LETTER OF INFORMATION AND CONSENT FORM TO ACT AS A RESEARCH PARTICIPANT IN BRAIN DONATION STUDY

Investigator(s): **Dr. Elizabeth Finger, MD, FRCPC, FAAN (Principal Investigator)**
Dr. Stephen Pasternak, MD, CM, PhD (Co-Investigator)
Dr. Lee-Cyn Ang, MBBS, PhD, FRCPC (Co-Investigator)
Dr. Qi Zhang, MBBS, PhD, FRCPC (Co-Investigator)

Location: **Cognitive Neurology, Parkwood Institute Main Building, 550 Wellington Road, London, Ontario, Canada, N6C 5J1, Phone: 519-646-6032**

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*The pronouns “you” and “your” in the letter should be read as referring to the participant rather than the substitute decision maker who may be signing the consent for the participant.

PURPOSE

Neurodegenerative diseases (such as Alzheimer’s disease, Frontotemporal Dementia, and Lewy Body Dementia) progressively damage cells in the brain, resulting in deficits in memory and thinking, personality, and behavior. While some progress has been

made in understanding these disorders, there are still many unanswered questions about how these diseases start in the brain and why they cause damage to brain cells. The ability to study brain tissue, blood and spinal fluid from patients with neurodegenerative diseases and dementia, and healthy participants is an important approach to understand the cause and risk factors towards finding treatments that can slow, prevent, or cure these disorders.

A biobank is a type of repository that stores biological samples (usually human tissue, blood etc) for use in research. These samples are retained indefinitely and distributed at large to local and external researchers who request them for future research (each of these future projects will obtain their institutional research ethics approval).

The goals of DEC Brain & BioBank are to 1) increase public awareness of the value of post-mortem brain donation; 2) simplify the process of becoming a donor; and 3), to act as a central resource to coordinate brain donation and facilitate the distribution of high-quality, well-characterized human post-mortem brain tissue to qualified researchers locally and globally, respecting complete confidentiality of the donor.

As a patient with a neurodegenerative disease, the investigators would like you to consider donating the brain and spinal cord after your death to DEC Brain & BioBank for research purposes. In addition, a blood draw is required for enrolment in the study while alive. A data collection form will also be filled out regarding your present and past medical history, at the time of the enrolment.

By signing this informed consent form, you grant permission to DEC Brain & BioBank team to transfer your brain and spinal cord tissue from the clinical pathology department at LHSC to the DEC Brain & BioBank at Robarts Research Institute, after the 2year mandatory clinical storage period. You also agree to have the blood samples, along with information of your medical history, age, clinical symptoms and signs, and neuroimaging findings to be stored in the DEC Brain & BioBank. You also give permission to DEC Brain & BioBank that genetic analysis can be conducted on the collected samples for research purposes. Genetic research is the study of DNA. DNA is what your genes are made of. Research with genes involves studying changes that are inherited (passed on in families). Heredity is the passing of genetic information and traits (such as eye colour) from parents to their biological children. Studying DNA can help explain why some people respond to some medications and others do not. It can also explain why some people get some diseases and others do not. Please remember this is an invitation to participate in the study.

WHAT IS EXPECTED OF YOU DURING INITIAL ENROLMENT & FOLLOW UP

To ensure a smooth donation process, it is essential that your family is aware and supportive of your decision to agree to brain and biosample donation. We strongly advise that you discuss your decision with your family and to have them read this letter of information. Planning before time of death will be much easier for the family and it will help a planned donation to proceed as arranged. You will need to identify an individual (spouse, relative or friend), called a "study partner/substitute decision maker," who is willing to communicate any changes in your health status and contact information during the period of this study, should you become unable to communicate to us directly.

You will be enrolled in the DEC Brain & BioBank Donation Program once you and/or your substitute decision maker have signed this consent form.

