms of depression and anxiety. At the end of the visit you will be provided with a packet of questionnaires to be completed at your convenience at home. This visit will take approximately 2-3 hours.

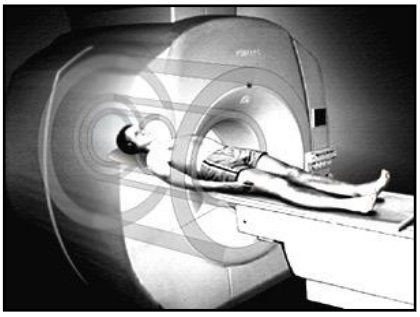
Investigation of Communication between participant and study partner (optional) – One of the things we want to study is how communication changes between people when one of them has cognitive changes. In order to do that we would like to audio-record a conversation between you and your study partner. If you agree, we would digitally record 15-20 minutes of conversation between you and your study partner during the snack break after the blood draw. The conversation you have can be on the topic or topics of your choice; it will be studied for conversational flow and understanding between the participant and the study partner. To avoid accidental recording of other people not involved in the study, this will occur in a private room with the door closed. If a third party not involved with the study is inadvertently recorded, that section or sections of the taped conversation will be erased. In addition, your study partner will be asked to complete a questionnaire on communication strategies. The audio recordings will be digitally uploaded to the CCNA data management system without identifying information and kept for 25 years. Access to these recordings will be restricted to only those with permission from the Publication and Data Access Committee (explained in detail in later section on Data Sharing and Future Use).

Visit 2 - Clinical & Physical Assessment For this visit, you will be asked not to eat or drink anything for at least 12 hours prior to coming to the clinic. This includes all food and drinks such as coffee, tea, milk and juice (water is OK). The first thing that will be done is that the nurse will take about 50 mls of blood (about 4 tablespoons). After this, you will be provided with a meal. You will also be asked to provide urine (about 20mls or 1.5 tablespoons) and saliva samples (about 4 mls or 1 teaspoon) at this visit. Your vital signs will be measured, as well as your height, weight, circumference of your waist, hips, neck and calf, and leg length. Your blood pressure will be taken while lying down, sitting, and standing. You will be asked about your perception of your health, your balance, and sleep. You will be asked about your current and past medications, your medical history, your mental history, your surgical history, and your family medical history. You will have a test of walking speed, both without doing another task at the time and while doing something else at the same time (saying words or doing calculations). You will be given tests of your vision, hearing, vision, smell identification, and grip strength. You will also be asked about your current condition and have a physical and neurological exam. The visit will take approximately 2 and a half to 3 and a half hours.

Fecal and Oral Samples (optional) - Bacteria in the gut and mouth may play an important role in neurodegenerative diseases and age-related disorders. We wish to collect oral and fecal samples to study changes that might occur in the bacteria of individuals with different forms of cognitive changes. If you agree to it, we will rub your inner cheek with a swab in order to collect mouth bacteria. We will also ask you would collect a fecal sample at home (we will supply a kit, gloves, and instructions), and then bring it in with you at one of your visits.

Visit 3 – Neuropsychological Assessment For this visit you will be given a series of tests to assess different aspects of your cognitive functioning. Most of the tests will be of a question and answer format, but some will involve paper and pencil and some will be done on computer. The tests will assess memory, language, attention, perceptual and construction abilities, processing speed, and response inhibition.The visit will take approximately 3 hours. You may be asked if this session can be observed by a neuropsychologist for the purposes of assessing and providing feedback to the site staff on the administration of these tests. It may be the case that the observation will occur with the neuropsychologist in the room or by secure and encrypted video link. If you do not wish to have this session observed either by someone in the room or by someone observing via video link, you have the option to decline the observation. If you have had a neuropsychological assessment for clinical purposes within the last year, tests from that assessment which are also in the COMPASS-ND neuropsychological assessment would not have to be repeated. You are being asked to consent to having your last neuropsychological assessment accessed by site staff and, when a COMPASS-ND neuropsychological test has been done, to have the results entered into the COMPASS-ND database without identifying information.

