McLean HOSPITAL
HARVARD MEDICAL SCHOOL AFFILIATE

Harvard Brain Tissue Resource Center
"From Knowledge Will Come a Cure"

HARVARD MEDICAL SCHOOL
TEACHING HOSPITAL

HARVARD BRAIN TISSUE RESOURCE CENTER (HBTRC)
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POSTMORTEM AUTHORIZATION FOR BRAIN DONATION

The HBTRC is asking you to provide consent for the removal and transport of your relative's brain and additional tissue specimens (meninges, and small samples of cerebrospinal fluid, blood, hair, muscle). In some instances, determined on the basis of clinical and scientific considerations, samples from other tissues (spinal cord, heart, intestines, lung, liver, kidney) may also be collected if donation for organ transplant has been ruled out. Collection of these latter tissues will be explicitly discussed with you. If you agree to the removal of these additional tissue samples, our HBTRC representative will check the relative boxes in page 3 before you sign this form. All specimens collected (hereafter referred to as 'tissue samples') will be transported and stored at our facility at McLean Hospital in Belmont, MA. The HBTRC collects, processes and distributes postmortem tissue specimens and medical information to scientists throughout the U.S. and abroad. These scientists use the tissue and information to conduct research that will further the medical understanding of neurological and psychiatric disorders.

At the time of death, an individual's body becomes part of their estate and its disposition is decided by the legal next-of-kin or other legally authorized representative. Although an individual can make a personal request to donate his/her brain, and related tissue, it is the surviving family member(s) or other authorized representative who has the responsibility of deciding whether the donation of these tissue specimens will be made. You, the legal next-of-kin or other authorized representative (such as the Executor of the donor's estate), are being asked to provide consent for the donation.

Purpose: The purpose of this research tissue bank is to collect, process, and store brain tissues and associated health information to be provided to researchers for scientific studies. The health information will be collected, with your authorization, from the donor's physician(s) and will be related to medical, psychological, psychiatric and neurological status. The tissue and information will be used mainly to study neurological and psychiatric disorders. De-identified data collected from this research will be shared in scientific databases that anyone can use. These databases will be kept for a long time and researchers around the world will use these for countless future studies. You will not receive any individual results or direct personal benefit from this future research, but it will benefit individuals who suffer from serious diseases and may lead to scientific advances that will benefit society in general.

Procedures: The Staff at the HBTRC will assign a code number to the tissue and health information. The donor's name, medical record number, or other identifiable data, and the key to the code that connects this data to the tissue and health information will be protected and stored securely. Only de-identified tissue samples and health information will be provided to researchers.

The coded tissue and health information may be shared with researchers at Partners institutions. They may also be shared with researchers at non-Partners institutions or with for-profit companies that are working with Partners researchers. The tissue will not be sold for profit. The tissue and information may be used to develop a new product or medical test to be sold. The hospital and researchers may benefit if this happens. There are no plans to pay you if the tissue and information are used for this purpose.

You can withdraw your permission at any time. If you do, the tissue and information will be destroyed. However, it will not be possible to destroy tissue and information that have already been given to researchers. If you decide to withdraw please contact the HBTRC staff in writing. Your decision will not adversely affect your care or your family's care at this institution.

We will only share information that identifies the donor with researchers within Partners who have approval of the Partners ethics board. We will not share information that identifies the donors with researchers outside Partners.

In order to allow researchers to share research results, agencies such as the National Institutes of Health (NIH) have developed secure banks that collect and store research samples and/or health information. The HBTRC will share potentially identifiable health information (e.g. date of birth, date of death, dates of admission to hospitals) with the national institutes of health (NIH; NIMH, NICHD, NINDS and NIA brain and tissue repository, Neurobiobank).

The central banks may share these samples or information with other qualified and approved researchers to do more studies. Results or samples given to the central banks will not contain information that directly identifies the donor. There are many safeguards in place at these banks to protect the donor's privacy. You will also receive a questionnaire about the donor's health. You may complete it and send back to us at a later time.

Privacy: In general, health information that identifies an individual is private under federal law. However, you should know that in addition to Partners researchers the following people or groups may be able to see, use, and share the donor's identifiable health information from the research and why they may need to do so:
* Any sponsor(s) of this bank and the people or groups it hires to help with the bank
* The Partners ethics board that oversees the project and the Partners research quality improvement programs
* People from organizations that provide independent accreditation and oversight of hospitals and research
* People or groups that we hire to do work for us, such as data storage companies, insurers, and lawyers
* Federal and state agencies (such as the Food and Drug Administration, the Department of Health and Human Services, the National Institutes of Health, and other US or foreign government bodies that oversee or review research). We share identifiable health information only when we must, and we ask anyone who receives it from us to protect the donor's privacy. However, once this information is shared outside Partners, we cannot promise that it will remain private. You have the right not to sign this form that allows us to use and share the donor's health information for research; however, if you don't sign it, we will not be able to use the donor's samples and information for research. A federal Certificate of Confidentiality (Certificate) has been issued for this research to add special protection for information and specimens that may identify the donor. With a Certificate, unless you give permission (such as in this form) and except as described above, the researchers are not allowed to share the donor's identifiable information or identifiable specimens, including for a court order or subpoena.