- Study staff will discuss the donation program procedures with you. Participation will require approximately 30 minutes for initial enrolment and blood draw.
- The following information would be collected: contact information for yourself and your study partner, your primary care provider, and designated mortuary, if applicable.
- You will be provided a wallet-size enrollment card, for you to sign and carry with you if you choose.
- You and your study partner will receive information about how to contact site staff at the time of your death.
- There is also an optional component of cerebrospinal fluid donation in this study via lumber puncture with a separate LOI.
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- We can send information to your primary care provider, upon request.
- Study staff will conduct follow up assessments (over phone annually for 5 minutes) to confirm your decision to participate in the study, review and verify contact information for you and your study partner, primary care provider, and designated mortuary, if applicable.
- If you live in a residential or care facility, we request that you confirm periodically with the staff that they remain aware of your enrollment in the brain donation program and of the importance of DEC Brain & BioBank staff being contacted promptly upon your death.
- You are required to notify us of any changes to your study partner, primary care provider, residential or care facility and designated mortuary (if applicable) during the course of the study.
- You will need to make arrangement for your study partner, family or caretaker to contact us immediately upon your death. This will help the post-mortem arrangements to be carried out smoothly in a timely efficient manner.

AFTER DEATH PROCEDURES

Following death autopsy will be performed by the pathologists at Autopsy Suite at the University Hospital, London, Ontario. The study coordinator at Parkwood Institute will assist your family and funeral home in arranging for the brain donation and transportation of the participant's body to and from University Hospital in London. In addition to this research consent form, a London Health Sciences Centre Autopsy Authorization (Consent) form for routine clinical autopsy of the brain is also to be completed by the individual giving consent or substitute decision maker. The autopsy will take between 1 and 3 hours. The brain donation will be performed in a manner that does not disturb the participant's face or hair, so an open-casket funeral is possible. Every effort will be in place to allow undisturbed flow of the funeral arrangements prepared for the participants.

BRAIN TISSUE SAMPLE STORAGE & FUTURE USE

Following a clinical autopsy and routine clinical storage of the brain tissue samples for 2 years by the Clinical Pathology Department, the participant's brain tissue will be transferred to the DEC Brain & BioBank at Robarts Research Institute, Western University, for indefinite storage. Brain tissue samples and neuropathological data will be labeled with a coded research identifier to protect identity of the participant. Study investigators will maintain and be responsible for deciding how this data and tissue will be used for future research.

All links with participant's identity will be removed from the data before they are shared. Although the researchers of the DEC Brain & BioBank will get some identifying information, such as name, date of birth, date of death, race and gender, only de-identified data (which does not include anything that might directly identify the participant) will be shared with other investigators or with the general scientific community and be used for research purposes only.

RISKS

Blood Draw During Enrolment: 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 study personnel will handle all the blood drawing procedures and sterile conditions will be maintained. Up to 50 milliliters of blood may be taken for this study and your body will make up for the loss shortly afterwards.

Genetic analysis: When you donate your blood or tissue for genetic testing or research, you are sharing genetic information, not only about yourself, but also about biological (blood) relatives who share your genes or DNA. There is a risk that information gained from genetic research could eventually be linked to participants. This potential re-identification of the information could lead to loss of privacy and to possible future discrimination in employment or insurance, against participants or their biological relatives. Participants should be aware that genetic information cannot be protected from disclosure by court order. Due to the rapid pace of technological advances, the potential future use of genetic information is unknown and therefore the potential future risks also are unknown.

Autopsy: Since the brain donation via autopsy will occur after death, there is no risk to the participant health.

Data: All data will be kept in locked files or secure computer servers, and only de-identified data will be shared with other researchers. However, some de-identified information about the participant (age, sex, diagnosis, family history of neurological diseases, medical history) will be available to researchers involved in the processing or analysis of the BioBank samples.

COMPENSATION FOR PARTICIPATING IN THIS STUDY

There is no compensation for taking part into the study. Procedures related to this study will be provided at no charge to the participant. There will be no costs to the participant for taking part in this study. Incidental costs directly associated with participating in this research study will be reimbursed to the substitute decision maker/next of kin of the participant such as transportation to and from the Autopsy Suite or parking for blood draw visit.

