HARVARD BRAIN TISSUE RESOURCE CENTER (HBTRC)

Director: Sabina Berretta, M.D.
Phone: 1-800-BRAINBANK (1-800-272-4622) ● **Email:** HBTRC@mclean.harvard.edu
Website: https://hbtrc.mclean.harvard.edu/ ● **Fax**: (617) 850-8711

INSTRUCTIONS – Consent Packet

In this packet, please find enclosed the following documents:

1) A blank copy of the HBTRC Postmortem Authorization for Brain Donation
(HBTRC Consent Form - marked with a circle ●)

2) HBTRC Brain Donation Information Form
(HBTRC Information - marked with a triangle ▲)

Please read the following instructions and information carefully. If you have questions, or need assistance, please call 1-800-272-4622. A HBTRC staff member will be happy to help.

1) **HBTRC Consent Form**.

This document needs to be signed by the Legal Next-of-Kin / Legal Representative and sent back to the HBTRC

- Please review this document carefully.
- This HBTRC Consent Form can only be completed and signed by the Legal Next-of-Kin after the donor's death.
- Before signing it, please contact the HBTRC and allow one of our staff members to review this authorization form and the Brain Donation Information form with you over the phone and answer any questions you may have.
- Our staff will also guide you on how to send the completed HBTRC Consent Form back to the HBTRC in a secure manner.
- Please make sure to send all 3 pages of this form back to the HBTRC

2) **HBTRC Information**

This copy is for your records.

This document is intended to provide you with answers to questions concerning the donation procedures, risks and costs, and benefits of the donation process. Additionally, you will be able to understand what measures are followed by the HBTRC to protect the confidentiality of the donor. It also indicates that you may contact the HBTRC at any time if you have any questions that were not answered by this document.

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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.

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.

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.

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*

☐ International Rett Syndrome Foundation.
☐ Tourette Association of America
☐ FOXG1 Research Foundation
☐ Lupus Research Alliance
☐ International Foundation for CDKL5 Research
☐ Dystonia Medical Research Foundation
☐ ROHHAD Fight
☐ 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:____

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:

McLean
HARVARD MEDICAL SCHOOL AFFILIATE

HARVARD BRAIN TISSUE RESOURCE CENTER

HARVARD MEDICAL SCHOOL AFFILIATE

HARVARD BRAIN TISSUE RESOURCE CENTER (HBTRC)

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BRAIN DONATION INFORMATION

1. The purpose of the Harvard Brain Tissue Resource Center (HBTRC)

• The purpose of the HBTRC is to collect, process, and store brain tissue and related tissues, i.e. cerebrospinal fluid, meninges, blood, hair, muscle and skin (referred to from hereafter as 'tissue samples'). Please note that skin **or brain** samples may be developed by **the HBTRC or** investigators into cell lines for research purposes. Tissue samples are then distributed to researchers to do research on brain disorders. In some instances, determined on the basis of clinical and scientific considerations, samples from other tissues (spinal cord, heart, intestines, kidney, lung, liver) may also be collected. Collection of these latter tissues will only be considered once donation of organs for transplant has been ruled out. Once determined that the organs are not viable for transplant, donation for research use will be explicitly discussed with the LNOK, who is asked to consent to collection of these tissues. Tissue samples housed at the HBTRC are used for research on the human brain and on brain disorders.

• Questions regarding the brain donation for which you are receiving this form, and the specific content of this form, can be addressed by the Legal Next-of-Kin/Legal Representative (LNOK/LR; see definition below) to the HBTRC staff at 800.272.4622 from Monday - Friday 9 am – 5pm. The HBTRC staff will be happy to address your questions.

• If you want to speak with someone not directly involved in the HBTRC, please contact the Partners Human Research Committee at 617-424-4100. You can talk to them about:

- Your rights as the Donor's LNOK/LR
- Your concerns about the research
- A complaint about the research

2. Overview of HBTRC procedures

• After death, tissue samples will be removed from the donor, transported and stored at the HBTRC for diagnostic and research purposes. Samples will be released to investigators within the US and abroad for research on the human brain and brain disorders.

