Human Body Donation Committee

HUMAN BODY DONATION PROGRAM BEST PRACTICES

First Edition- December 2023

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American Association for Anatomy (AAA)
HUMAN BODY DONATION COMMITTEE

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I. MISSION AND OBJECTIVES

MISSION

The American Association for Anatomy (AAA)'s Human Body Donation Committee advances the mission of the association by increasing awareness about whole body donation for education and research. We advocate for the body donors' best interests; develop and contribute to best practices; strive to inform policymakers about regulatory efforts; and support legal and ethical program operations and activities for educators, researchers, body donors, and our greater community.

OBJECTIVES

- Increase awareness of issues important to human body donors and the body donation process.
- Advocate for (or against) legislation and regulations that impact human body donors and donor program institutions.
- Promote best practices, develop guidelines, and maintain resources that support education and research while protecting the best interests of human body donors and their families before, during and after donation.

INTRODUCTION

Whole body donation is a valuable altruistic contribution to society; it is important for the education of health professionals, for improving surgical and medical practice, as well as expanding research knowledge. Body Donation Programs (BDP) manage the donation process of the donors from registration through use and final disposition. Their goal is to provide donors to educational and research institutions in a respectful, dignified and ethical manner.

The appropriate management of BDPs can impact multiple entities: the donors, their estates and families; the faculty, staff and students who participate in education or research; the schools and universities in which this education or research is performed; the broader education and research communities across the United States; and the public at large. These impacts can be psychological, legal, financial, and ethical so adherence to the highest professional standards in management of BDPs is in the best interests of the donors, the program, a wide range of medical research and training organizations, and the community.

The following recommendations have been developed to provide foundational, standardized guidelines that all body donation programs can follow. These are recommended guidelines based on the current best practices in the field. They are not prescriptive and have no legal or enforcement ramifications.

These guidelines were prepared by a Task Force commissioned by the AAA, made up of individuals directly involved with management and oversight of BDPs in several states.

II. RECOMMENDED BEST PRACTICES FOR BODY DONATION PROGRAMS

1. Ethical Use of Human Body Donors

The main purpose for the establishment of BDPs is to provide medical and healthcare institutions with human bodies for the study and enhancement of education and research. The individuals that donate their bodies altruistically to these programs deserve the utmost respect and dignity. Throughout these guidelines, this fundamental belief is pervasive. It is therefore important to have a specific section of these guidelines that emphasizes this belief and describes the ways in which the proper ethical treatment of donors occurs in education and research. Human body donors have long been used for teaching purposes. For this reason, many policies and procedures have been put in place to ensure that they are treated with honor and respect. Meanwhile, there is an increasing use of human body donors for research purposes and clinical training which introduces new challenges for body donation programs. Regardless of the capacity by which end users work with the donor, it is important for body donation programs to:

- Use the seven guiding principles below (including the 4 principles of bioethics: Autonomy, Beneficence, Justice and Non-maleficence) to provide dignity to the donors
- Establish an ethics review process for education and research involving human body donors
- Require donors' informed consent in a transparent process on their involvement in education and research activities
- Educate users on issues related to research involving human body donors

Autonomy: The ability for an individual to freely choose what happens to their body - both in life and in death is an important fundamental principle. The use of an informed process for consent to body donation and the use of an individual's remains after death is as important as consent to research on the living. Additional consideration is needed to effectively account for decisions that may be made after death where the will of the donor may not be apparent.

Beneficence: This principle seeks to produce positive value from any research or education that would occur with the use of a living or deceased human. If no positive value is to be obtained from the use of the donors' tissues, then the justification for their use is not valid.

Justice: BDPs should be cognizant of how and if donations to their institution reflect the demographics and socio-economic status of the region they serve. Informational campaigns about body donation as a choice of disposition should be inclusively offered within the community. Donations should be made willfully under an informed process for consent. Body donation programs should not accept unclaimed or unidentified individuals into their programs as a matter of justice. When studies have an impact on living subjects, diversity, equity and inclusion should be factored into sample size considerations.

Non-Maleficence: The principle of non-maleficence applied to living human subjects must also apply to human body donors. Users of body donors must consider the probability and magnitude of harm anticipated in their use research and avoid this risk in all ways possible to reduce that risk. Unethical handling of donor remains could harm the donor's reputation, and inflict mental and emotional distress on their next of kin, family, and friends. In this context, scientific and educational preparations and dissections, clinical and surgical procedures are not considered damage, as these actions serve the intended purpose of the donation.

Privacy: It is crucially important to maintain the donor's privacy. A breach of privacy can have detrimental effects on a person's reputation, their relatives and community - as well as for the donation program. The donor may, voluntarily, provide additional information on their medical or social history to increase the learning potential for the users, but this information should be restricted to the learners and should be protected in the same manner as personal information is protected for the living. For example, following the principles underlying the Health Insurance Portability and Accountability Act (HIPAA). All users of human material should be cautioned against discussing any information about the donors in public places - especially that information that could be personally identifying (tattoos, specific scars, or health information).

Respect: Human body donors must be treated with respect for the value and dignity of the once-living person. This behavior honors the ethically binding agreement made with the donor before death, but also reflects the integrity of everyone involved. Moreover, respectful treatment of body donors honors their surviving family and friends who have a strong connection between the body and their loved one.

Stewardship: Researchers, educators and clinicians- all end users- must be made aware of the obligation of stewardship when working with body donors. This is reflected in maximizing the use from this generous donation by taking all necessary actions and precautions. The donors provided their bodies for education and research and this should be relayed to the users to help avoid emotional stress. A part of stewardship is recognizing that the gift of a donor's body is precious and is a loan, so that all who use them become stewards of this loan and treat donors in a way that befits their precious gift.

2. The Body Donation Program

A body donation program is an institution or organization authorized to receive and allocate an anatomical gift. Such gifts are donations by an individual or their legally authorized representative of all or part of that individual's body after their death for the purpose of research or education.

