

FACT SHEET

Study title: MGH-Biogen Autopsy Tissue Repository for Trials in Neurologic Diseases

Principal Investigator: Matthew P. Frosch, MD, PhD

Who we are?

We are a group of researchers from the Massachusetts General Hospital and research collaborators at Biogen who want to learn how to understand, prevent, diagnose, and treat brain diseases.

What is the purpose of this study?

The purpose of this Biogen-funded research tissue bank study is to collect, process and store post-mortem brain tissues, spinal cord, muscle, or other types of tissues from individuals who are enrolled or had been enrolled in a Biogen ('Biogen') clinical trial. We hope that examining brain tissue will add information about the clinical trial.

Who can participate? How many people will participate?

Our research tissue bank is for Biogen clinical trials participants (over age 18) and is located at the Massachusetts General Hospital's (MGH) Pathology Service. There is no set limit to the number of individuals who provide samples to this bank. The more samples that we can collect, the more useful the tissue bank will be for research.

Why is this research important? Who will use my data?

Brain donation and post-mortem tissues are extremely valuable for understanding the causes of neurologic disorders and for finding potential treatments for such diseases. Because you participated in a trial looking to treat your neurologic disease, we believe that examination of tissue can add understanding to the results of that trial. Tissue samples in this bank will be used for research on brain diseases by MGH and Biogen research collaborators. Samples may also be used by other academic or commercial researchers with the approval of a joint steering committee consisting of authorized MGH & Biogen representatives.

We may use your samples and information to develop a new product or medical test to be sold. Biogen, the hospital, and researchers may benefit if this happens. You will not be paid if your samples or information are used for this purpose.

How do I enroll in this tissue bank study?

First, you will need to identify a reliable study partner who will serve as an additional contact person for researchers and will be available when you may no longer be able to contact us in the future. Second, you and your study partner will speak with our study coordinator to tell you more about the research study and help you make an informed decision about taking part in the study. You will have as much time as needed to consider study participation. If you agree to enroll this means that you intend to

participate in brain donation but it is important to remember that final consent for this study will be obtained from your legal representative such as a next-of-kin after your death.

What happens after I am enrolled?

We will ask you for the name(s) of the Biogen clinical trial(s) that you had participated or are participating in, the institutions(s) where the trial(s) was/were conducted at, the name(s) of the trial(s)' principal investigator(s) and your study participant ID(s) in these Biogen trial(s). You will be able to get that information from the clinical trial site. We may ask a few questions to find out how you have been doing at each interview. The brain donation process – including the discussions about having autopsies be done either at the MGH or at a local pathology facility closer to where you are – will also be reviewed during these interviews.

We will provide a brain donor pocket card that contains important contact telephone numbers after you enroll in the study. This card should be kept by a next-of-kin or by those whom you designate the follow through with your brain donation upon your death.

How does my legal representative (next-of-kin) donate my brain?

When a brain donor dies, the health care proxy or next of kin should contact the MGH Pathology Service (617-726-1728 or 617-726-2000 and page beeper # 21300 (Neuropathology) and inform us of their decision to proceed with the brain donation. Final consent which can be done over the phone will be required in order to comply with the donor's wishes for a brain autopsy. Therefore, it is important that a donor's decision regarding brain donation should always be discussed with a next-of-kin or legal representative ahead of time.

Can I still donate by brain if I don't live close to the Massachusetts General Hospital?

Yes. Depending on the location of the donor, a MGH pathologist who is familiar with the study will obtain final consent and/or identify a designated pathologist located closer to the donor to obtain final consent. Instructions will be provided for the preservation of the body, coordination of the body transportation of the deceased to the MGH and thereafter, to a funeral home or location selected by the next-of-kin. The most important aspect is that the brain tissues must be removed as soon as possible after death, before embalming or other funeral preparations. Our study staff will direct all charges related to the local brain donation procedure (e.g. body transportation, pathology fees, use of mortuary facilities) to the MGH for payment. The final disposition (e.g. burial, cremation) of the donor's body remains the responsibility of the next-of-kin.

If death occurs outside of the United States, we will unfortunately not be able to proceed with brain tissues collection from outside of the United States. This is due to anticipated delays caused by regulatory requirements for transporting a body across international boundaries.

What does a brain autopsy involve?

The first step of the brain autopsy is to make a simple incision of the scalp. Using surgical procedures, the skull is opened and the brain is removed. After the brain is removed, the skull is closed and the incision is stitched as in a surgical operation. The body is then typically released to a designated funeral director or person according to the next-of-kin's wishes. An open casket service or other traditional arrangement will still be appropriate after the brain autopsy.

