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

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*The pronouns "you" and "your" in the letter should be read as referring to 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 substitute decision maker on behalf of the participant in the current research, the investigators would like you to consider donating the brain of the deceased individual to DEC Brain & BioBank for research use. A data collection form will also be filled out regarding participant’s medical and neurological history at the time of enrolment in the study.

By signing this informed consent form, on behalf of the participant you grant permission to DEC Brain & BioBank team to transfer participant’s brain and spinal cord tissue from the clinical pathology department at LHSC to the DEC Brain & BioBank at Robarts Research Institute, after the 2 year mandatory clinical storage period. You also agree to have the information of participant’s medical history, age, clinical symptoms and signs, and neuroimaging findings to be stored in the database of 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.

PROCEDURES

Following consent, 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. Every effort will be made to allow undisturbed flow of the funeral arrangements prepared for the participants.

BRAIN & SPINAL CORD TISSUE SAMPLE STORAGE & FUTURE USE

Following a clinical autopsy, neuropathological analysis 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. 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

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

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 information about the participant (age, diagnosis, family history of neurological diseases, medical history) will be available to researchers involved in the processing or analysis of the BioBank samples.

When blood or tissue is donated for genetic testing or research, genetic information is shared, not only about participant, but also about biological (blood) relatives who share participant's 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.

COMPENSATION FOR PARTICIPATING IN THIS STUDY

Procedures related to this study will be provided at no charge to 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.

VOLUNTARY PARTICIPATION

Participation in the brain donation study is voluntary. A decision not to participate will not result in any penalty or loss of benefits to which the participant may be entitled. At any point should the substitute decision maker/next of kin of participant wish to withdraw the participant from the study they may do so by contacting the study coordinator. At this stage the samples will be removed from BioBank and destroyed as per the hospital’s biological sample disposal policy and no longer be available to future researchers. Samples that already have been shared before the request is made can no longer be retrieved.

CONFIDENTIALITY

Information obtained from the brain donation will be retained and kept confidential. 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. Any images will be de-identified and given a unique code. Information related to participant’s age, sex, race, health condition, 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. We may publish the results of this study for others to read, but participants will not be identified in any articles by name, address, or any other direct personal identifier. Researchers who request data and tissue samples from the DEC Brain & BioBank will only receive de-identified data, which (does not include anything that might directly identify participant) will be shared with other study members or with the general scientific community for research purposes.

ALTERNATIVES TO PARTICIPATING IN THE STUDY

The alternative is not to participate in the study.

POTENTIAL BENEFITS OF PARTICIPATING IN THE STUDY

Although the study is of no direct benefit to the participant, 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.

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 participant's biosample and associated data to the successor brain bank with similar research objectives

Or

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

By signing this page of behalf of the participant, you are confirming the following:

- You have read all of the information in this consent form, and you have had time to think about it.

- All of your questions have been answered to your satisfaction.
- You voluntarily agree for the participant 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 participant’s personal health information as described in this document.
- You give permission to DEC Brain & BioBank team for the acquisition of any of participant’s demographic, present and past medical or neurological data from his/her respective physicians.

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

You are giving consent to the use of participant’s data (demographic, medical, neurological) and biological materials for large scale, multi-center studies that may combine data from similar populations. Participant’s data and biological samples will be stored with a coded research identifier to protect the identity. Only de-identified data, which does not include anything that might directly identify the participant, will be shared with the study members and the general scientific community for research purposes only. This data may be entered into study databases to be used from this date and going forward. Genetic data may be made available on NIH-approved secure databases for research publication purpose only.

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

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