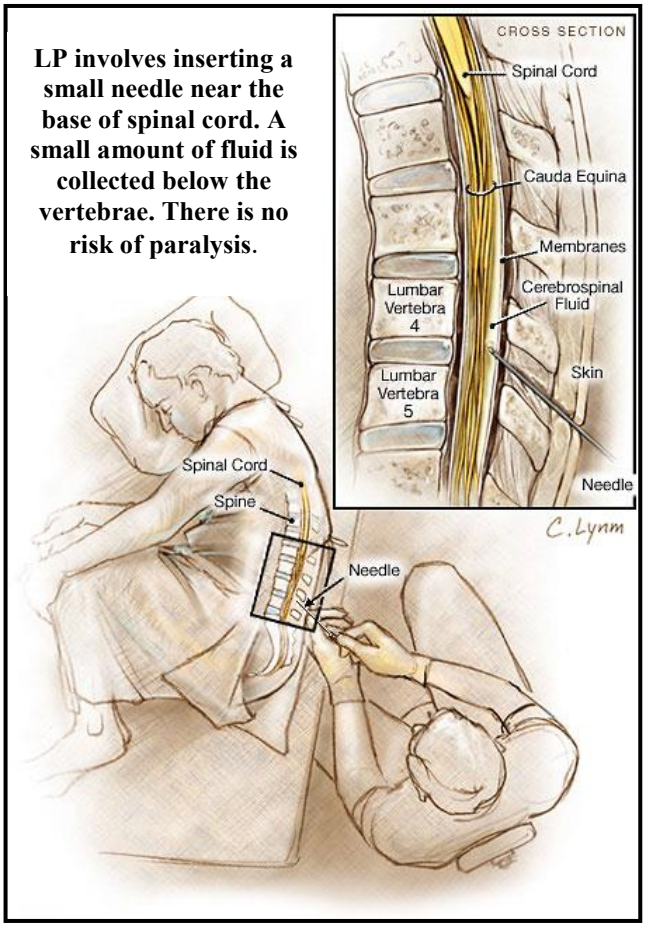
Visit 4 - Magnetic Resonance Imaging (MRI) Scans. This visit will take place after the initial screening visit but before the optional lumbar puncture. An MRI is an electronic picture of your brain created using a strong magnet instead of x-ray energy. Each MRI will take approximately 45 minutes to complete. You will lie on your back and enter the MR machine for the study. As the study is going on you will hear loud knocking noises. This visit will take approximately 1 hour. The MRI will be carried out at the specific MRI location used at your study site.



Sample MRI Machine

People with pacemakers, aneurysm clips, cochlear implants, or metal/foreign objects in their eyes are not permitted to undergo MR studies. The MRI is a mandatory part of this study so if you have any of these conditions or otherwise decline to undergo the MRI, you will not be eligible to participate in the study.

Visit 5 - Lumbar Puncture (LP) (optional). A lumbar puncture is a procedure in which a small amount of the spinal fluid that surrounds the brain and spinal cord is removed by inserting a needle in the lower back. You will be asked not to eat or drink anything (water is Ok) for at least 6 hours before the lumbar puncture visit. For this procedure, you will be positioned lying on your side and curled up in a ball, or sitting up and bent forward, whichever is easier for you. The lower part of your back will be cleaned with antiseptic. The study doctor will inject local anesthetic (lidocaine, 1%) into the skin of your lower back. When the area is numb, a very thin needle will be inserted into the spinal canal in the lower back, well below the level where the spinal cord ends. About 20 milliliters (1½ tablespoons) of spinal fluid will be removed for analysis and storage. Your body replaces this spinal fluid within 1-2 hours.



