

Effective Date: April 21, 2021

POLICY

RESEARCH AND SCHOLARLY ACTIVITIES

BU Research Compliance Policy on Acquisition and Documentation of Post-Mortem Human Samples

RESPONSIBLE OFFICE

Research Compliance

This policy governs all acquisitions of post-mortem human samples for purposes of research by the University or any of its researchers, agents and employees.

1. Compliance with Law:

All acquisitions of post-mortem human samples must comply with the Massachusetts Anatomical Gift Act, M.G. L. ch. 113A §§1-25, the Uniform Anatomical Gift Act and all other applicable laws.

2. Documentation:

Consent for the donation must be documented in writing using one of the approved forms signed by the authorized person(s) as specified on each form. No one may accept a donation if the donation is not documented in accordance with this policy. No donation by a person not

authorized to make the donation may be accepted. At the time of the Donor's death, it is desirable to have the Donor's next of kin sign an Acknowledgment, but this is not required. Please use Form 2 for this purpose.

3. Types of Donations:

a. Antemortem consent is given during the Donor's lifetime by an adult, or a legally emancipated minor, or the parent or guardian of a minor who is not emancipated.

i. Please use Form 1 for this purpose.

ii. At the time of the Donor's death, it is desirable to have the Donor's next of kin sign an Acknowledgment, but this is not required. Please use Form 2 for this purpose.

b. Postmortem authorization may be given by the deceased Donor's next of kin, if the Donor did not refuse donation during his/her lifetime.

i. Please use Form 3 for this purpose.

ii. Postmortem consent may be given by persons authorized under the law to dispose of the Donor's body, most frequently:

1. Donor's spouse
2. Donor's adult child
3. Donor's parent
4. Donor's adult sibling
5. Donor's adult grandchild
6. Donor's grandparent
7. Adult who exhibited special care and concern for the Donor
8. Donor's legal guardian
9. Other person having the authority to dispose of the Donor's body

c. If there is any question as to the authorization of a person to donate organ, tissue, or body specimens, please contact the BU Office of General Counsel.

4. Witnesses:

Two persons are required to witness each antemortem or postmortem gift. As noted on the forms, one witness must be disinterested, meaning persons who are not the spouse, child, parent, sibling, grandchild, grandparent or guardian of the Donor. The second witness may be the Donor's next of kin if available, or a second disinterested person.

5. Acceptance:

A donation is not effective unless and until accepted in writing at or after the time of the Donor's death by the Boston University Principal Investigator. Forms 1 and 2 contain a section for an authorized person to sign indicating acceptance.

6. HIPAA Authorization for Release of Protected Health Information:

HIPAA allows covered entities, including hospitals and other health care providers, to disclose a Donor's protected health information to entities engaged in the procurement and banking of cadaveric organs and other specimens, without any specific authorization. 45 CFR § 164.512. On occasion, covered entities may not understand that and may be reluctant to provide necessary information. Given the time sensitivity in brain and specimen donation, it may be helpful to have Form 4 signed by the person making the donation (Donor or Donor's authorized next of kin or agent) in order to facilitate obtaining information from the Donor's health care providers for purposes of the donation.

7. Modification of Forms:

Researchers may not unilaterally modify the language of the forms appended to this policy. If a modification is desired, contact Research Compliance.

8. Compliance with Terms:

Any terms specified in the written donation must be followed.

9. Document Retention:

The Boston University Principal Investigator must maintain the written documentation of the donation and acceptance. Each brain/specimen should have:

- a. Either an Antemortem consent by donor or a Postmortem authorization by next of kin (Form 1 or Form 3), including an Acceptance signed by the Boston University Principal Investigator at or after the time of the donor's death.
- b. An Acknowledgement signed by the Donor's next of kin, if used.
- c. HIPAA Authorization

10. Auditing:

Research involving post-mortem human samples may be audited by BU Research Compliance or by BU Internal Audit to ensure this policy is being followed.

Attachments

- **Form 1:** Antemortem Anatomical Gift by Donor
Word – [Policy on Post Mortem Donations Form 1](#); **PDF** – [Policy on Post Mortem Donations Form 1](#)
- **Form 2:** Acknowledgment by Next of Kin (optional but helpful in connection with an Antemortem Anatomical Gift by Donor)
Word – [Policy on Post Mortem Donations Form 2](#); **PDF** – [Policy on Post Mortem Donations Form 2](#)
- **Form 3:** Postmortem Anatomical Gift by Donor's Next of Kin
Word – [Policy on Post Mortem Donations Form 3](#); **PDF** – [Policy on Post Mortem Donations Form 3](#)

- **Form 4: HIPAA Authorization**

Word – [Policy on Post Mortem Donations Form 4](#); **PDF** – [Policy on Post Mortem Donations Form 4](#)

END OF POLICY TEXT

Additional Resources Regarding This Policy

Forms

- **Form 1: Antemortem Anatomical Gift by Donor**
Word - [Policy on Post Mortem Donations Form 1](#); **PDF** - [Policy on Post Mortem Donations Form 1](#)
- **Form 2: Acknowledgment by Next of Kin (optional but helpful in connection with an Antemortem Anatomical Gift by Donor)**
Word - [Policy on Post Mortem Donations Form 2](#); **PDF** - [Policy on Post Mortem Donations Form 2](#)
- **Form 3: Postmortem Anatomical Gift by Donor's Next of Kin**
Word - [Policy on Post Mortem Donations Form 3](#); **PDF** - [Policy on Post Mortem Donations Form 3](#)
- **Form 4: HIPAA Authorization**
Word - [Policy on Post Mortem Donations Form 4](#); **PDF** - [Policy on Post Mortem Donations Form 4](#)

Categories: Protected Health Information - HIPAA, Research and Scholarly Activities, Research Compliance and Safety
 Keywords: donor, donor human tissue, donors, human, human research, human research sample, human research samples, human sample, human samples, human tissue, post-mortem, postmortem, postmortem gift, postmortem gifts, research sample, tissue

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