POTENTIAL BENEFITS OF PARTICIPATING IN THE STUDY

Although the study is of no direct benefit to you, the knowledge gained through research is expected to be beneficial to society and future generations by enhancing the understanding of the mechanisms of these neurodegenerative diseases, and therefore potentially informing new approaches to treatment for these currently incurable brain diseases.

ALTERNATIVES TO PARTICIPATING IN THE STUDY

The alternative is not to participate in the study. You may wish to withdraw from the study at any point and not donate your brain after death anymore. In this case the collected fluid sample will be destroyed as per hospital procedures and all your data information removed from Brainbank database. Should your relatives or substitute decision maker wish to withdraw your sample from the bank after your death it can also be accomplished in the same manner stated above. A study staff will help with such process. However any sample or data that has already been shared with other researchers (before the withdrawal request is made) can no longer be retrieved.

VOLUNTARY PARTICIPATION

Participation in the brain donation study is completely voluntary. A decision not to participate will not result in any penalty or loss of benefits or standard of care to which the participant may be entitled.

CONFIDENTIALITY

Information obtained from the brain donation study will remain confidential as the law demands. The laws of this province and Canada will be respected. All data will be electronically stored on an electronic data capture system called REDCap hosted by Lawson Health Research Institute. Identifiable information will be stored after 15 years. Only information necessary for the research study will be collected. To protect your identity, any images will be de-identified and given a unique code. Information related to your age, sex, race, health condition, medical history and other relevant clinical information will be related to the sample code and hence unidentifiable. Information resulting from any biomarker research will not be entered into participant's regular medical records. Genetic datasets are stored 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. We may publish the results of this study in medical journals, newspapers, media or share with other people at scientific meetings, but participants will not be identified in any articles by name, address, or any other direct personal identifier. Researchers who request data and tissue from the DEC Brain & BioBank will only receive de-identified data to share with other study members or with the scientific community in general.

OTHER ASPECTS

By signing the consent form, you are not waiving any of your legal rights.

QUESTIONS/INFORMATION

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:

Dr. Elizabeth Finger, 519-646-6100 Ext 66032
Mailing address:
St. Joseph's Health Care
Department of Neurology, Dr. E. C. Finger
P.O. Box 5777, Station B
London, Ontario Canada
N6A 4V2
If you have any questions about your rights as a research participant or the conduct of this study, you may contact St. Joseph's Health Care London Patient Relations Consultant at 519-646-6100 ext. 61234
In the event the Brain BioBank ceases to exist, please choose one of the following options:

[ ] I choose to transfer my biosample and associated data to the successor brain bank with similar research objectives

Or

[ ] I choose to destroy my biosample and associated data lawfully as per the hospital neuropathology lab policy

By signing this page, you are confirming to the following:

- You have read all of the information in this consent form, and you have had the time to think about it.
- All of your questions have been answered to your satisfaction.
- You voluntarily agree to be part of this research study, to follow the study procedures, and to provide necessary information to the study doctor, nurses, or other staff members, as requested.
- You may freely choose to stop being a part of this study at any time.
- You allow the study doctor to use and disclose your personal health information as described in this document.

- You give permission to DEC Brain & BioBank team for the acquisition of any of your demographic, present and past medical or neurological data from your respective physicians.
- Your study partner/ substitute decision maker will notify the brain BioBank coordinator as soon as possible after your death.

You will receive a copy of this signed consent form for yours to keep.

You are giving consent to the use of your data and biological materials for any large scale, multi-center studies that may combine data from similar populations. Your data and biological samples will be stored with a coded research identifier to protect the identity. Only de-identified data will be shared with study 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 data may be made available on NIH-approved secured databases for research and publication purposes only.

By signing below, you voluntarily agree to participate in brain donation to the DEC Brain & BioBank.

Study Participant Name (print)	**Signature**	**Date**
Substitute Decision Maker (print)	**Signature**	**Date**
Person Obtaining Consent (print)	**Signature**	**Date**