The results of research using the donated tissue may be shared on public scientific websites, in scientific meetings, and in scientific journals. This authorization means that your family member's genetic information and related data may be shared with other researchers, but this will not include any information that could personally identify you or your family member. It is possible that your family member's genetic information could be used to identify him/her when combined with information from other sources, but we believe this is unlikely to happen. We do not think that there will be further risks to your privacy by sharing your family member's genetic data with these databanks; however, we cannot predict how genetic information will be used in the future.

Our HBTRC representative will need to know the donor's name, time of death, neurological or psychiatric diagnosis **if any**, and the location of the body. The HBTRC will work directly with appropriate personnel to make arrangements for the brain removal and will provide instructions for its packaging and transport. It is essential that the donation procedure occur within 24 hours from the time of death of the donor. Only the donor's specimens mentioned above will be sent to the HBTRC.

Please note that standard serological screening is carried out on all samples on a routine basis. Should the results show that the donor was serum positive for HIV, Hep B or Hep C, or if found to be affected by prion disease, the HBTRC will not be able to issue a Neuropathology Report. Should the donor be found to be serum positive, we will inform you of the results by mail so that you may consult a medical provider and take precautions if needed, and inform other family members if necessary. The donated tissues will be cremated or, for HIV positive donors, they may be transferred to the NeuroAIDS Consortium (NNTC). Only de-identified PHI, but no PII, will be transferred to the NNTC. By signing this form, you give us permission to transfer relevant tissues to NNTC.

If you want to speak with someone not directly involved in the Bank, contact the Partners Human Research Committee at 617-424-4100. You can talk to them about: your concerns about the research or any complaints about the research.

As the legally authorized representative of the donor and entitled by law to control his/her remains, you authorize the removal, retention, use, and distribution of his/her whole brain and specimens above by the HBTRC for research purposes as has been described. You further direct that the medical records of the donor be released to the HBTRC and shared as described to provide information critical to the research. You authorize HBTRC staff members to contact you to provide materials and assist you in requesting the medical records. You may withdraw your consent at any time by writing the HBTRC Director. If you do, the donor's brain will be disposed of in a manner consistent with disposal of biological material, and his/her medical information will be destroyed. However, it will not be possible to retrieve tissue and information that have already been given to researchers.

Is this brain donation done on behalf of one of the following Entities? ☐ Yes ☐No

If Yes, please review this section before you sign this Consent Form.

☐ Rett syndrome.org
☐ Tourette Association of America
☐ International FOXG1 Foundation
☐ Lupus Research Alliance
☐ International Foundation for CDKL5 Research
☐ Dystonia Medical Research Foundation
☐ ROHHAD Fight
☐ Brown U. Tissue Resource for Rare Neurogenetic Disorders (BATON study)

Do you give permission to the HBTRC to share the donor's identifiable information (e.g., name, date of birth, date of death, clinical and neuropathological information) with the Entity? ☐ Yes ☐No*

***** Please note: if NO is selected, (a) de-identified, anonymized, information will be shared with the Foundation; (b) de-identified information might still lead to identification in rare disease cases

Additional Tissue Samples

In some instances, the HBTRC representative may have discussed with you the possibility of donating additional tissue samples. **If so, and you consent to the removal of these additional tissue samples, our HBTRC representative will check the relative boxes below. Please review them before you sign this form.**

IMPORTANT*: Kidney, Heart, Lung and Liver can only be donated for research once use for organ transplant has been ruled out.*

☐ Spinal Cord ☐Intestines ☐ Kidney ☐Heart ☐Liver ☐Lung

Donor's Name:_____ Donor's Date of Birth:_____

Donor's Date of Death:_____

Legal Next-of-Kin or Other Authorized Representative:

I have read this Consent Form, had the opportunity to ask questions and I understand the information given to me

Name:_____ Relationship to Donor:_____

Address:_____

Signature:_____ Date:_____ Phone:_____

HBTRC staff only- Please do not write inside this box

HBTRC Staff responsible for this Consent Process - Name:_____

☐ **REVIEWED CONSENT FORM WITH LEGAL NOK OVER THE PHONE**
☐ **REVIEWED BRAIN DONOR INFORMATION WITH LEGAL NOK OVER THE PHONE**
☐ **ADDRESSED LEGAL NOK CONCERNS/QUESTIONS**

Signature:_____ Date:_____

Note: Please initial and date any corrections made to the information filled in this consent form. If there is a discrepancy between the signature date of the Legal Next-of-Kin and that of HBTRC Staff, please explain reason below: