

HARVARD BRAIN TISSUE RESOURCE CENTER (HBTRC)

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Frequently Asked Questions (FAQ)

Before the Brain Donation:

Is registration required for brain donation?

No.

- Brain donation can still occur without registering ahead of time.
- Registration to be a brain donor is optional and non-binding.
- Registration does not guarantee acceptance as a brain donor at the time of post-mortem screening and consent.

Registration provides the HBTRC with knowledge of how many people are interested in pursuing brain donation and in what areas of the United States they live in. Registration also allows the HBTRC to stay connected with people interested in pursuing brain donation. Registration has been found to be very helpful for potential donors and their families as a way to introduce and promote the concept of brain donation and research to others involved in the life of the registrant.

If a registrant becomes a successful brain donor then their registration form will be added to the donor's case folder and the clinical information will be referenced.

Does registration guarantee acceptance as an HBTRC donor at time of death?

No.

- Brain donation can still occur without registering ahead of time.
- Registration to be a brain donor is optional and non-binding.
- Registration does not guarantee acceptance as a brain donor at the time of post-mortem screening and consent.

There may be instances when the HBTRC has to decline a donation from a registered donor. This could be due to numerous reasons including but not limited to:

- lack of timely notification of a potential donor's death
- lack of sufficient mortuary refrigeration or temperature regulation
- lack of available recovery staff to perform the brain removal
- lack of an available recovery facility
- flight availability

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- adverse weather conditions

Ultimately, the HBTRC strives to consent, recover, ship, and perform a full dissection in Massachusetts within 24 hours so the brain is in a condition that will be useful to researchers. Unfortunately, the factors listed above are often beyond the control of the HBTRC.

Who can register?

- Potential donors over the age of 18 years old may register themselves.
- Potential donors may be registered by an adult Legal Next-of-Kin or 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:

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

What brain diagnoses are accepted at the HBTRC?

The HBTRC can accept an exhaustive list of neurodevelopmental, neurodegenerative, and psychiatric diagnoses. The HBTRC also welcomes and accepts donors who are not affected by any brain-related diagnoses (often called "Unaffected Controls").

Current exclusionary criteria to be a brain donor at the HBTRC:

- Infectious diseases: Hepatitis B, Hepatitis C, and HIV/AIDS
- Prion diseases / transmissible spongiform encephalopathies (TSEs)
- Massive Stroke* (*Transient Ischemic Attacks, TIAs, are accepted*)
- Penetrating Injury to the head*
- Extended Respirator Use*

*Rare brain diagnoses may be further considered for acceptance by the HBTRC regardless of circumstances listed above. Please call and inquire with HBTRC staff.

How has COVID-19 changed the HBTRC donation process?

The HBTRC can accept potential donors whom are COVID-positive, COVID-negative, or COVID-unknown. The HBTRC considers a donor "COVID-negative" if the donor has negative test results within 2-3 days from death.

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In order to protect and maintain optimal safety measures for recovery staff and recovery facilities, the HBTRC requires additional safety precautions in place for donors with a COVID-unknown or COVID-positive status. Additional safety precautions may cause logistical and timing constraints.

If COVID testing is accessible and appropriate, having a potential donor tested prior to death in order to confirm negative status may assist with decreasing the logistical and timing constraints that can occur with an otherwise “COVID-unknown” or “COVID-positive” case.

The COVID pandemic and its effects on the process of brain donation is continuously evolving as more information is known about the virus. Please call the HBTRC for up-to-date information on our procedures related to the coordination and recovery of COVID-positive, COVID-unknown, and COVID-negative brain donations.

The Brain Donation:

Can I give my own (first-person) legal consent in advance of my death to become a brain donor with the HBTRC?

No.

Our IRB-approved protocol requires a post-mortem consent. While you can register with the HBTRC to become a registered brain donor, the actual donation relies on the involvement of others to notify the HBTRC at the time of death and to provide post-mortem consent and clinical records. The HBTRC does not solicit donations and relies on the proactive notification and involvement by those involved in the donor’s care and decedent affairs.

It is important to inform your family or another legal representative that you have registered as a prospective brain donor with the HBTRC and/or are interested in becoming a future brain donor. Make sure they know to call the HBTRC quickly after the time of your death, or when death is imminent, in order for the donation process to proceed.