There are numerous legal, ethical, and logistical considerations in the operations of a body donation program. This document discusses the best practices and considerations of program operations, including the following factors:

- Programs must follow all national, state, and local laws
- A governing body should provide oversight to the program (Oversight Committee)
- Operations management should be separate from the governing body
- Legal counsel should be consulted during development of the program and drafting of any paperwork
- A donor registry should be utilized to document donations and track donor movement
- The physical plant of the facility should be designed and organized in a manner that ensures donor security and safety
- A revenue neutral budget should be implemented
- Specific embalming and preparation protocols should be developed
- A policy and policy education program should be developed
- A review process for appropriate use of donors should be implemented

The following sections of this document will discuss each of these factors in detail.

Laws

Authorization for body donation in the United States can be made by a donor (self-donation) or in some circumstances, by their Legally Authorized Representative (LAR) - often the next of kin or an agent of the donor. The Uniform Anatomical Gift Act ("the Act") which has been adopted in some form by all US states, specifies how a donation can be made and who can make a donation as well as the order of authority for making a donation. This Act applies to donations for transplant, therapy, research and education. It is based on uniform language but contains modifications as amended by state legislatures that may vary among states. A consent to donate combines requirements of the Act as it applies to donations for education and research; and, policies and practices of the Body Donation Program. Body Donation Programs can create policies and practices that are more restrictive than the Act but they cannot be more permissive. For example, some programs accept self-donation only while others allow a LAR such as a spouse, registered domestic partner or child to authorize donation. The LAR is defined in accordance with the Act.

The model language of the Act has been adapted and implemented by most states in the United States and allows for any individual of sound mind and legal age to donate all or parts of their body, effective upon their death. The Act governs anatomical gifts for transplant, clinical therapy, education and research. When a gift is made for education or research, the receiving organization must use the gift for "medical or dental research, education or the advancement of medical science or therapy" (Gilligan and Stueve, 2011: 23).

Legally, under the Act, the donor's wishes for donation take precedence over any contrary wishes of the survivors (Gilligan and Stueve, 2011: 23). However, each body donation program must carefully consider the ethical and legal implications of accepting a donation against the wishes of the next of kin.

A LAR may donate a decedent's body in some U.S. states and under certain circumstances. The body donation program should consider whether they will accept donations legally made by another person and under what circumstances. The Act outlines the order of priority as to who may donate a body. Conflicts, however, sometimes arise within families and BDPs should develop a policy and practice for handling such circumstances. Notably, a BDP can decline a donation for many reasons including need, eligibility, suitability, facility limitations and other reasons (see Section 7 below). Knowledge of the Act including the order of priority of who may donate can help BDPs and their legal counsel decide how to proceed in difficult situations.

In addition to compliance with the Act, the gift must also be consistent with both local and state laws. Body donation programs should stay apprised of any changes in legislation and be aware that laws may differ among jurisdictions. Additionally, programs should be aware that laws regarding the treatment of human remains may be more stringent for funeral homes than for body donation programs; however, every effort should be made to adhere to these more stringent requirements whenever possible as they generally err on the side of the rights of the deceased.

3. Policies and Procedures

3.1 Institutional Policy

Institutions should develop detailed policies for the body donation program that reflect the values of the institution and the mission of the donor program. These policies should delineate the program's roles and responsibilities and describe the procedural requirements and general processes of the program. The policy should address governance, oversight and reporting structures for the program; donor registration and consent; tracking, users and uses; financial models; staff; facilities and security as well as how policy violations will be reported. All policies should be reviewed and updated regularly.

3.2 Financial model

It is a best practice that body donation programs operate as revenue neutral entities. The practice of operating as a non-profit aligns with the ethical obligations of programs to support educational needs without the goal of generating profits to support non-donor program uses. The following factors should be considered when designing a BDP budget:

- Profit / surplus revenue usage for maintenance
- Separation of duties among personnel
- Supplies to be budgeted
- Fee structures that reflect actual costs of BDP operations
- Accommodation for temporary fund accumulation for large revenue projects

The uses of any profits generated by the BDP should be decided by the governing body. Initial start-up costs and operational expenses for running the program should be calculated. The budget should be sufficient to permit staffing at a level that facilitates a separation of duties among personnel (Champney et al., 2020). It is recommended that licensed funeral professionals with training in embalming and mortuary regulations be hired (Champney et al., 2020). Budget estimates should include equipment, chemicals and other laboratory supplies, information technology, security systems, professional personnel and support for program administration (Champney et al., 2020).

Fee structures should be developed that permit the program to cover its costs without generating revenue beyond that needed to meet its public service or institutional service goals. The service fees should be regularly reviewed and adjusted as program expenses change (Champney et al., 2020). Incoming revenue should be only enough to cover the costs associated with supplies, staff salaries, and equipment. The program's revenue generation should also be separated from that of the home institution, and not used by the institution to cover other expenses (Champney et al., 2020). The goal is for the program to be self-sustaining and not a profit generating entity.

Accommodations may be made for funds to be accumulated temporarily for planned expansions and / or improvements. If a program identifies a future expense that would result in

improvement of the program and / or services provided, it may opt to bring in more revenue than necessary to cover its current costs in order to secure enough funding to cover the desired improvement.

3.3 Policy Education Program

A policy training program should be implemented to educate end users about the program policies and the appropriate use of human body donors. Such a program ensures not only that end users will follow policies and procedures outlined by the program but also that they will gain a greater understanding of the ethical considerations of working with body donors in education and research. Training can be customized and tailored to the needs and specifics of each program and the context of end user interaction with donors (e.g., education, research). Offering Continuing Medical Education (CME) credit in context with other activities such as ground rounds may facilitate greater participation (Schmitt et al., 2014).

Educate Researchers

Providing researchers working with human body donors with the opportunity to learn about the issues associated with body donation will help improve the way they work with donors. Below are some of the topics that could be addressed based on the same principles that Institutional Review Boards apply to research projects on living human subjects.

3.4 Procedures

A Standard Operating Procedure Manual (SOPM) should be developed to address administrative and technical procedures, to document safety requirements and staff training. Other procedures may be developed to support established policies and committee charters. The development of clear procedures provides consistency in operations, clarity for reviews and a streamlined training process. Each section of this manual can serve as a resource in developing strong policies and procedures in a BDP.