At the time of the brain autopsy and provided that final consent is obtained, we may wish to collect additional body tissues, blood samples and cerebral spinal fluids (CSF) for research. Cerebral spinal fluids are fluids that surround the brain. Spinal cord, muscle and other types of tissues are usually obtained only from people with Amyotrophic Lateral Sclerosis (ALS) or other neurologic diseases involving the body's nervous systems.

What happens after brain donation?

The MGH Pathology Service will acknowledge the receipt of the brain donation to the donor's legal representative such as a next-of-kin. The finalized autopsy report will be available (if wanted) through MGH medical records after all studies have been completed. It typically takes about 3 to 6 months for a clinical autopsy report to be finalized.

Can I request a full-body clinical autopsy at the time of brain donation? Can I also donate my body for research?

We will facilitate these requests – whether they would be done at the MGH or at a local pathology facility – as much as we can. With the exception of brain donors who had been patients of the MGH¹, costs beyond that of a brain autopsy will remain the responsibility of the brain donor's next-of-kin.

Body donation to other anatomical gifts programs (typically at medical schools): As these programs are not part of the MGH-Biogen brain tissue bank study, our study staff will not be able to coordinate with these programs. Donors' next-of-kin will need to make separate arrangements with these body donation programs on their own. If you participate in another donation program you cannot participate in this MGH-Biogen study.

What are the risks to me?

Family members or loved one may be uncomfortable or sad when discussing brain donation. The main risk of allowing us to store limited personal information such as your address is a potential loss of privacy.

¹ Full-body clinical autopsies of MGH patients that are done at the MGH are provided free of charge.

How are my samples stored?

Staff at the bank will assign your samples the same study code number as that of your Biogen clinical trial study participant ID number and store them in a secured, locked freezer in a restricted-access laboratory. The use of the same study code number will allow us to connect your sample to clinical trials data collected at Biogen.

How long will my samples and information be kept? Can I stop allowing my samples and information to be stored and used for research?

Your samples will be kept for as long as Biogen is able to fund the maintenance costs for the tissue bank. Your samples will be destroyed at Biogen's expense in the event that Biogen is no longer able to fund the study.

Yes, you have the right to withdraw your permission. Your legal representative such as a next-of-kin retains the rights to withdraw permission after your death and your samples will be destroyed. It will not be possible to destroy samples that have already been given to researchers. If you or your legal representative decides to withdraw your permission, the tissue bank's director (Dr Matthew Frosch) must be contacted in writing: Dr Matthew Frosch, MGH Pathology Services, Warren Building Suite 334, 55 Fruit Street, Boston MA 02114.

How will my information be protected?

We will protect your privacy by labeling your study files only with a study ID code number rather than with your name and will store the files in a secured, locked office that is located in a limited-access building. The key to the code that links your study ID and your name will be kept separately in a secured, password-protected and malware-protected database that is maintained by Mass General Brigham. Any study information that is stored electronically will also be secured in a password-protected, malware-protected database that is managed by Mass General Brigham.

Your de-identified information may be used or shared with other researchers without your additional informed consent.

We are required by the Health Insurance Portability and Accountability Act (HIPAA) to protect the privacy of health information obtained for research. This is an abbreviated notice, and does not describe all details of this requirement. During this study, identifiable information about you or your health will be collected and shared with the researchers conducting the research. In general, under federal law, identifiable health information is private. However, there are exceptions to this rule. In some cases, others may see your identifiable health information for purposes of research oversight, quality control, public health and safety, or law enforcement. We share your health information only when we must, and we ask anyone who receives it from us to protect your privacy.

Is there a cost to me or my family? Will I be paid for my samples?

Our research tissue bank does not charge study participants or their legal representatives (e.g., next-of-kin) for taking part in the brain donation study. We will pay for all costs or charges that are related to the brain donation process, including but not limited to the costs of transportation to the MGH or any other pathology laboratory for brain removal; costs of transfer of the body to any funeral home or designated location after the brain removal procedure, or costs of temporary body storage in mortuary facilities.

How may I benefit from being in this study?

There is no direct benefit from being in this study. Donating your brain will allow researchers to understand the causes and potential treatments of neurologic disorders, as well as the outcomes of the clinical trial you participated in.

What if I have questions about my rights as a research participant?

If you want to speak with someone not involved in this research about your rights as a research subject, or any concerns or complaints you may have about the research, contact the Mass General Brigham IRB at (857) 282-1900.

To speak directly with the Principal Investigator, Dr Matthew Frosch, call 617-726-5156 M-F 9a-4p.

Your participation is voluntary and can stop at any time and deciding not to participate will not affect medical care you receive at Mass General Brigham now or in the future