After the lumbar puncture is completed, you will remain in the clinic for about 30 minutes. You will be given something to eat and drink before you leave. You should not do any strenuous physical activity for the next 24 hours. This includes lifting, bending, doing housework and gardening, or doing exercise such as jogging or bicycle riding.

Study staff will call you the day following your lumbar puncture to discuss how you are feeling.

Telephone Checks and 2 year Follow-up

A member of the study team will contact you and your study partner by phone on a yearly basis to assess possible safety concerns, new medical conditions and new physical symptoms. Other questions may address whether there have been any changes in your behaviour or emotional state. If the study team feels that any new changes are of concern, further evaluations may be arranged. These calls will take approximately 5 – 10 minutes.

In 2 years, you will be invited to come back to the clinic to repeat the clinical and physical assessment, blood, saliva, and urine collection, neuropsychological assessment, and MRI scan. If in the meanwhile, due to a change in your condition, a decision is made by yourself and your family that someone other than yourself should be responsible for making decisions regarding what is best for you, the person with that decision-making responsibility will have to sign a consent form agreeing to your continued participation in the study.

Audio-recording of certain assessments: Some of the tests you will be given are required to be audio-recorded for the purposes of training, scoring, data monitoring and speech analysis. The tests which will be recorded are the memory and thinking tests in the screening visit and the entirety of the neuropsychology testing. All recordings will be labelled with a study code and will not have any

identifying information attached to them. The recordings will be uploaded to the study database to be monitored for data quality assurance. The recording will only be accessible to data quality assurance staff. Those recordings not required for speech analysis will be erased from the database after monitoring (no longer than 6 months after the recording). The recordings required for speech analysis will be kept on the database for research. The entire recording will also be kept on an external hard drive at the site of your assessment that will not be connected to the internet and kept in a locked cabinet. This copy of the recording will be kept for a period of 25 years.

Brain Donation (optional): Doctors generally diagnose dementia by asking patients and informants to report on changes they have noticed and identifying symptoms that are hallmarks of the disease, such as memory loss or loss of ability to do things one could do before. Despite advances, there is always some uncertainty about the diagnosis and the cause of the dementia. The only way to confirm the diagnosis and determine the cause of dementia with certainty is to look at brain tissue under a microscope after death. A brain autopsy is therefore a very important tool to help understand the cause of dementia and neurodegenerative diseases. Understanding the causes may help us to find more effective treatments in the future. To help scientists find the causes of neurodegenerative diseases, as well as discover new treatments, we request your permission to remove your brain at the time of death, and allow its use for research purposes. If you agree, a note will be put in your research file and procedures will be put in place to ensure that collection and transport of the brain is timely and minimally disruptive. The procedure for brain extraction does not disfigure the body and takes into consideration funeral preferences. A 24-hour delay, however, should be foreseen. Your consent will be re-affirmed at each telephone check. If at some point in the future a substitute decision maker for you is delegated, his or her consent for the procedure will be sought as well. Your brain will be sent to the closest of 6 hospitals in Canada (Queen Elizabeth II Health Sciences Centre, Halifax, NS; Douglas Mental Health University Institute, Montreal; Sunnybrook Health Sciences Centre, Toronto; University Health Network, Toronto; Foothills Medical Centre, Calgary; Vancouver General Hospital, Vancouver) where it will be stored in a brain bank. It will be stored for as long as it can provide useful scientific information. Should you decide at any time to withdraw your consent for brain donation, it will not affect your medical care or your continued participation in this study.

RESEARCH BIOSPECIMEN COLLECTION. Within the fluids of the body are components that may help to track the progression of dementia, as well as distinguish different types of dementia from each other. These components are referred to as biomarkers. Blood, saliva, cerebrospinal fluid (CSF) and urine will be collected in the Memory Clinic for different purposes in this research study. Blood will be analysed for hormone levels, lipid profile, and markers of general health and inflammation. Saliva will be analysed for metabolism related markers. Urine will be analysed for renal (kidney) function markers, and CSF will be analysed for proteins related to brain health. A portion of each type of sample will be put in storage for research on potential biomarkers in the future.