3.5 Policies on Use of Digital Images of Donors

All users of donated tissues should follow, disseminate and enforce a policy on images of donor material that meets the Terms and Conditions of the body donation program. Although it is not illegal to publicly disseminate donor images that contain identifiable features (e.g., an undissected face), it may violate the donor consent, the BDP Terms and Conditions, or could have negative implications for others. The public may find both the images themselves and their public dissemination to be upsetting, inappropriate, or offensive. Offense at public dissemination of donor images could result in negative reaction to the users and the body donation program. These damages could include decreasing public respect and confidence in the health professions, decreasing donations, and / or legal liability. Offense at public dissemination of donor images could also affect the responsible individual, including negative impact on their professional

reputation and career, as well as legal liability. Accordingly, it is necessary for the user organization to regulate their use.

With these considerations in mind, the following uses should be considered. Electronic images can only be made with written approval of the BDP Oversight Committee and under the guidance of the person with designated responsibility under the use at hand; i.e., faculty or other individuals approved by the Oversight Committee. Electronic images can only be made using equipment provided by the user and stored on their secure network, or the pre-approved method. These images can only be transferred over a secured managed network. Electronic images should only be made accessible to current students or employees of the user who have a professional interest in the material. These users should have explicit policies regarding publication of images for research purposes that mirror the policies of the BDP.

Certain uses should be explicitly disallowed. Transfer of images off the users' network onto end user private computers should not be permitted. Images should not be collected of parts of donors that might be easily identifiable, including but not limited to undissected faces and tattoos. Making or transferring images of donors with privately owned electronic devices should be disallowed, including, but not limited to phones, cameras, and tablets. Storing images on devices that are not password protected and encrypted should be prohibited. Clear consequences for failure to strictly adhere to the image policies should be specified.

The IFAA has published guidelines on use of donor images. This should be consulted when developing policies and procedures.

4. Governing Body and Oversight

4.1 Governing Body and Oversight of Body Donation Programs

Institutions with Body Donation Programs should have a governing body (Oversight Committee). Oversight should be conducted by a group with the following characteristics:

- Governing body separate from the program administration
- Familiarity with applicable laws
- Willingness to conduct periodic reviews
- Decision making on ethically challenging issues

Body donation programs should have oversight from a governing body or Board in order to ensure adherence to protocols and regulations as well as ethical oversight. The Oversight Committee should be an established group familiar with applicable laws, best practices, and standard operating procedures that is made up of subject matter experts who can advise on institutional values and practices as well as program policies and procedures. Institutional review of the program and facilities should be conducted on a regular basis. Most states do not have an official regulatory body that is responsible for oversight of body donation programs, and the degree of regulation varies depending on the state.

Examples of governing body members include:

- Responsible executive from the institution
- Legal counsel
- BDP director
- Faculty representatives
- Environmental Health and Safety officers
- Compliance officer
- Biomedical Ethicist
- IRB officer/ Office of Research representative
- Representative end users
- Public member
- Chaplain or other spiritual/ religious leader

4.2 Operations Management

Body donation programs should have a system of operations management that is distinct from the governing body providing oversight. Program operations management should be responsible for supervising the program's staff, ensuring that standard operating procedures are being followed, responding to the day-to-day needs of the body donation program, assessing quality control, and reporting to the governing body.

4.3 Legal Counsel

Each body donation program should consult with legal counsel about the development of new procedures and any new paperwork. Programs housed within a university or other educational organization should consult with their organization's general counsel.

Programs not affiliated with a larger organization should hire legal services from an external firm. In these cases, the counsel retained should be familiar with mortuary law and the Uniform Anatomical Gift Act as applicable to their state, as well as any other relevant to body donation.

4.4 Ethics review process

Research on deceased human body donors is not required to be reviewed by Institutional Review Boards (IRB) as body donors are not living human subjects. It is however important to have a review process in place to approve such research and a mechanism to continuously oversee the process. Reviewing research on human body donors in order to provide ethical approval requires a team with a wide range of expertise. In this case, the Oversight Committee / governing body should include members with subject matter expertise in research.

5. Donor Program Personnel

5.1 Management

Program management must include a person who is responsible for the day-to-day operations of the BDP. This person must be knowledgeable on the laws, rules, and regulations that are applicable to BDPs, including those related to the relevant mortuary and cemetery codes in the state(s) the program serves. The manager should be responsible for supervising the program staff, ensuring that standard operating procedures are being followed, assessing quality control, and making decisions on requests for anatomical material. This individual may also be responsible for tasks such as managing the program's operating budget. Managers should provide periodic reports to the governing body for review, raise agenda items that represent new or unique topics, and participate as a subject matter expert on the governing body. A best practice for governing bodies and daily operational decision makers must include checks and balances.

Generally, the management team consists of subject matter experts, including those with qualifications such as a degree in Mortuary Science or a Ph.D. in a field relating to Anatomy. Ideally, managers will have greater than 5 years of work experience specifically in body donation programs, though context-specific criteria should be considered such as the individual's capability, initiative, reliability, and vision. Additionally, a program should consider having dedicated operational staff that are separate from the end users in order to avoid real or perceived conflicts of interest.

5.2 Training and Professional Development

As there are less than 200 BDPs in the United States, there are limited opportunities for training programs specific to the unique processes of whole body donation. On-site training is typically performed by the donor program and / or institution. Job-specific training as well as more generalized knowledge about the program itself should include:

- Donor consent and ethics
- Relevant laws
- Media practices
- Safety protocols, such as: general lab safety, chemicals, personal protective equipment, and blood-borne pathogens

Currently, there is a lack of formal inter-institutional training opportunities. Thus, professional development and networks of BDP personnel are critical to the optimization and efficiency of donor program operations. Professional development opportunities should be provided to body donation program staff. Opportunities to network in the form of listservs, and virtual or in-person conferences, may facilitate these relationships. Some options include:

- Anatomy Network, a discussion board of the American Association for Anatomy
- American Association for Anatomy symposia and webinars
- Listservs of Regional Body Donation Consortia (West Coast, Midwest, East Coast)

- Virtual and / or in-person meetings of Regional Body Donation Consortia (West Coast, Midwest, East Coast)
- Biannual symposium at the American Association of Clinical Anatomists' annual meeting

5.3 Staff roles:

Depending on the size and scope of the program, the roles described below may vary, and tasks may be assigned to one or more roles. Regardless, there should be adequate staffing within the BDP for appropriate checks and balances, including prevention of human error. The SOPM should be regularly updated to include current procedures for completing all tasks.

Donation Coordinator: This role is responsible for coordinating day-to-day administrative aspects of the program.

