

LOI FOR TRANSFER OF LEFTOVER SAMPLES TO DEC BRAIN & BIOBANK FROM PARTICIPANTS WITH NEURODEGENERATIVE DISEASES



**LETTER OF INFORMATION AND CONSENT FORM
TO DONATE LEFTOVER SAMPLES FROM STANDARD OF CARE OR OTHER
RESEARCH STUDIES TO DEC BRAIN & BIOBANK**

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Phone: 519-646-6032

Funding: London Health Sciences Foundation (LHSF)

*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

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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 participant in the current research, the investigators would like you to consider donating your leftover or unused blood, serum/plasma and cerebrospinal fluid (CSF) samples, from other studies that you have participated with us in the past or currently ongoing, or from any standard of care procedure, to DEC Brain & BioBank for storage and research purpose. 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 that any of your leftover blood, serum/plasma or CSF samples, to be donated to DEC Brain & BioBank for storage and research use. 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

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To ensure a smooth donation process, it is essential that your family is aware and supportive of your decision to agree to biosample donation. We strongly advise that you discuss your decision with your family and to have them read this information. Participation will require approximately 15 minutes for initial enrolment and consent sign. During your regular clinic visit and/or telephone visit/check, we will confirm your decision to participate. You will need to identify an individual (spouse, relative or friend), called a “study partner,” 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 are required to notify us of any changes to your study partner, primary care provider, residential or care facility during the course of the study.

SAMPLE STORAGE & FUTURE USE

All samples will be stored at the DEC Brain & BioBank at Robarts Research Institute, Western University, for indefinite storage. Samples and 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 sample 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, 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

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.

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

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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. There will be no costs to the participant for taking part in this study.

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. 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 leftover sample donation to DEC Brain & BioBank is completely voluntary. A decision not to participate will not result in any penalty or loss of benefits or standard of care to which you may be entitled.

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CONFIDENTIALITY

Information obtained from this sample donation 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 samples 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

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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.

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- 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.

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 publication purpose 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