1) **Preparation for Biospecimen Collection–** You will be asked not to eat or drink anything (water is Ok) for at least 12 hours before biomarker blood draw and for at least 30 minutes before the saliva collection. There are no special preparations on the part of the participant for the other biospecimen collections.
2) **Genetic Research and Genotyping** – The cells of your body contain deoxyribonucleic acid or "DNA" for short. The DNA in most cells of your body is the same, and does not change during life. It carries the code for the genes that determine your physical appearance such as the color of your hair and eyes. You are being asked to agree to test DNA from your blood. DNA will be extracted from this blood sample for genetic research to assess the presence of a host of genes that may affect cognitive performance with aging.

Storage of Blood, Saliva, CSF and Urine Samples – You are being asked to agree to the storage of your biological samples at the Canadian Biosample Repository in Edmonton, Alberta which is run by Dr. Bruce Ritchie (for more information on this biobank, you may consult their website: http://www.biosample.ca/). Important research can be done in the future on samples collected today.

INCIDENTAL FINDINGS. Occasionally, an unexpected finding comes up in the course of assessing a participant that may require further medical attention, such as blood test results indicating elevated blood sugar or high cholesterol. All data collected in this study will be reviewed by an experienced reviewer for possible medically significant findings within 90 days of its collection. Any possible medically significant findings will be transmitted via the data management system to the study site staff where the participant was seen. The study site physician will be responsible for determining the significance of the finding. If the finding is judged medically significant, you will be contacted by either the study physician or your family doctor to arrange a visit to discuss the finding along with possible treatment options. The finding and its follow-up will be documented in your research file and its outcome will be monitored until it has been resolved or as long as you remain in the study. No information regarding this research will become part of your health record.

DATA STORAGE AND FUTURE USE

All data collected in this study will be stored in the Longitudinal Online Research and Imaging System (LORIS), a controlled access database at McGill University in Montreal that meets international security and safety standards. Numerous safeguards are in place to keep your information confidential. In particular,

- Personal identifiers will be removed (i.e. name, date of birth, etc.);
- Your personal details will be kept separate;
- Your data will be attached to a random series of 6 numbers which will be how it is identified within the study
- Stringent security measures will prevent unauthorized access or misuse.

These safeguards make it difficult to know which personal information came from you or any other participant. However, we cannot guarantee that you will never be re-identified. In the event of a problem with privacy, the site study investigator or his/her delegate will notify you immediately. Only coded data, which does not include anything that might directly identify you, will be shared for research purposes.

Audio recordings will be kept on the database and/or on external hard drives for 25 years. After that time, the audio recordings will be erased from the database and all storage devices.

SAMPLE STORAGE AND FUTURE USE

Researchers are working to find genes and other markers that play a role in the occurrence of neurodegenerative diseases and aging-related disorders. Blood, saliva, urine, and cerebrospinal fluid will be drawn for genetic and biomarker research tests, and DNA and RNA storage. While part of the samples you give will be used for research soon after its collection, some will be kept in storage to be used at a later time for research studies of neurodegenerative diseases and aging-related disorders that haven't been conceived of at this time. You are being asked to allow these samples to be stored for 25 years for future studies. The samples will be stored at the Canadian Biosample Repository in Edmonton, Alberta. They will be kept frozen during this time until they are studied.

MRI IMAGES STORAGE AND FUTURE USE

Your MRI images will be stored in LORIS at McGill University in Montreal. Your imaging data will be labeled with a coded research identifier to protect your identity. All links with your identity will be

removed from the data before they are shared. Only coded data, which does not include anything that might directly identify you, will be shared for research purposes.