• After the brain donation is completed, we will send you forms for the release of the donor's health records. The HBTRC will also review and collect information from the donor's medical records and store some of his/her health information in the study database. All pertinent medical records will be reviewed and duplicated as necessary. Specifically, the HBTRC will collect and review Protected Health Information (PHI) relating to medical, psychological, psychiatric and neurological status. In addition, the HBTRC collects Personally Identifiable Information (PII) including names (first, last, middle names), address (including apartment number, street, city, county, zip code), telephone number, fax number, dates including date of birth, dates of hospital admission(s), discharge(s), and dates associated with medical or psychiatric diagnoses, receipt of medications, laboratory tests and medical or psychiatric procedures. Medical record(s) are reviewed and information retained for research purposes. However, NO information that may identify the donor will be intentionally revealed to unauthorized parties.

- We will also ask you to complete a Confidential Brain Donor Questionnaire about the medical and family history of the donor, designed to learn more about the donor's clinical condition.

- We may contact you in the future to get additional information.

3. Types of research carried out using donated tissue samples

- The HBTRC does not carry out research in itself, with the exception of limited studies on how to improve tissue processing and data validity. The main purpose of the HBTRC is to distribute the tissue samples, and the necessary related information, to investigators within the US and abroad.

- These investigators will use the tissue samples donated, and de-identified information about the donor, for the purpose of researching brain 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.

- At times, tissue samples from healthy controls may be the primary focus of the study, as information about the healthy brain is critical to the understanding of brain disorders.

- Tissue samples and information may also be used for research on different conditions, for example, as comparisons to other diseases.

- Investigators may perform a variety of biological and genetic research with the donated tissue sample. Genetic research may include looking at some or all of the genes and DNA to see if there are links between genetic variants and the donor's health condition.

4. Results of research done using donor's samples

- When the medical records and the Confidential Brain Donor Questionnaire have been collected at the HBTRC, a final neuropathology report is generated by the HBTRC staff neuropathologist for postmortem diagnostic purposes. A detailed review of the medical records, questionnaire and neuropathology report will be done to confirm the brain diagnosis and other relevant conditions. This is done so that the HBTRC can reliably give researchers the correct tissue samples needed for their studies. The LNOK/LR may receive a copy of the final neuropathology report and may request that a copy of this report is sent to the donor's physician.

- The LNOK/LR may request, in writing, that tissue samples be sent to a medical facility of their choice for further screening, such as genetic testing. Specific documents, such a Material Transfer Agreement, will need to be prepared for this purpose. You will not be asked to share with us the results from these tests.

- The research carried out by investigators receiving donated tissue samples will contribute to a better understanding of brain disorders. However, this research will not in itself be directly relevant to the donor, you or other members of your family. Therefore, information from this research will not be returned to you or your doctor. Investigators will publish their findings in medical journals, but those findings will not be identifiable as pertaining to a specific donor. You will not receive any individual results (other than the neuropathology report mentioned above) or direct personal benefit from this future research, but it will benefit individuals who suffer from serious brain disorders and may lead to scientific advances that will benefit society in general.

5. Benefits of tissue sample donation

- The direct benefit of brain donation to a donor's family is that a diagnostic neuropathology report will be sent, upon request, to the donor's LNOK/LR, free of charge. This report is often very useful to the family to better understand their relative's medical condition. The LNOK/LR may also request that the neuropathology report be sent to a clinician previously involved in the care of donor, who may help them interpret the findings. Finally, the LNOK/LR may grant permission to release the neuropathology report to an organ bank if the donor's organs were donated for transplant, as this information may be particularly relevant to this process. Please note that we will not be able to issue a Neuropathology Report if our standard serology screening shows that the donor was serum positive for HIV, Hep B or Hep C, or if found to be affected by prion disease.

- More generally, this tissue sample donation will help scientists throughout the United States and abroad understand the basis of brain diseases.