Does the HBTRC require the whole brain or is it just a sample or biopsy? Is any other tissue besides the brain collected?

The whole brain is gifted, removed, and sent to the HBTRC.

The HBTRC post-mortem consent form covers the removal and transport of the donor’s brain and additional tissue specimens (meninges, and small samples of cerebrospinal fluid, blood, hair, muscle, skin). Please note that skin samples may be developed by 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, heart, intestines, lung, liver, kidney) may also be collected if donation for organ transplant has been ruled out. Collection of these latter tissues is a rare occurrence and will be explicitly discussed with the Legal Next-of-Kin/Legal Representative.

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.

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These scientists use the tissue and information to conduct research that will further the medical understanding of neurological and psychiatric disorders.

Is there any cost to the family to become an HBTRC Brain donor?

No.

The HBTRC is funded by the federal government and foundations, and from the support of benefactors to carry out its mission.

There are no financial charges to the Legal Next-of-Kin/Legal Representative for the costs incurred in recovering, shipping, processing, or distributing a donated brain. The HBTRC assumes all financial responsibility for the transportation of the deceased donor from the location of demise to the designated recovery specialist (if needed).

The HBTRC is **not** responsible for any other costs that are considered part of the regular expenses of a funeral.

Is this procedure disfiguring and does it prevent a viewing or open casket?

No.

The recovery process is not disfiguring and does not prevent funeral viewing or an open casket. Brain recovery is compatible with traditional funeral arrangements such as embalming and cremation as long as the brain is recovered first and quickly according to our protocol.

What happens to the decedent's body after the brain recovery has been performed?

Brain recoveries for the HBTRC often occur in funeral homes, hospitals/pathology departments, Medical Examiner Offices, or private autopsy facilities. The HBTRC is not involved with arrangements of the decedent's body after brain recovery has taken place. Funeral arrangements such as cremation or burial are not the responsibility of the HBTRC.

If coordination of the brain recovery requires the decedent's body to be transported to another facility, then the HBTRC will cover the costs associated with this type of transportation. For example, the HBTRC will arrange and cover the costs associated with the decedent's body being transported from a funeral home to a private autopsy facility and then after the brain recovery takes place back to the funeral home.

Can an Organ Donor also be a brain donor?

Yes, most of the time.

If you are a registered organ or tissue donor, it is still possible to donate your brain to research. Please know that being an organ donor for transplantation does not involve the same consent process as the HBTRC's brain donation for research. The HBTRC will still need to be notified of the potential donor's death and will need to have the post-mortem consent signed by the Legal Next-of-Kin or Legal Representative.

At times, procedures needed for organ donation may affect our timing constraints for brain donation. Organ donation for transplantation takes precedence over brain donation for research. The HBTRC will work cooperatively with organ procurement organizations (OPOs) across America in order for both types of donations to occur if possible.

Can a person donating their whole body to education and research still be a brain donor with the HBTRC?

Yes, most of the time.

The HBTRC has worked with many Anatomical Gift Programs across America in order for the brain to be donated to our program and the body to remain with their program. Many Anatomical Gift Programs have been very helpful in assisting with the brain coordination process as being a resource for recovery staff as well as providing a facility for the brain recovery procedure.

Some Anatomical Gift Programs require keeping the brain for their own program. In these cases, the HBTRC will not be able to receive the brain donation. If this is a concern, then it recommended the potential donor or their family, discuss the matter and their concerns directly with the body donation program they have selected. The HBTRC will work cooperatively with Anatomical Gift Programs across America in order for both types of donations to occur if possible.

What are the critical timing concerns for a successful brain donation?

The reason for timeframe limitations is because human brain tissue degrades quickly following death. In order for the HBTRC to provide the highest quality brain tissue to the research community, we follow these timing guidelines:

- The decedent should be placed in mortuary refrigeration within 6 hours after death. If mortuary refrigeration is not available at the facility, the HBTRC can coordinate with the funeral home and/or hospital ways to keep the cranium cold until brain recovery can occur.
- Post-mortem consent by the legal next-of-kin or legal representative needs to occur shortly after the time of death in order for the HBTRC to proceed with coordinating brain recovery and shipment procedures
- The HBTRC strives to coordinate consent, recovery, shipment, and the HBTRC's local dissection within a 24-hour time period

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Although this may seem like a very time-intensive process, the HBTRC has been open since 1978 and has streamlined the coordination process significantly. The HBTRC has been able to successfully consent, recover, ship, and dissect brains originating from the far west coast of America within this 24-hour period many times before.