SHARING OF FINAL RESEARCH DATA AND SAMPLES

Data and sample sharing is important for further translation of research results into knowledge, products, and procedures to improve human health. Data and samples from this research study, once they have had all identifying information removed, will be shared with CCNA researchers. If you agree to participate in another CCNA sponsored study, you may be asked for permission to have the data collected in COMPASS-ND used as part of that study. Data and samples will also be shared with other researchers around the world and used in future biomedical research projects that have received ethics approval. These projects can take place in universities, hospitals, non-profit groups, companies, and/or government laboratories. All researchers must respect the laws and ethical guidelines for biomedical research.

In order to access the data generated in this study, researchers must agree to abide by the CCNA Publication and Data Access policy, a document prepared by the CCNA Publication and Data Access Committee (PDAC) and which can be downloaded at www.ccna-ccnv.ca. The PDAC is made up of members of CCNA and is chaired by a member of the CCNA Research Executive Committee. Access to and analyses of CCNA acquired data by CCNA investigators will be granted automatically upon request of access to the PDAC and receipt of a signed copy of PDA policy. For non-CCNA investigators, CCNA data will not be available until one (1) year after data collection on the entire cohort has been completed, uploaded into LORIS, quality-controlled and cleaned, and subsequently locked. After the embargo period, non-CCNA investigators may be granted access to CCNA acquired data upon submission to the PDAC of background materials, a project outline supporting their data access request, and receipt of a signed copy of PDA policy. They will only be granted access to data related to the project outlined. CCNA partners will have the same access to CCNA acquired data as non-CCNA members, although they may ask CCNA investigators to pursue projects on their behalf.

Biological samples collected in this study will be stored at the Canadian Biosample Repository in Edmonton, Alberta. Approximately half of the samples will be used for planned analyses which will occur at the Jewish General Hospital Clinical Laboratory in Montréal, Québec (on blood and urine), the laboratory of Dr. Judes Poirier at the Douglas Mental Health University Institute in Montréal, Québec (CSF), and the laboratory of Dr. Roger Dixon at the University of Alberta in Edmonton, Alberta. The rest will be available for investigators who wish to perform further analyses on the whole cohort or a subset. Access to these remaining samples will be regulated by the Biological Sample Access Committee which is made up of members of CCNA (members list available on request). Requests for access will be assessed for feasibility, scientific rigour, and alignment with the consent of the participants. In order to be granted access to samples, investigators must agree that the data they generate from the samples will be included in the larger CCNA database on LORIS within 2 years of sample batch receipt.

RISKS

Participation in this study may involve some added risks or discomforts, which are outlined below.

BLOOD DRAWS. Removal of blood by a needle and syringe poses a small risk of pain or bruising at the site of the needle stick, but this is temporary. Some people may experience fainting or dizziness, and there is also a slight risk of infection at the site of the needle stick. To minimize these risks, experienced medical personnel will handle all the blood drawing procedures and sterile conditions will be

maintained. Up to 62 milliliters (about 4 Tablespoons) of blood may be taken during the baseline and 2 year follow-up assessments of this study and your body will make up for the loss.

MRI. There are no known biological risks associated with MR imaging. MRI does not use ionizing radiation (radiation that can alter chemical or biological compounds) or any type of radiation that is linked with cancer. An MRI may cause possible anxiety for people due to the loud banging made by the machine and the confined space of the testing area. There is also a risk of injury if metal is brought into the imaging room, which might be pulled into the MRI magnet. People with pacemakers, aneurysm clips, artificial heart valves, ear implants or metal/foreign objects in their eyes are not permitted to have an MRI. You will be asked if you have any of these things prior to having the scan.

EVALUATIONS. Evaluations of mood and mental status may cause frustration, boredom, or fatigue. Some questions in the evaluation, however, may trigger distressing feelings or memories. If you do feel distressed at any time during the evaluations, let the study staff know and they will stop the testing and allow time for the distress to dissipate. They will attend to you until you feel better and then consult with you about continuing the evaluation. Whether you wish to continue, stop for the day, or withdraw from the study, your wishes will be followed. If you feel distressed while completing the take-home questionnaires, put the document aside for a little while. If, after some time, you do not feel you can complete the questionnaires, return the document to the research staff and let them know what happened. They will consult with you about proceeding with the rest of the evaluations and respect your decision.

You may be asked to have your cognitive evaluations observed in person or via videolink by a neuropsychologist. If you agree to have your cognitive evaluations observed by a neuropsychologist via video link, the link will be encrypted and every effort will be made to insure you are not on camera except for your hands. However, there is the possibility that the link may be covertly decrypted and observed by a third party. The video link will not be recorded or stored.

LUMBAR PUNCTURES (LP). In total, up to 20 milliliters (about 1.5 Tablespoons) of spinal fluid may be taken during this entire study and your body will make up for the loss. During the procedure, you may have temporary pain and discomfort in your back. Headache may occur in people who undergo a lumbar puncture. Occasionally, a low pressure headache may develop, presumably due to leakage of spinal fluid. If this headache persists it may require additional treatment. Uncommonly a blood patch (injection of some of your blood into the lumbar puncture site to patch the spinal fluid leak) may be required. This often relieves the headache immediately. Although very rare, it is possible that you may have an allergic reaction to the local anesthetic (lidocaine l%) used for the lumbar puncture. This would cause swelling and a rash on your skin where the anesthetic was injected. Please tell us if you have ever had a reaction to local anesthetic before (such as when you were visiting the dentist). Potential but rare risks of lumbar puncture include infection, damage to nerves in your back, bleeding and bleeding that may affect the spinal cord or brain. The risk of these is very small (they occur once for every ten thousand people who undergo the procedure). The lumbar puncture procedure will be performed by a doctor specifically trained and experienced in the procedure.

GENOME-WIDE ASSOCIATION STUDY (GWAS): The genetic data extracted from your blood sample and submitted to the GWAS database will be coded, meaning it will not include anything that might directly identify you. There is a slight risk that there could be a breach in the security of this database system resulting in the access of information. Safeguards are in place to minimize this risk. Data is being provided to the database for broad sharing to approved investigators. There is not currently

technology available to identify you; however, people may develop ways in the future that would allow someone to link your genetic information back to you.

One of the risks associated with this research project relates to the disclosure of the results or the disclosure of your participation to third parties. Mere participation in genetic research projects could compromise or diminish your chances and the chances of your family of obtaining insurance (life insurance, disability, mortgage, or health) or certain types of employment.

BENEFITS OF PARTICIPATING IN THIS STUDY

There is no guarantee that you will personally benefit by participating in this research study. Your participation in this study will help the investigators learn more about the usefulness of biomarker and imaging studies for the future prevention and treatment of neurodegenerative diseases. The development of biomarker and imaging studies that track the development of neurodegenerative diseases and reflect the change in people's bodies may help other people who have a similar medical problem in the future. This study will not make your health better.

ALTERNATIVE MEDICATIONS AND TREATMENTS

The alternative is not to participate in this study and to continue under standard medical care in the memory clinic.

PARTICIPATION IN OTHER STUDIES

Participation in other clinical studies will be permitted. Once you are part of this study you may also be approached to participate in additional treatment and evaluation sub-studies related to this one (unless you specifically request not to be contacted further). Your participation in related studies does not affect your participation in this one. If you agree to participate in other CCNA sponsored studies, you may be asked if the data collected from you in this study can be shared with those studies. All shared data will be de-identified. If you are a participant in either the Ontario Neurodegenerative Disease Research Initiative (ONDRI) study or the *Consortium pour l'Identification précoce du Maladie d'Alzheimer du Québec* (CIMAQ) study, you will be asked if you agree for data that has been collected from you for that study to be shared with this study. The only data that will be shared is for procedures that are identical between the two studies. If you agree, it will result in fewer procedures needing to be done to complete this study.

CONFIDENTIALITY OF RECORDS

While you take part in this study, the site investigator and her or his study team will collect and take down information about you in a research study file. Only information necessary for the research study will be collected.

