



**SUB STUDY LETTER OF INFORMATION AND CONSENT FORM
TO OBTAIN CEREBROSPINAL FLUID WITH LUMBAR PUNCTURE – AN OPTIONAL
PROCEDURE IN BRAIN DONATION MAIN STUDY**

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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

DEC BRAIN & BIOBANK SUB STUDY LOI FOR LUMBAR PUNCTURE (CSF)

You are being invited to take part in this optional sub study because you have already consented to donate your blood and postmortem brain tissue to the DEC Brain & BioBank. As a participant in the current research, the investigators would like you to consider donating a sample of your cerebrospinal fluid (CSF) to DEC Brain & BioBank, which will be obtained through a lumbar puncture procedure by a specialized physician.

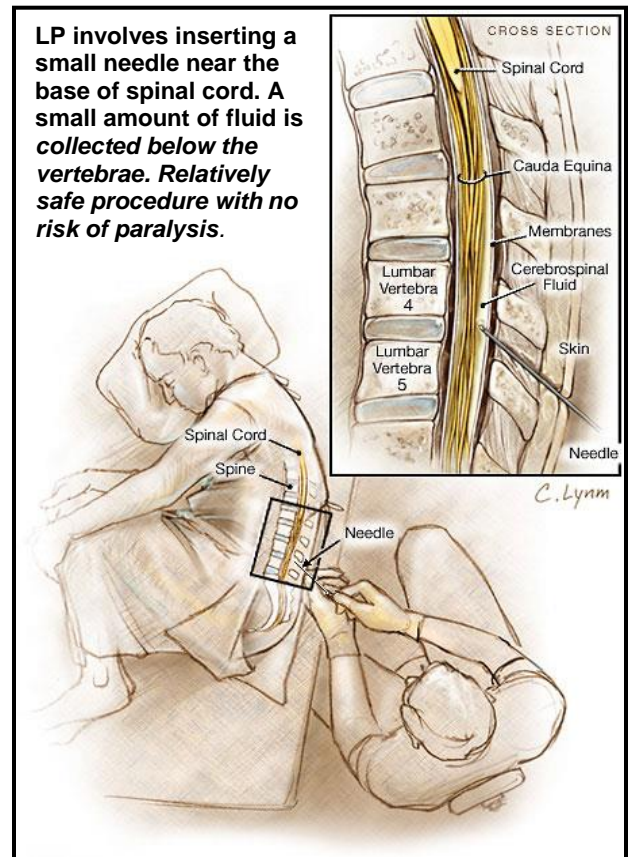
By signing this informed consent form, you grant permission to DEC Brain & BioBank team to obtain a sample of CSF from you, and transfer the collected sample to DEC Brain & BioBank for storage and research use. You also agree to transfer any information collected during the procedure to be stored at the BrainBank database. Please remember this is an invitation to participate in the study.

WHAT IS EXPECTED OF YOU (WHAT TO EXPECT IN A LUMBAR PUNCTURE)

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 information. Participation will require approximately 60 minutes for the lumbar puncture and CSF draw.

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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 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 10 milliliters 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.



CSF SAMPLE STORAGE & FUTURE USE

CSF 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 study members or with the general scientific community for research purposes only.

RISKS

CSF Draw by Lumbar Puncture : Up to 10 milliliters of spinal fluid may be taken for this study and your body will make up for the loss within 2 hours. 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 1%) 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 highly qualified doctor specifically trained and experienced in this procedure.

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 this portion of the study. There will be no costs to the participant for taking part in this procedure. Incidental costs directly associated with participating in this research study will be reimbursed to the participant such as meal after LP and parking.

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 (though we hope you may not as this is for a greater cause). In this case the collected 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 CSF donation sub study is completely voluntary. A decision not to participate will not result in any penalty or loss of benefits to which you may be entitled. You may refuse to participate at any time with no effect on your future care or participation in the main brain donation study.

CONFIDENTIALITY

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Information obtained from the CSF 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. 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

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*

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

<p>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</p>
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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.

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