



## **HARVARD BRAIN TISSUE RESOURCE CENTER (HBTRC)**

Director: Sabina Berretta, M.D.

**Phone:** 1-800-BRAINBANK (1-800-272-4622) • **Email:** [HBTRC@mclean.harvard.edu](mailto:HBTRC@mclean.harvard.edu)

**Website:** <https://hbtrc.mclean.harvard.edu/> • **Fax:** (617) 850-8711

### **POSTMORTEM AUTHORIZATION FOR BRAIN DONATION (1-Step Consent)**

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, skin). Please note that skin or brain samples may be developed by the HBTRC or investigators into cell lines for research purposes. In some instances, determined on the basis of clinical and scientific considerations, samples from other tissues (spinal cord, myocardium, 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 tissue specimens and associated health information to be provided to researchers for scientific studies and for education purposes. 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 brain health and disease, but there may be other types of studies as well. De-identified data collected from this research, including data from genetic studies, 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.

Approved \_\_\_\_\_

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.

This authorization means that your family member's clinical and genetic information may be shared with researchers, but this will not include any information that could personally identify you or your family member. The results of research using the donated tissue, including genetic information, may be shared on public scientific websites, in scientific meetings, and in scientific journals. Although only experts will know how to interpret this information, there is a chance that somebody could connect you [your family member] with the information from the study of the sample you give. The information could potentially be used to discriminate against you or your family members. In the US, there are State laws and a Federal law, the Genetic Information Non-discrimination Act, that provide some protection against this type of discrimination by making it illegal for most employers and health insurers to use information about your genes to discriminate against you or your family. 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.

Should the donor's tissue samples have been obtained through a Medical Examiner's Office or an Organ Procurement Organization, you also authorize us to share with their representatives the donor's neuropathology report that we will generate as part of our procedures. This document will contain donor's information (e.g. the donor's name and date of death) needed to link the neuropathology report to the donor. This information will be included in their records. Note that these agencies are subject to HIPAA regulations and therefore held to protect the privacy and health information of the donor and your family.

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 may 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.

Approved \_\_\_\_\_

The donated tissues may be cremated

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.

Approved .....

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 Entities below?**  Yes  No

**If YES, 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

- |  |  |
|--|--|
| <input type="checkbox"/> International Rett Syndrome Foundation. | <input type="checkbox"/> International Foundation for CDKL5 Research |
| <input type="checkbox"/> Tourette Association of America         | <input type="checkbox"/> Dystonia Medical Research Foundation        |
| <input type="checkbox"/> FOXP1 Research Foundation               | <input type="checkbox"/> ROHHAD Fight                                |
| <input type="checkbox"/> Lupus Research Alliance                 | <input type="checkbox"/> Brown U. BATON study                        |

### 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, Myocardium, Lung and Liver can only be donated for research once use for organ transplant has been ruled out.*

- Spinal Cord     Intestines     Kidney     Myocardium     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:** \_\_\_\_\_

Approved \_\_\_\_\_

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:*

Approved \_\_\_\_\_