



**INFORMED CONSENT
TO ACT AS A STUDY PARTNER IN:**

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

Site Investigator(s): Susan Vaitekunas, Howard Chertkow, Susan Gold, Olivier Beauchet, Elise Levinoff, Haibin Yin, Patrice Tremblay TEL: (514) 340-8222 ext. 23621

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 Foundation, the Saskatchewan Health Research Foundation, the Women's Brain Health Initiative, the Michael Smith Fund for Health research, Alzheimer's Research UK, the Alberta Prion Institute, the Nova Scotia Health Research Fund, and the Canadian Nurses Foundation).

PURPOSE AND GENERAL PLAN OF THIS STUDY

You (the study partner) are being asked to be a study partner 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, 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 be a study partner because there are concerns about the participant's memory, thinking or speaking ability, behaviour, abnormal movements or problems walking. The responsibilities of the study partner in this study are to:

- Accompany the participant to all of the study visits
- Complete questionnaires about aspects of the participant's life and circumstance
- Communicate to the study staff of changes in the participant's 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 volunteers and study partners from this facility will participate in this study. Your participation may involve up to 5 visits now as well as up to 5 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:

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- Accompany the participant to the visits;
- Consider being audio-recorded while you have a conversation with your study partner – this is optional;
- Provide information on the participant's activities of daily living, quality of life, possible changes in behavior, and your experience of caregiving;
- Consider Brain Donation from the participant at the time of his or her death – this is optional.

During this study, Dr. Vaitekunas and her staff will be monitoring the participant's condition.

DESCRIPTION OF STUDY EVALUATIONS

Visit 1 - Screening Evaluation & Demographic Information Gathering During this visit, we will determine the participant's and your eligibility for the study. You will not be considered enrolled for the study until you have signed this consent form. You will be asked about the participant's daily functioning. You may be asked about the participant's age, handedness, living circumstances, education, reproductive history, employment history, household income, driving history, nutrition and oral health if they are unable to provide this information. 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.

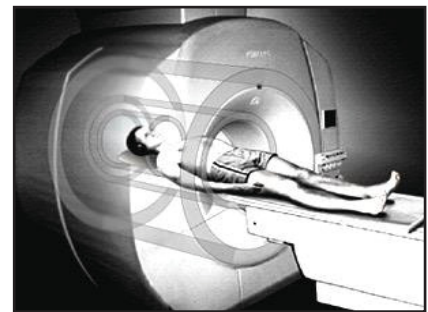
Investigation of Communication between participant and study partner (optional) – One of the things we want to study is how communication changes between people when one of them has cognitive changes. In order to do that we would like to audio-record a conversation between you and the study participant. If you agree, we would digitally record 15-20 minutes of conversation between you and the study participant 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, you 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 to insure the participant not 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) from the participant. After this, the participant will be provided with a meal. The participant 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. The participant's vital signs will be measured, as well as height, weight, circumference of the waist, hips, neck and calf, and leg length. His/her blood pressure will be taken while lying down, sitting, and standing. S/he will be asked about his/her perception of his/her health, balance, and sleep. S/he will be asked about current and past medications, medical history, mental health history, surgical history, and family medical history. You may be asked to provide some of this information if the participant is unable to. S/he 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). S/he will be given tests of vision, hearing, smell identification, and grip strength. S/he will also be asked about his/her 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 agreed to, we will rub the participant's inner cheek with a swab in order to collect mouth bacteria. We will also ask for a fecal sample to be collected at home (we will supply a kit, gloves, and instructions), put in a freezer, and then brought in at one of your subsequent visits. You may be asked to assist the participant with this.

Visit 3 – Neuropsychological Assessment For this visit the participant will be given a series of tests to assess different aspects of 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 2 to 3 hours.

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 the brain created using a strong magnet instead of x-ray energy. Each MRI will take approximately 45 minutes to complete. The participant will lie on his/her back and enter the MR machine for the study. 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 the participant has any of these conditions or otherwise declines to undergo the MRI, the participant and you, the study partner, 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. The participant 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, the participant will be positioned lying on his/her side and curled up in a ball, or sitting up and bent forward, whichever is easier for the participant. The lower part of his/her back will be cleaned with antiseptic. The doctor will inject local anesthetic (lidocaine, 1%) into the skin of the 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. The body replaces this spinal fluid within 1-2 hours.

After the lumbar puncture is completed, the participant will remain in the clinic for about 30 minutes and given something to eat and drink before he/she leaves. The participant 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 the day following the lumbar puncture to discuss how the participant is feeling.

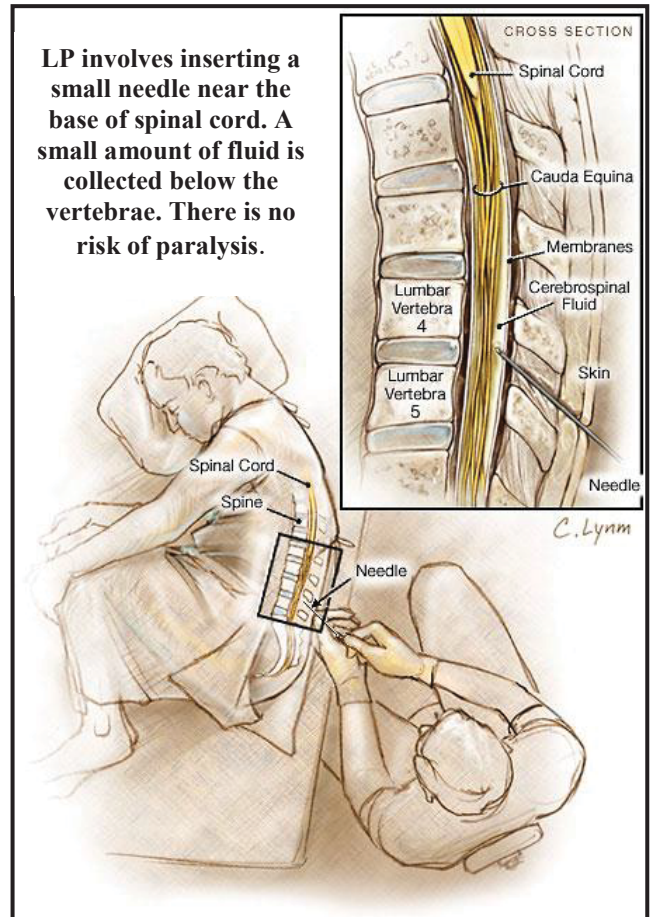
Telephone Checks and 2 year Follow-up

A member of the study team will contact you and the study participant by phone on an annual basis to assess possible safety concerns, new medical conditions and new physical symptoms. Other questions may address whether there have been any changes in the study participant's 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 and the study participant 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.

Audio-recording of certain assessments: Some of the tests given to the participant 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 research 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): To help scientists find the causes of neurodegenerative diseases, as well as discover new treatments, we request your permission to remove the study participant's brain at the time of death, and allow its use for research purposes. If you and the study participant agree, a note will be put in the study participant's research file and procedures will be put in place to ensure that collection and transport of the brain is prompt and without incident. Information about desired funeral arrangements will be gathered at the time of the donation. Removing the brain should not interfere with the funeral service as there are usually no visible scars and a donor can have an open casket visitation if he/she or the family wish. A 24-hour delay, however, should be foreseen to insure for proper preparation of the body. Consent will be re-affirmed at each telephone check. At the time of death, the participant's brain will be collected and sent to the closest of 6 hospitals in Canada (Queen Elizabeth II Health Sciences Centre, Halifax, NS; Douglas Mental Health University Institute, Montreal; Sunnybrook



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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 is deemed of scientific value. Should you or the study participant decide at any time to withdraw your consent for brain donation, it will not affect the study participant's medical care or continued participation in this study.

RESEARCH BIOSPECIMEN COLLECTION. Blood, saliva, cerebrospinal fluid (CSF) and urine will be collected in the Memory Clinic for different purposes in this research study.

- 1) Measurement of **Biomarkers** – The participant will be asked not to eat or drink anything (water is Ok) for at least 12 hours before biomarker blood draw.
- 2) **Genetic Research and Genotyping** – The cells of the body contain deoxyribonucleic acid or “DNA” for short. The DNA in most cells of the 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. The participant is being asked to agree to test DNA from his/her 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. First degree relatives of the participant may also be asked to provide blood for DNA testing. If so, further details and a separate consent form will be provided and explained at the time of the request.

Storage of Blood, Saliva, CSF and Urine Samples – The participant is being asked to agree to the storage of his/ her blood, saliva, CSF, and urine samples. The samples will be stored 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, the study participant will be contacted by either the study physician or his/her family doctor to arrange a visit to discuss the finding along with possible treatment options. The finding and its follow-up will be documented and its outcome will be monitored until it has been resolved or as long as the study participant remains in the study.

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 study participant's and their study partner's personal 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 coded; and
- 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.

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 these data be 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 after 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..

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.

RISKS

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

EVALUATIONS. Repeated evaluations of mood and mental status may be slightly frustrating or produce fatigue and boredom.

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 clinical, biomarker and imaging studies for the future prevention and treatment of neurodegenerative diseases. The development of clinical, 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.

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 about you in the participant study file could include your relation to the participant and how often you interact with them. Your file could also contain other information, such as your name, and sex.

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.

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, the participant's study file as well as his/her 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

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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.

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

If you suffer an injury as a result of participating in the study, all necessary medical treatment will be provided at no additional cost to you. By signing this consent form you do not give up any of your legal rights nor relieve the sponsor, institution and investigator from their professional and legal 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 safety. 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 STUDY PARTNER IN:**

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(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 be **AUDIO-RECORDED** for the purposes of studying communication in relation to **cognitive change (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**