The information in your study file could include your past and present medical history, information about your way of life and test results from exams and procedures done during this study. Your file could also contain other information, such as your name, sex, date of birth and ethnic origin.

All the information collected about you during the study will remain confidential as the law demands. The laws of this province and Canada will be respected. To protect your privacy, your information will be identified with numbers and or letters (coded). Only the site investigator and her or his study team in charge of the study knows the numbers and or letters that link them to you.

The study will use the information collected about you for research purposes, only to reach the study goals as they are explained in this Information and Consent Form. Your study information will be kept by the researcher in charge of the study for 25 years after the study has ended.

The study information could be printed in medical journals or shared with other people at scientific meetings, but only in a way that makes it impossible to identify you.

To make sure the study is being done properly, your study file as well as your medical file could be checked by the study doctor, the study staff, a person authorized by the Research Ethics Committee of the Hospital, and the study Sponsor. These people and groups are obliged to respect your privacy.

You have the right to look at your study file in order to check the information gathered about you and to correct it, if necessary, for as long as the study researcher or the study site keeps this information (25 years after completion of the study). However, you may only have access to certain information once the study has ended so that the quality of the research study is protected.

GENETIC STUDIES: GWAS information and datasets are stored in the LORIS databases under strict security provisions, including multiple firewalls, separate servers, and data encryption protocols. Data submitted to any databases are de-identified and coded, meaning it will not include anything that might directly identify you. There is a slight risk that there could be a breach in the security of this database system resulting in the access of information. Safeguards are in place to minimize this risk. Data is being provided to the database for broad sharing to qualified investigators.

COMPENSATION

Procedures related to the study will be provided at no charge to you. Transportation costs (taxi or parking) will be covered up to $30/visit (this covers both the participant and the study partner, not each individually).

COMMERCIALIZATION

Your participation in this research study could lead to the making of commercial products. However, you will not receive any money from the sale of these products.

COMPENSATION IN CASE OF INJURY

Should you suffer harm of any kind following any procedure related to the research study, you will receive the appropriate care and services as required by your state of health.
By agreeing to participate in this research study, you do not give up any of your legal rights nor discharging the doctor in charge of this research study, the sponsor or the institution, of their civil and professional responsibilities.

CONTACT PERSONS

You have the right to ask, and have answered, any questions you may have about this research. If you should have any questions about this research or feel that you have suffered from a research related medical problems at any time during this study, you may contact the study doctor, **Dr. Susan Vaitekunas** at **(514) 340-8222** or the coordinator, **Chris Hosein** at **(514) 340-8222 ext: 23621**.

If you have any questions about your rights as a research subject, you may call the local commissioner of Rosemary Steinberg **at (514) 340-8222 ext: 25833** to report a research-related complaint.

VOLUNTARY PARTICIPATION

Your participation in all aspects of this research study is entirely voluntary. You have the right to refuse to participate, or may discontinue participation in this project at any time without jeopardy to the

medical care you receive at this institution. There is also the possibility that the investigators may decide to terminate your study participation at any time. You will be informed of any new findings that may affect your continued participation. If you are terminated early from the study for any reason, you will be asked to come in for a final visit to ensure your questions about termination and any changes to your medical care are addressed. You may request that your data and any unused samples be destroyed. However, data and samples that have already been shared will not be retrieved.

You may also revoke the authorization to use or disclose personal information about your health. If you choose to withdraw your authorization, you must notify Dr. Susan Vaitekunas.
The information collected about you prior to your withdrawal from the study will still be used. Information that has already been sent to the sponsor cannot be withdrawn.

INFORMED CONSENT
TO ACT AS A RESEARCH PARTICIPANT IN:

THE COMPREHENSIVE ASSESSMENT OF NEURODEGENERATION & DEMENTIA (COMPASS-ND) STUDY

STATEMENT OF CONSENT

I have read the information and consent form. I have had the research project and this information and consent form explained to me. My questions were answered and I was given the time to make a decision. Upon reflection, I consent to participate in this research project under the conditions set out in this form.