- First point-of-contact, receiving communications from prospective donors, families, and any other interested parties wanting information about the program
- Sends and receives paperwork, checking for eligibility and completion
- Sources medical history from healthcare providers in compliance with HIPAA
- Maintains the registration database

Anatomical Preparator: This role is responsible for receipt, preparation, transfer, and final disposition of the donor body.

- At the time of death, receives calls about the death of a registrant
- Observes the body, documenting findings and confirming eligibility/ suitability criteria are met
- Upon acceptance, creates chain of custody materials to track the donor
- Prepares the donor body for use
- Upon completion of use, prepares the body for return to family or final disposition
- Inventory, ordering, and maintenance of supplies and equipment
- Cleaning and maintenance of facilities following EH&S and/or OSHA guidelines

Lab Technician: This role is responsible for maintaining the laboratories (e.g., anatomy, clinical skills) where education and research is conducted. The role may be assigned in full or in part to the BDP budget.

- Orientation and supervision of end users under EH&S and/or OSHA guidelines
- Set-up laboratory following end users needs
- Inventory, ordering, and maintenance of supplies and equipment
- Cleaning and maintenance of facilities following EH&S and/or OSHA guidelines

6. Public Relations and Donor Education

Body donation programs rely on their reputations and relationships with the public to maintain their viability as a community resource. Community members use information shared by and about the program when considering donating their body to science. Donor education is an essential part of an informed consent process, and every interested individual should be treated as a potential donor whether or not they are currently eligible for donation. For example, though there are acceptance criteria at the time of death, the program may not know if someone is medically suitable at the time of donation. Similarly, while many programs do not allow donors below the age of 18, educating individuals of all ages may encourage them to donate at a later date.

Given the sensitive nature of the work of body donation programs, communications about donors and the program should follow from principles of transparency, dignity, respect, sensitivity, and accuracy. Respectful terminology should be used at all times, and words chosen with care. To that end, consistent terminology will reduce confusion and the chance of conveying mixed messages. Moreover, programs should have transparent, clear and concise policies, procedures and public facing operational descriptions that educate end users and interested parties while deterring speculation and morbid curiosity. The dissemination of accurate information is essential and inquiries about the program should be referred to trained and knowledgeable individuals.

Body donation programs should develop explicit goals and policies regarding advertising and contact with potential donors in order to avoid coercion or enticement. Consideration should be given to the diversity of the donor pool and the accessibility of information to ensure that a wide range of groups are represented, that the program and forms are accessible and that vulnerable populations are not disproportionately targeted.

When educating the public about whole body donation, program staff should make efforts to educate prospective donors about whole body donation and how their program fits into the broader picture, such as improving education and delivery of healthcare, and whether their organization is a nonprofit or not-for-profit. This provides information for prospective donors to make their most informed choice. Those interfacing with the media should have basic training in public relations.

6.1 Initial Engagement

Prospective donors and their families hear about body donation programs from many sources. Regardless of the source, it is important that program information is disseminated to a diverse audience in a manner that is free of any form of coercion or enticement.

Word-of-mouth between two individuals who know each other and have no connection to the donor program is a common mode of engagement. This is arguably the most ethical type of initial

engagement for dissemination about a donor program, as the program itself is not involved in the impetus for sharing the information. Legacy donations fall into this category, where generations of families choose to donate their body to a given whole body donation program. Word-of-mouth promotion, where the information conveyed may be inaccurate or incomplete, may require additional information from the donor program.

Hospitals and hospices: Direct solicitation of terminal patients in the hospital or hospice by the donor program is not a best practice. However, medical providers and hospice workers can be made aware of the possibility of whole body donation to provide information if a patient inquires about donating their body..

Establishment media, paid or unpaid advertisements: Newspaper articles and other features are considered an ethical form of dissemination of knowledge so long as it does not exploit specific populations, is free of misinformation and coercion, and there is no form of social contract and / or relationship between prospective donors and program staff.

Social media: This type of engagement must be carefully crafted and considered before publishing due to the brevity of the platforms and the ubiquity of dissemination. Social media has been a source of misinformation and therefore requires careful deliberation prior to use.

Body Donation Program Website: This ethical form of engagement should be developed to reflect the mission of the program as well as provide information on how to enroll in the program.

Anatomy coursework, typically donor-based: These courses typically introduce end users to the options available for donating one's body after death. End users can then go on to educate others or become donors themselves.

Many donor programs prefer to hold outreach events. Several examples are listed below:

Annual commemoration ceremonies: When families and friends of the donors are invited to these ceremonies, it is often an emotional event that can inspire attendees to donate their own bodies. However, the emotional nature of the event means that donor programs should have a policy against registration at the event. The decision to donate should be made after careful consideration and conversations with loved ones.

Caregiver and similar conferences: As these events do not speak to the prospective donors themselves, they are considered ethical since they inform caregivers of the variety of options available for final disposition of an individual.

Anatomy laboratory outreach: These events may introduce members of the public to body donation through anatomy education.

6.2 Further information

After initial engagement, further information is typically found in detailed consent forms as described in the next section. Program staff should be ready and available for conversations to elucidate information disseminated in the options above and consent forms. They must be familiar with the information found across media, and it must be consistent in message and should be in the primary language of the donor.

7. Donor Registration and Donation Consent

Donor registration and donation consent are the documentation and authorization mechanisms that a donation program uses to track an anatomical gift to their organization. A Body Donation Program records and maintains information on individuals who have signed a donation consent in a donor registry. This may include Personally Identifiable Information (PII), such as an individual's name, birthdate, or social security number. The donation consent, also known as a Document of Gift, is the cornerstone of a BDP. It conveys information about the program and contains the details necessary for an individual to make an informed decision about body donation to a specific institution or organization. Informed consent is a term most commonly used when a living person participates in research. Many of its principles can be applied to a Document of Gift that authorizes a body donation for education and research.

7.1 Registration Process

A Body Donation Program's registration process must provide accurate information about body donation. It must provide adequate information to allow an individual to make an informed decision when considering body donation to the organization. It must convey information that can be easily understood to a lay person and contain: program contact information and instructions on how to complete donation-related documentation; any financial implications for the donor's estate; information on donation eligibility, medical suitability or exclusionary criteria; death notification, registrant screening and donor transportation protocols; and, frequently asked questions (FAQs).

