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)

T. Wilson Woo, M.D., Ph.D., Medical Director; Sabina Berretta, M.D., Scientific Director
Phone: 1-800-BRAIN BANK or (617) 855-2400 ♦ Fax: (617) 855-3199
E-mail: (office hours) HBTRC@mclean.harvard.edu - (after hours) HBTRCoc@mclean.harvard.edu http://www.brainbank.mclean.org

INSTRUCTIONS – Consent Packet

In this packet, please find enclosed the following documents:

1) **A blank copy of the HBTRC Postmortem Authorization for Brain Donation**
2) **HBTRC Brain Donation Information Form**
3) **A blank copy of the Authorization for Release of Protected Health Information form**

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 Postmortem Authorization for Brain Donation**.
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 Authorization for Brain Donation 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 Authorization for Brain Donation back to the HBTRC in a secure manner.

2) **HBTRC Brain Donation Information**
This copy is for your records.
This document is intended to provide you with answers to questions concerning the donation procedures, benefits, risks and costs 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.

3) **A blank copy of the Authorization for Release of Protected Health Information form**
Copies of this authorization form need to be sent directly to each provider (or facility) who is likely to have medical records relevant to the donor.

   - For your convenience, we will send you additional copies of this form, and further instructions, as part of a packet to be mailed to you soon after the brain donation. Feel free to wait until then to complete and mail these Authorization for Release of Protected Health Information forms to medical providers.

   - Please, do not send this form back to the HBTRC. Medical providers will need to receive it directly from you, together with a copy of the Death Certificate.

   - Providers may include: Primary Care Provider, psychiatric/mental health professionals, neurologists, head or brain CT scans, MRIs or other imaging, as far back and from as many facilities or providers as may have them. Laboratory results only for the last one year of life. Please complete each form, sign it and date it and send by regular mail to each provider.

POSTMORTEM AUTHORIZATION FOR BRAIN DONATION

Harvard Brain Tissue Resource Center (HBTRC) T. Wilson Woo, M.D., Ph.D., Medical Director; Sabina Berretta, M.D., Scientific Director
Phone: 1-800-BRAIN BANK or (617) 855-2400 ♦ **Fax**: Office hours (617) 855-3199 – After hours (617-850-8711)
E-mail: Office hours HBTRC@mclean.harvard.edu - After hours HBTRCoc@mclean.harvard.edu http://mcleanhospital.org/hbtrc/

The HBTRC is asking you to provide consent for the removal and transport of your relative's brain and related tissue specimens (meninges, spinal cord if applicable, cerebrospinal fluid, blood; hereafter referred to as 'tissue samples') to our facility at McLean Hospital in Belmont, MA, where we collect, process and distribute 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 indefinitely until researchers need them to do research. 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. The tissue and information may also be used for research on other conditions; for example, as comparisons to other diseases. This could include a wide variety of conditions such as mental illness, HIV/AIDS, cancer, reproduction and others.

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 information will not be stored with the tissue or health information. The key to the code that connects the name and other identifiers to the tissue and information will be stored securely in a separate file.

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 bank staff in writing.

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, and NINDS 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 HBTRC Staff members 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.

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Our HBTRC representative will need to know the donor’s name, time of death, neurological or psychiatric diagnosis, 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. If you want to speak with someone not directly involved in the Bank, contact the Partners Human Research Committee at **857-282-1900.** . You can talk to them about: your concerns about the research or any complaints about the research.

Informed Consent and Authorization for Collection of Tissue and Health Information for Research

DONATION CONSENT BY NEXT-OF KIN or OTHER AUTHORIZED REPRESENTATIVE

As the legally authorized representative(s) 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 Directors. 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 Foundations?
If so, mark the correct one.

☐ Rett syndrome.org
☐ Tourette Association of America
☐ International FOXG1 Foundation
☐ Foundation for Research and Education in Eating Disorders (FREED)
☐ International Foundation for CDKL5 Research
☐ Dystonia Medical Research Foundation
☐ ROHHAD Fight

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 Foundation? ☐ 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

* I have read this consent form.

* I have had the opportunity to ask questions.

* I understand the information given to me.

Donor’s Name:______________________________ Donor’s Date of Birth :____________________

Donor’s Date of Death:____________________

Legal Next-of-Kin or Other Authorized Representative:

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:

B# ●

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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, spinal cord and blood (referred to from hereafter as 'tissue samples') until researchers need them to do research. Tissue samples in this bank will be used mainly for research on brain disorders.

- Questions with regard to the HBTRC, and the specific content of this form, can be addressed by the Legal Next-of-Kin/Legal Representative (LNOK/LR; see definition at the bottom of this document) to the HBTRC staff at 800.272.4622 from Monday - Friday 9 am – 5pm. Our Donation Coordinator, Mr. Joseph Manzo, Clinical Liaison Ms. Kathleen Sullivan, or Drs. Wilson Woo and Sabina Berretta, the HBTRC Medical and Scientific Directors, respectively, 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 and stored at the HBTRC for diagnostic and research purposes. Samples will be released to investigators within the US and abroad for research on brain disorders.

