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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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 (referred to from hereafter as 'tissue samples') and to distribute them 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