Providing the HBTRC with notification of impending death [if known] will assist the HBTRC in better coordination.

Can someone undergoing a full autopsy still be a brain donor?

Yes, most of the time.

Brain donation to the HBTRC can occur if the pathologist, medical examiner (ME), or coroner facilitates the brain removal according to our protocol and timeframe. However, these services are not always available 24/7/365. These professionals are within their rights to decline the brain donation to the HBTRC, especially if they deem it necessary to determine cause of death.

After the Brain Donation:

What should the Legal Next-of-Kin/Legal Representative do after a brain donation has occurred?

Within a few business days after the donation is made, the HBTRC will mail a package of forms to the legal next of kin. This “Condolence Package” contains the following forms:

- Condolence letter
- A copy of the signed consent packet
- A family questionnaire to fill out
- Multiple copies of medical release forms to fill out
- Instructions

If the **Legal Next-of-Kin/Legal Representative already has** relevant donor medical records that you would like included in the donor’s HBTRC case record, please mail these copies along with the completed family questionnaire and a copy of the death certificate (if available) to the HBTRC.

The medical release forms should be filled out by the Legal Next-of-Kin or Legal Representative and accompanied with a copy of the death certificate. These forms should be sent directly to the donor’s medical providers and/or medical record departments. These medical facilities will then provide copies of the donor’s medical records directly to the HBTRC.

What is a Neuropathology Report? And who receives a copy of the information?

The Neuropathology Report ensures that the HBTRC can be absolutely certain of the neuropathological diagnosis of the brain donor. This report ensures that researchers receive the correct tissue for the specific diagnoses being researched.

When the donor's brain arrives at the HBTRC, half of the brain is immersed in formaldehyde (a preservative) for a few weeks. After this fixation period, the HBTRC's Neuropathologists examine the exterior and interior of the half-brain and notes any abnormalities found. This is called the gross examination. A standardized set of brain regions are placed in cassettes to be examined microscopically. Our histopathology laboratory processes and embeds these regions into wax blocks. Very thin sections are cut from these wax blocks on a microtome. The sections are then placed on glass slides and stained with a variety of dyes that show the microscopic structure of the brain tissue and the damage done to the tissue by various brain diseases. Using a microscope, our Neuropathologists evaluate numerous stained slides per a donor. Based on their findings, they write a detailed neuropathology report that confirms, corrects, or expands upon the previous clinical diagnosis.

The Legal Next-of-Kin/Legal Representative is eligible to receive a Neuropathology Report. The Neuropathology Report is mailed to the Legal Next-of-Kin and anyone else the Legal Next-of-Kin may designate to receive a copy of the report. Requesting to receive a copy of the Neuropathology report is contained within Part 1 of the Family Questionnaire paperwork received by postal mail approximately a week after the donor's death.

Will the HBTRC share any information about the donor?

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.

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

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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.

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.

Consent from the LNOK/LR will be requested in order to send a copy of the neuropathological report to a Medical Examiner or Transplant Organ Bank if the organizations were involved in tissue sample recovery.

Will I get feedback later from the HBTRC about what research was completed using the tissue gifted?

No.

Any information that we might provide to qualified researchers must be de-identified. The researchers do not receive any identifying donor information and therefore cannot tie any data back to a particular donor.

- 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.

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- 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.

The NIH NeuroBioBank provides a list of recent publications from Investigators whom requested and used post-mortem brain tissue in their research: <https://neurobiobank.nih.gov/publications/>

Does the HBTRC perform genetics testing or DNA analysis?

If you are interested in pursuing genetics or DNA testing, it is recommended that you and/or your family should coordinate this through a primary care physician or a qualified genetics counselor while the donor is living and able to provide any necessary specimens or samples.

The Legal Next-of-Kin/Legal Representative 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. **Although providing the results of the test to the HBTRC would be appreciated.** The HBTRC will not be responsible for covering any costs related to genetic testing on behalf of the Legal Next-of-Kin/Legal Representative.