7.2 Donation Consent

A donation consent must comply with the Uniform Anatomical Gift Act in the applicable state and contain details about how a donor's personal and health information may be used and how it is protected. It should contain details about how a donation supports the organization's mission including the following information, as applicable: possible preparation types; possible uses; types of users both internal and external; possibility of transfer(s) to include in-state, domestic and international; duration of use or permanent retention of whole body or parts; including methods and safeguards in place to ensure the body donors are tracked throughout the donation, use, and disposition processes; disposition type(s) and options for return or internment.

Donation consent must include any known activities that the program may allow or prohibit, such as whether images or video of the donor would be collected and for what purpose (teaching, publication, or a commercial purpose); whether the donor program could profit financially from the donor's tissues directly or could create, or allow a user to develop a commercialized product through the use of the donor; whether the donor could be disarticulated or parted ("dismembered"). It must indicate whether the donor or parts of the donor could be transferred to programs or users outside of the donor program or to other states or internationally and how

long they may be retained. It must explain whether the donor could be used for any research or education that may identify them or their hereditary family including genetic research.

The consent forms should also describe any disposition and distribution of bodies and body parts at separate times or in different locations. It should detail any possible uses for forensic or military purposes. It should explain whether the donor program organization may change policies to allow for future education and research uses and how or if a registrant or donor's responsible party would be notified. If donor names are potentially included in Permanent Memorial Displays, donors should be given the opportunity to exclude their name from the display.

Donor program guidelines vary as to whether or not they allow donors to choose from the above options. In either case, the program must address the intended use of the donor body. It is a best practice that BDPs provide consent documents with adequate information to allow an individual to choose to donate in an informed manner.

Specific recommendations are made in the Appendix, from Johnson et al. 2023.

7.3 Consent Format

Donation consent forms can be formatted in a way that best suits the program and organization's needs. Oftentimes, they are included in an informational package that contains more information about the program and institution or organization such as an overall mission, program FAQs, instructions for completing and returning forms, health and social history worksheets, state or other required forms such as a release of body form or cremation authorization. A medical record release or HIPAA authorization may also be necessary. PII that is collected may be used to verify a donor's identity at the time of death or to complete state required paperwork such as a death certificate. Consideration should be made for text size, readability and accessibility. Donation forms should be provided in native languages and delivered through mechanisms that can be accessed by differently-abled individuals.

Programs may also consider constructing the consent form to allow for a donor to opt-in or opt-out of certain program practices if applicable, such as transferring the donor to another institution or participating in certain types of uses like those that collect genetic information or support military testing. A checklist may facilitate this process. A program must have a mechanism to track and apply any option that is included in the donation consent forms. Some programs may wish to state the parameters for their program as it applies to all donors and not allow modifications. In either case, body donation is an option for disposition and anyone who chooses it must make the decision in an informed manner that is free from misinformation and coercion.

Consideration is also needed to address how a program may change over time. For instance, a program that supports only anatomy education could expand to support other types of education or research over the course of many years. Including a statement that acknowledges this possibility is important. Programs may re-consent individuals by sending new forms to the donor

registry. If the program intends to support a small, unique project, it may wish to seek alternate consent from a LAR post donation. If the consent a donor signed does not adequately cover the education or research needs at hand, a BDP may choose to employ a process that allows the donor to designate a proxy decision maker to consent for these uses on behalf of the donor. In any case, it is desirable for the governing body to engage ethicists and subject matter experts in the discussion and decision process.

Finally, transparency is needed when disclosing financial aspects of the program. Providing information on how a program may recoup costs from end users and if, or in what ways, it supports the development of a commercial product through the use of the donor's tissue, data or images can impact an individual's decision to donate.

7.4 Consent for Research

Human body donors need to provide informed consent before being included in any research project. This consent should be provided as part of the donation process whether in person or through the next of kin or proxy decision maker. Different approaches can be used to achieve this goal. This could be achieved by providing examples of research conducted at the time of donation or by providing this information at any time upon request. Other means could include providing an option to be excluded from any research. An additional method would be including a checkbox for types of research that would be allowed or disallowed. These procedures will allow a body donor and their next of kin greater control over the types of research that could be conducted on the donor. A BDP must be capable of tracking and applying any options it offers for use and disposition.

8. Determination of Donor Body Eligibility and Suitability

A BDP should develop eligibility criteria and suitability guidelines for donations that can be disseminated to interested parties as they consider body donation and make end-of-life plans. Criteria should be developed with the guidance of a medical director with infectious disease expertise. Eligibility criteria should include information about an individual's capacity to make a donation or requirements that must be met by donors. Suitability guidelines set forth the parameters that an individual program uses to determine acceptance at the time of death.

Program eligibility and suitability will vary from program to program. Some programs may consider certain criteria as eligibility factors, applied to every donation. Others may consider the same information a suitability guideline that may be acceptable on a case-by-case basis. A body donation program should also reevaluate both eligibility and suitability on a regular basis.

One example of a criterion that may differ among programs is body composition. A program may set an eligibility requirement by height, weight or BMI (high and / or low) such that any donor falling outside the range is not eligible to register with the program. It is important to note that while BMI is widely used in healthcare, it is a calculation derived from data that does not represent diverse populations including people of color and females. BMI use can be inaccurate and discriminatory. However, an understanding of body composition may be needed to serve as a guideline to determine suitability for specific education or research endeavors and BMI may be useful for this purpose. Body donation programs should strive to use alternate body composition markers whenever possible.

8.1 Eligibility Criteria

Eligibility criteria should address the program's requirements for capacity, medical status, and other considerations that preclude an interested individual from becoming a donor to the program. Categories of eligibility criteria include:

Capacity

- minimum age for consent
- legal authority to consent on behalf of another during life and after death
- altered mental status
- vulnerable populations

Medical status

- conditions that alter anatomy (trauma, organ donation)
- communicable diseases

Others

- funeral preparations

- family disagreement
- body mass / body condition

Capacity refers to the mental or emotional ability to consent or authorize a donation. There may be legal requirements for capacity, such as a minimum age at which a person can consent for themself, or legal parameters for having the authority to authorize donation on behalf of another person. Institutions may wish to set limitations that are more restrictive than the law. For example, the law may state that an emancipated 16 year old can legally consent for themself, but an institution may further restrict donation by allowing donation of those who are at least 18 years of age. Consideration for capacity may include the neurological capabilities of a potential donor, including individuals with altered mental status. Vulnerable populations should also be considered when determining capacity restrictions. Some examples of vulnerable populations include: individuals who are incarcerated, those who are unable to consent for themselves such as individuals who are incapacitated, and adults placed under the protection of a legal guardian or government entity, such as a court.

Medical status includes current health information of a prospective donor including conditions that alter the anatomy or may contain risks to personnel or end users. Conditions that may alter anatomy include extensive metastatic cancer, amputation, extensive recent surgery, or trauma. Some communicable diseases to consider may include tuberculosis, prion diseases, untreated MRSA / Sepsis, Clostridium Difficile, Hepatitis or HIV. Body donation programs should factor in post mortem interval, the intended preparations and uses when considering which medical conditions are acceptable. Treatments for many communicable diseases are evolving and regular review of eligibility and suitability criteria should be conducted.

There are many other factors that may be considered when evaluating eligibility of an individual. Such factors may include geographic considerations, funeral preparations and the concurrence of family or loved ones regarding the choice of anatomical donation.

8.2 Suitability

Suitability guidelines are criteria that may be used to help a program determine which donations best meet current needs for education and research. Revisiting suitability criteria is a good practice because donor status may change between registration and death. Additional criteria to consider may include:

- body characteristics
- body condition
- time since death or method of storage
- decomposition
- manner of death
- autopsy or organ donation
- family disagreement or objections

Guidelines for body characteristics such as height and weight may be considered for specific uses as well as facility limitations or safety of personnel or end users. The condition of the body at the time of death, including factors that impact uses such as emaciation, edema, limb constrictions and others should be considerations when determining suitability.

Consideration is also needed for the amount of time that has passed since death and how the body has been stored. Time and heat accelerate decomposition and it is important to have accurate records of both when considering if a deceased person will be accepted. BDPs that use serology testing may need to adhere to specific protocols in timeliness for blood sample acquisition.

Considering the manner of death is also helpful in determining acceptance (natural, suicide, homicide, pending or unknown). Concerns with the manner of death should take into account any ethical concerns that pertain to the circumstance or manner of death. For example, special consideration may be needed for non-natural manners of death, traumas, medically-assisted deaths or other individual situations. Other preparations or procedures can alter the suitability of a donor for use. The consideration of mortuary preparations, autopsy and organ or tissue donations when determining suitability are likely to be BDP specific since the needs of end-users vary.

Family dynamics are an important consideration that may not directly affect suitability but play a critical role in whether a donor is ultimately available for a BDP. BDPs should encourage donors to clearly communicate their final disposition wishes with family or anyone who is anticipated to enact their wishes. A body donation program will often interact with several family members, all of whom may have differing opinions on whether body donation is the best option. Common situations include cases where the body donor self-consented before death and the family is unaware or situations where family members may not agree. These situations require special consideration by the BDP and consult with general counsel.

9. Time of Death Considerations

Following the death of a registered body donor, time is of utmost concern. It is important to perform suitability and time sensitive preparation procedures while allowing loved ones to go through the grieving process.

Regulations and policies of local government, as well as those of individual donor programs, determine who performs each of these activities, and the order in which they are performed.

At the time of death of a registered donor, there are four major actions which need to occur:

- Notification of the BDP
- Determination of donor body suitability
- Transportation of the donor body
- Documentation (death certificate, disposition permit, notifying Social Security Administration)

9.1 Notification of the BDP

The body preparation process should be initiated as soon as possible. Depending on the circumstances of death, including the location and time of death, prompt notification to the donation program should be made by surviving loved ones. Donors are therefore strongly encouraged to inform family members of their donation and to ensure that they have the relevant body-donation information.

9.2 Transportation of the Donor

Once the donation program is notified soon after death, procedures for retrieval of the donor should be swiftly initiated. In most cases, a licensed funeral director or mortuary service will oversee the transport of the donor's body. Due to inherent time concerns, it is recommended that the donor is transported directly to the body donation program, especially if the body donation program has access to a licensed funeral director or if they contract with an independent funeral director or service. Though, in some instances, donor bodies will be transported to a funeral home and then to a BDP.

9.3 Documentation

Several vital record documents should be filed following an individual's death. The documents listed below are required regardless of body-donation status. However, the BDP may be involved in applying for and acquiring the documentation, depending on the state and the specific processes of the donor program.

Death Certificate: A proper and accurate death certificate must be completed following an individual's death. The purpose of the death certificate is to create a permanent record of the cause and manner of death.

States differ regarding who performs the vital records service of generating a death certificate; therefore, it is important to refer to the Vital Records Act of the state in which the individual died for specific mandates. A death certificate is most often signed by a treating physician or may be completed by a medical examiner or coroner.. Some states employ a dedicated death investigator, while in other states a funeral director may initiate and file the death certificate to vital records. Sometimes, a body donation program performs the functions necessary to file a death certificate.

Disposition Permit: A disposition permit outlines how human remains will be processed. State laws determine who applies for and who processes applications for disposition permits. In most states, a funeral director or person acting as such (which may include a body donation program) will be responsible for obtaining the disposition permit.

Notifying Social Security Administration (SSA) and Veterans Affairs as applicable: After death, it is important that the United States Social Security Administration is notified. Depending on the state, the individual responsible for notifying SSA differs. In most cases, the funeral director will report the person's death. In some cases, this may be performed by the body donation program. Veterans Affairs notification is applicable for donors that have served in the military.

9.4 Family Responsibilities

It is important that a family member notifies the BDP soon after the death of the donor to ensure that the donor’s body will be evaluated for acceptance, to receive any information important for enacting the donation and to have transportation arranged.

10. Donor Preparation and Use

A BDP must use the donor body in a manner that conforms with the donor's wishes and directives as outlined in the consent / authorization agreement. Initial receipt of a donor body may include a quarantine period in which blood or serum may be tested for pathogens or in which donor medical history or medical records may be evaluated. In most instances, the body will be washed and disinfected, tagged with a unique identification number and a preparation type may be determined.

10.1 Preparation Methods

BDPs preparation methodologies will vary according to the education and research initiatives they support. Generally, donors are used in preserved, unpreserved or skeletonized states. Preservation methodologies may be embalming or soft-embalming with preservatives of various compositions (aldehydes, alcohols, salts and other proprietary or nonproprietary techniques). Plastination is another form of preservation. Techniques like colored vascular injections may be used with or without preservation. Unpreserved donors may be used fresh, or fresh-frozen. Techniques like skeletonization may be used to facilitate education and research in anatomy, osteology, anthropology and other disciplines.

Separate standard operating procedures (SOPs) should be developed for each type of preparation technique. As there are unique public health issues and risks associated with embalmed versus unembalmed anatomical material, staff should receive appropriate and specialized training in safety precautions and in the types of care required for each preservation type. Institutions with Body Donation Programs must ensure that personnel receive adequate training in these areas to ensure staff safety, program compliance with OSHA and other health safety standards, while maintaining dignity and respect of donors. Considerations also include the needs of the end user. Preparation protocols and procedures should balance the operating procedures with the needed end product.

10.2 Separation, Labeling and Packaging

Regardless of preparation type, some donors may be used in a whole body state while others may be used as individual body parts that have been separated from the whole. Body donors support diverse needs in education and research. Not all classes and training programs require the use of a complete donor and, in some cases, a donor may be able to support multiple education or research needs when parts are separated. For example, a podiatry program may require only lower extremities, while a dental program may require only the head and neck region of the body. Therefore, another consideration for BDPs is to evaluate the circumstances and ethical considerations, if any, to engage in the physical separation of a body donor into anatomical regions or parts. These decisions are nuanced and involve balancing respect for the physical integrity of the donor with the desire to honor the donor's wishes by ensuring that the entire body of the donor is fully utilized for study in medical education.

Anatomical material must be clearly labeled with a unique, non-identifying code on the item itself and on the external packaging. SOPMs should contain detailed procedures for the type and placement of labels and the specifics of packaging for the appropriate storage, inventory and transportation methods the anatomical materials may be subject to in the course of education and research use. If a public carrier is used for shipping body parts, all carrier protocols must be followed.

11. Storage, Database, and Tracking

11.1 Facility Physical Plant

It is a best practice that buildings housing anatomical materials are secured with access limited only to authorized persons. In particular, each BDP should be housed in a facility with the following characteristics:

- Secure identification to enter
- Alarm system
- Strict visitor policy
- Secure storage
- Monitoring procedures

Ideally, a double-identification system should be used in which an unauthorized person with a key would still not be able to enter the building (e.g., a key plus PIN or identification badge). An alarm system and / or security cameras can be utilized inside and outside the building, including in donor storage areas but should not image uncovered donors . Visitors to the facility should only be permitted to enter if they have a valid professional reason, and they should not be left unsupervised in the program space.

Programs may want to limit access from within the institution even to custodial and facilities staff, such as requiring BDP personnel to be present at all times when other non-BDP staff are in the facility.

11.2 Storage

Every effort should be made to safely and securely store and protect all anatomical material in the program's custody. SOPMs should address the respectful and organized storage, maintenance, and inventory of differently preserved donors. BDP storage systems should include:

- Freezer or cold storage
- Individually labeled racks or tables
- Lift systems
- Sturdy, nonporous tables suitable for preservation chemicals
- Protective wrappings and coverings
- Regular fluid maintenance
- Transfer boxes

Depending on how the program prepares donors, freezers or other cold storage may be necessary. As a best practice, physical storage of donors should be in individually labeled racks or tables with designated numbers that can be linked to the donor number in the database. Tables and racks should be sturdy, preferably stainless steel or other chemically inert, non-toxic material that can be easily cleaned and disinfected.

Donors in storage should be protected by wrapping in muslin or other cloth, covering with shroud, and / or body bag. Body regions vulnerable to dehydration may require additional coverings including plastic bags specific to those regions. The condition of donors should be assessed periodically and maintenance tasks performed, including the removal of excess fluid, mold treatment, additional disinfection, and / or changing the cloth wrapping, as needed. Donors may be stored in durable cardboard boxes for transfer, but ideally they should not be kept in this manner long-term.

11.3 Database

A crucial component of body donation best practices is the accurate and up-to-date tracking of registrations, body donations and anatomical material. Best practices dictate that each BDP must maintain a current and active database of all registered donor applicants and anatomical gifts. The registry should have secure access sufficient to maintain personally identifiable information. It should be searchable and contain detailed information about each donor. Each program should implement a record management plan, in compliance with institutional guidance and applicable laws, rules and regulations, that indicates how records will be stored or archived and for how long.

The database must be password-protected and accessible only to designated individuals. It should be backed-up regularly, preferably daily, onto an external secure server or by other means of storage. Information to be listed in the database should include, but is not limited to, personal donor information (e.g., name, gender, date of birth, date and location of death, cause of death, method of final disposition), screening or serology results, date of arrival to the program, document of gift, chain-of-custody documents, other associated documentation including transportation paperwork, status of donor (e.g., received, transported to end user, at rest), preparation techniques, and current location of donor or donor remains.

Database software can be expensive, and many small body donation programs may not be able to afford top-of-the-line software. In these cases, alternative options such as an Excel spreadsheet backed up in multiple locations may suffice. Some universities may also opt to generate their own in-house software which is customized to their needs.

11.4 Tracking of material from delivery to final disposition (chain-of-custody)

In this context, tracking refers to the method of recording the physical location of a donor from the time they enter the program until final disposition. The tracking system should contain the following features:

- Tracking numbers
- Identification markers / tag
- Numbered tables and racks

At the time of death and upon acceptance into the program, it is best practice to assign each donor a unique internal tracking number. An identification marker with this tracking number shall stay physically attached to the donor and the external packaging /container until final disposition. In order to maintain donor anonymity, other personal identifying information should be removed. The tracking number must be used to track movement of the donor both within the facility (e.g., between embalming table and racks) and outside of the program (e.g., from program to anatomy lab to crematory) via the database, a chain-of-custody mechanism and regular inventory procedures. Tables and racks should be numbered, so that each donor's precise location within the facility is trackable. As a donor is moved around the facility, their location information should be updated in the database.