- The LNOK/LR will not receive payment for the samples donated.

6. There are no costs involved in donating tissue samples to the HBTRC

- The HBTRC is funded by the federal government and foundations, and gifts from many people to carry out its mission. Fees are not collected from researchers receiving our tissue, nor are there any charges to the LNOK/LR for the costs incurred in shipping the donated brain to the HBTRC.

- The HBTRC assumes all financial responsibility for one-way transportation of the deceased donor from the location of demise to the designated pathologist (if needed), as well as the cost incurred for brain removal and shipment. The donor's LNOK/LR/family will be responsible for all other costs that are considered part of the regular expenses of a funeral.

7. Tissue samples and health information storage in the HBTRC

- Staff at the HBTRC will assign a unique code number to tissue samples and health information. The donor's name, medical record number, or other data that easily identifies the donor 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.

8. Which researchers can use the donor's samples and what information about the donor and LNOK/LR can they have?

- The donor's coded samples and health information will be distributed to scientists at academic institutions and for-profit entities throughout the U.S. and the world. These samples will not be sold for profit. Researchers receiving tissue samples and information may develop a new product or medical test to be sold and may benefit if this happens. There are no plans to pay you if these samples and information are used for this purpose.

- Information that identifies the donor will be accessible to a restricted number of Partners' employees part of the Partners Healthcare Infrastructure Support, Enterprise Research Information Systems and Information Security Officers, who may need access for database maintenance and security checks.

- The HBTRC will share personal health information about the donor, such as results of the neuropathological report and clinical information and some potentially identifiable 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 NeuroBioBank mediates sample and information distribution from the HBTRC to qualified and approved researchers in a controlled access database.

- A copy of the neuropathological report may also be sent to a Medical Examiner or Transplant Organ Bank (if the latter was involved in tissue sample recovery). Consent from the LNOK/LR will be requested to do so.

9. How long will the HBTRC keep tissue samples and information?

We will store the donor’s tissue samples and information indefinitely. Exceptions are tissue samples from serology positive donors (HIV and Hepatitis B and C) and, rarely, not fully used samples, which after decades of storage become unsuitable for research. These samples are cremated.

10. Withdrawing permission to store and use the donor’s tissue samples and information for research purposes

The LNOK/LR can withdraw consent at any time. In that case, the donor’s samples and information will be destroyed. However, it will not be possible to destroy samples and information that have already been given to researchers. If you decide to withdraw please contact the HBTRC staff in writing.

Letters can be mailed to:
Harvard Brain Tissue Resource Center, McLean Hospital, Mail Stop 138, 115 Mill Street, Belmont, MA 02478

11. Risks associated with tissue donation

- The main risk of allowing us to collect and store the donor’s tissue samples and health information for research is a potential loss of privacy. We protect your privacy by coding the tissue samples and health information.

- The donor’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 the donor. It is possible that the donor’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.

12. Privacy Protection

- In general, health information that identifies an individual is private under federal law. However, it is important to know that, in addition to HBTRC staff, 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:
- Federal and state agencies (such as the National Institutes of Health - NIMH, NICHD, NINDS, and NIA, Brain and Tissue Repository, NeuroBioBank), 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
- We share the donor’s identifiable health information only when we must, and we ask anyone who receives it from us to protect your privacy. However, once this information is shared outside the HBTRC, we cannot promise that it will remain private.

Definition of Legal Next-of-Kin/Legal Representative

Under the Massachusetts Uniform Anatomical Gift Act, the hierarchy for those legally authorized to make a donation of the potential donor’s brain after his/her death is as follows:

- An agent of the potential donor, including, but not limited to, a health care agent appointed under a health care proxy
- Legal Spouse
- Adult Child
- Either Living Parent
- Adult Sibling
- Adult Grandchild
- Grandparent
- An adult who exhibited special care and concern for the potential donor
- A person who was acting as a guardian of the person of the potential donor at the time of death
- Any other person having the authority to dispose of the body