By signing this consent you are authorizing the use of your data for large scale, multi-center studies that will combine data from similar populations. These multi-center studies are being conducted by the Canadian Consortium on Neurodegeneration in Aging (CCNA) a consortium of universities and research institutes. Your data will be stored with a coded research identifier to protect your identity. Only coded data, which does not include anything that might directly identify you, will be shared with CCNA members and the general scientific community for research purposes. This data will be entered into study databases to be used from this date and going forward. Genetic study data will also be made available through the Database of Genotype and Phenotype following NIH policy.

Unless you authorize the use and disclosure of your personal health information, you cannot participate in this research study. If you refuse to give your authorization, your medical care will not be affected.

You agree to have the cognitive testing you will undergo **OBSERVED BY A NEUROPSYCHOLOGIST IN PERSON OR VIA VIDEOLINK for the purposes of staff training and assessment (optional)**.

☐ **Yes** ☐ **No** _____ **Participant Initials**

You agree to be **AUDIO-RECORDED for the purposes of studying communication in relation to cognitive change (optional)**.

☐ **Yes** ☐ **No** _____ **Participant Initials**

You agree to provide a **FECAL and ORAL sample (optional)**.

☐ **Yes** ☐ **No** _____ **Participant Initials**

You agree to undergo a **LUMBAR PUNCTURE PROCEDURE (optional)**.

☐ **Yes** ☐ **No** _____ **Participant Initials**

INFORMED CONSENT
TO ACT AS A RESEARCH PARTICIPANT IN:

THE COMPREHENSIVE ASSESSMENT OF NEURODEGENERATION & DEMENTIA (COMPASS-ND) STUDY

STATEMENT OF CONSENT CONTINUED

You agree to **DONATE YOUR BRAIN at time of death (optional).**

☐ **Yes** ☐ **No** _____ **Participant Initials**

You agree to **BE CONTACTED FOR OTHER STUDIES RELATED TO THIS ONE (optional)**

☐ **Yes** ☐ **No** _____ **Participant Initials**

If you are also enrolled in the Ontario Neurodegenerative Disease Research Initiative (ONDRI) study or the *Consortium pour l'Identification précoce du Maladie d'Alzheimer du Québec* (CIMAQ) study:

You agree to **the DATA collected about you in that study being SHARED with this study.**

☐ **Yes** ☐ **No** _____ **Participant Initials**

You agree **that the SAMPLES of blood, saliva, CSF, and urine collected from you in this study should be retained until depleted. Important research can be done in the future on samples collected today.**

☐ **Yes** ☐ **No** _____ **Participant Initials**

You agree **to the DATA and SAMPLES collected from you in this study being SHARED in anonymized form with international researchers for research projects that may take place in universities, hospitals, non-profit groups, private companies and/or government laboratories and used for research studies not as yet conceived of.**

☐ **Yes** ☐ **No** _____ **Participant Initials**

You will receive a copy of this consent form.

I authorize the research team to have access to my medical records.

By signing this consent form, I do not waive any of my legal rights.

I consent to participate in this study.

INFORMED CONSENT
TO ACT AS A RESEARCH PARTICIPANT IN:

THE COMPREHENSIVE ASSESSMENT OF NEURODEGENERATION & DEMENTIA (COMPASS-ND) STUDY

STATEMENT OF CONSENT CONTINUED

Study Participant (print)	**Signature**	**Date**

Signature of person obtaining consent

I explained to the participant the research project and this information and consent form and I answered the questions asked of me.

Person Obtaining Consent (print)	**Signature**	**Date**

Commitment of the site study investigator

I certify that this information and consent form has been explained to the participant and that his questions have been answered.

I agree, with the research team, to respect what has been agreed to in the information and consent form and to provide a signed and dated copy to the participant.

Site Study Investigator (print)	**Signature**	**Date**