- We will also look at 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 Personal Health Information relating to medical, psychological, psychiatric and neurological status; Name: first, last, middle names; Address: including apartment number, street, city, county, zip code, telephone number, fax number; Dates (day, month, year): including date of birth, date of admission(s), date of discharge(s), date or dates associated with medical or psychiatric diagnoses, date or dates associated with receipt of medications, date or dates associated with laboratory tests and medical or psychiatric procedures; and Medical record(s) number will be reviewed and information retained for research purposes. However, NO information that may identify the donor will be intentionally revealed to unauthorized parties.

- We will 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 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 information about the donor, mainly to study neurological and psychiatric disorders.

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

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

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

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 and an examination of the brain under a microscope will be done to confirm the brain diagnosis and other relevant diseases or conditions. This is done so that the HBTRC can reliably give researchers the correct tissue samples needed for their specific 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.
- If you, the LNOK/LR, wish, you may request, in writing, that tissue samples be sent to a different medical facility for further screening, such as genetic testing. You will not be asked to share with us the results from these tests.
- The research to be carried out by investigators who will received the donated tissue samples will contribute to a better understanding brain disorders, but will not in itself be directly relevant to the donor, you and 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.

5. Benefits of tissue sample donation

- The direct benefit of the brain donation is that a diagnostic neuropathological report may be sent to the donor's LNOK/LR free of charge. This report if often very useful to the family to better understand their relative's medical condition. The LNOK/LR may also request that the neuropathological report be sent to a clinician previously involved in the care of donor, who may help them interpret the findings. Finally, if the donor's organs were donated for transplant, the neuropathological report may enhance the organ bank work process.
- More generally, this tissue sample donation will help scientists throughout the United States and abroad understand the basis of neurological and psychiatric disease.
- 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 donor's LNOK/LR/family will be responsible for all other costs (including transportation of the body) 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 information that easily identifies the donor will not be stored with the samples or health information. The key to the code that connects your and the donor's name to your samples and information will be stored securely in a separate file.

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, and NINDS Brain and Tissue Repository, NeuroBioBank). This central bank 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).

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.

HBTRC – 115 Mill Street Belmont MA - HBTRCoc@mclean.harvard.edu

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.
- We do not think that there will be further risks to privacy by sharing the donor's coded samples with other researchers; however we cannot predict how genetic information derived from studies by investigators that receive the tissue samples could 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, and NINDS 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

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AUTHORIZATION FOR RELEASE OF PROTECTED HEALTH INFORMATION

A. DECEASED INFORMATION

DECEASED NAME:

DECEASED DATE OF BIRTH:

B. PERMISSION TO SHARE: I hereby authorize the Physician, Institution or Health Service named below to release Medical Records and other Health Information to the HBTRC. The HBTRC received the postmortem brain and tissues of the Deceased and requires the information specified below for research purposes

Name of Physician, Institution or Health Service to whom this request is addressed to:	
Purpose:	HBTRC Tissue Donation Program
Information should be sent to:	Joseph Manzo Jr. c/o T. Wilson Woo, M.D., Ph.D., Medical Director Sabina Berretta, M.D., Scientific Director Harvard Brain Tissue Resource Center McLean Hospital Mailman Research Center Mail Stop 138 115 Mill Street Belmont, MA 02478
Send by:	Mail (see address above) Fax: (617) 855-3199

C. INFORMATION TO BE RELEASED (Please check all that apply)

	Medical Records/Dates		Neurologic Consults/Evaluations
	Clinic Visit Notes/Dates		Psychiatric Consults/Evaluations
	Admission and Discharge Summaries for each admission		Report of any surgical procedures
	Lab Reports/dates		Family History
	Pathology Reports/dates		Medication Records
	Report of special procedures, including CAT, MRI, NMR, PET scans		Autopsy, Neuropathology and Medical Examiner's report

D. Please check YES to indicate if you give permission to release the following information if present in your record:		
	YES	HIV test results
	YES	Genetic Screening test results
	YES	Alcohol and Drug Abuse Treatment Records Protected by Federal Confidentiality Rules 42 CFR Part 2 (Federal rules prohibit any further disclosure of this information unless further disclosure is expressly permitted by written consent of the person to whom it pertains or as otherwise permitted by 42 cfr part 2.) This consent may be revoked upon oral or written request.
	YES	Details of Mental Health Diagnosis and/or Treatment provided by a Psychiatrist, Psychologist, Mental Health Clinical Nurse Specialist, or Licensed Mental Health Clinician
	YES	Confidential Communications with a Licensed Social Worker
	YES	Details of Domestic Violence Victims' Counseling
	YES	Details of Sexual Assault Counseling

E. I understand and agree that:
• I may withdraw this authorization at any time by submitting a written request to the Director of Medical Records. Authorization may be withdrawn except to the extent that action has already been taken in reliance on this authorization.
• Information released on this authorization, if redisclosed by the recipient, is no longer protected by the HBTRC.
• This release will expire one year from the date below or as otherwise specified:

Legal Next of Kin or other Legal Representative: Please make sure that all appropriate sections above are completed before signing this authorization. Do not sign a blank authorization.

____

Signature of Legal Next of Kin or other Legal Representative

____

Printed Name of Legal Next of Kin or other Legal Representative

Date____________________________________

The HBTRC does not have funding to compensate your Facility for the copying of records. We are a Federally funded organization. Thank you for your cooperation.
Please direct any questions and correspondence to Joseph Manzo Jr. 1-800-272-4622