Guidelines on transport of bodies within states, across state lines, and internationally

It may sometimes be necessary to transport a donor within a state, between states, or even internationally. Transportation of anatomical gifts must adhere to all applicable federal, state, and local laws as well as all protocols of the shipper or carrier. A BDP's transport procedure should include chain-of-custody documentation and secure packaging. Transportation may be through a mortuary or mortuary services vendor or a medical courier. Disposition permits must be filed or re-filed according to the laws, rules and regulations of the originating and receiving state or nation. If public or private shipping is needed, the program should utilize an appropriate choice of parcel carrier that sets forth a specific and transparent process for the shipping of human remains, preserved or unpreserved. Appropriate documentation should accompany the shipment and signatures should be required upon delivery.

In the United States, cremated remains may only be shipped via the United State Postal Service (USPS) Priority Express Mail (Fritch and Altieri, 2015). Carriers such as UPS and FedEx do not accept cremated remains for shipment. According to the National Funeral Directors Association (NFDA), cremated remains should be placed in a thick (2 mm), durable plastic bag, sealed with a zip tie, inside an urn / container with an identification marker on the top or bottom (NFDA, 2014). Best practices also include selecting the option for a required signature upon delivery.

When it is time for the donor to be delivered to the end user, the tracking information should be clearly communicated to the user. If the user and program belong to the same institution, the databases may be linked to facilitate tracking. The end user should also have a method for tracking the location of donors within the laboratory or other secure facility. After the period of study, the transfer of the donor back to the program or directly to the crematory must be handled in the same manner.

Barcode systems or small electronic tracking devices such as radio frequency ID's (RFID), can be used to monitor the location of the donor or parts of the donor at all times. The location of all donors and donor specimens in any facility must be known and documented for return or final disposition.

12. End Users

End users are educators, researchers, clinicians, students, or other individuals who use anatomical material from a BDP. They must operate within an End User Organization (EUO), such as an educational or research institution (university, college, medical school, academic medical center, hospital, clinic, research facility). EUO leadership is responsible for adhering to the Terms and Conditions agreements with the Body Donation Program. The Terms and Conditions specify the EUO responsibilities while donor material is in their custody, including security of donor material, tracking, chain of custody and return to the body donation program. EUO leadership should develop and implement policies and procedures in their organizations that mirror and support the BDP Terms and Conditions. The EUO must have a contact who has primary responsibility for knowing and dissemination information about the approved use of body donors. They are responsible for management of the teaching or research facilities in which the material is housed and used by end users.

12.1 Teaching and / or Research Facilities

The teaching and research facilities – the physical spaces where teaching and research activities take place where human donor material is stored and used – should be vetted by the BDP and managed by specific individuals (facility managers). These managers work for the EUO within a well-defined management hierarchy. They should be clearly identified, appropriately trained, empowered to implement EUO Policies and Procedures. They should be supported by appropriate management structures. Managers should have training in anatomy laboratory management, including ethical, legal, and safety issues surrounding the use of body donations. They should possess appropriate training, certification or licensure in a related discipline and have experience with dissection. They should be able to work with diverse groups, have high ethical standards, and maintain the dignity and respect due to the donors.

Responsibilities of facility managers include:

- Familiarity with and authority to enforce body donation program and EUO policies regarding the use at hand not limited to:
    - security and tracking of donor material
    - donor maintenance
    - training and monitoring end users
    - respectful treatment of donors
    - user safety (in coordination with OSHA representatives)
    - capture and use of film and digital images.

12.2 Request for Use

BDP's must develop request processes and documentation to collect adequate information about a use and end user(s) to ensure that all uses match the terms of the donation consent and comply

with the BDP Terms and Conditions. The request process should identify a primary requester, the department chair or senior leader and contain a detailed description of the requested use including:

- Current contact information
- Type and number of donor materials requested
- Preparation type
- Length of use
- If images in any medium are part of the request
- Location of the use
- A description of the end users

Requests should be reviewed by the BDP operational team that manages the day-to-day aspects of the donation program under the policies and procedures developed by the Oversight Committee. If the request does not easily fit into the policies and procedures, is atypical or contains new concepts, an ethical review should be triggered and the Oversight Committee engaged. No use should occur until the request information has been received, reviewed and approved in writing.

It is recommended that End Users sign a pledge that specifies their responsibilities regarding the respect and dignity due to the donor and the Terms and Conditions of the BDP, including adhering to applicable health and safety requirements. Disciplinary consequences for violation of the pledge should be clearly articulated, strictly enforced and violations reported to the BDP.

12.3 Security and Tracking of Donor Material

Donor remains that are in the possession of the end user need to be housed in a secure facility, for which access is restricted to only those individuals approved by the EUO. Accidental access should not be possible. A record should be kept of all individuals accessing the facility, including date and time. Location and chain of custody of the donors should be recorded. Facility managers should:

- Only receive donor material from sources approved by their EUO
- Acknowledge and record receipt of donor material
- Record and monitor the location of donor material in their custody
- Record the transfer of custody of donor material to other responsible individuals in the user organization, if pre-approved by the BDP

12.4 Donor Maintenance

Appropriate maintenance of donor material is an important aspect of respectful treatment because it ensures that the material can be used as completely, efficiently, and safely as possible.

12.5 End User Training

End users should be given guidance on respectful treatment of donors in the lab and the implications and consequences of disrespectful treatment. They should be instructed on donor privacy, to the fullest extent possible while meeting the goals of the institution. It is recommended that the information provided to users meets their needs for the request at hand within the confines of the terms of the donation consent. EUOs may then determine what information is then accessible to their personnel. End users should be trained on laboratory, blood-borne pathogen, chemical and other applicable safety requirements. Careful training on the pre-approved use and storage of donor images, if allowed, is also necessary.

12.6 User Safety

End User Organizations should develop and implement lab safety policies that meet national, state and institutional guidelines regarding:

- Personal Protective Equipment
- Blood Borne Pathogens
- Hazardous Chemicals
- Biohazardous Waste
- Use and disposal of sharps, such as scalpel blades
- Use of specialized equipment and tools
- Emergency procedures
- Location of nearest Emergency Department

End users should be made familiar with these policies through training and their acknowledgement of having completed the training should be recorded in the SOPM. Reports and records of injuries and accidents in the lab should be made as required by the EUO, OSHA and / or EH&S.

13. Donor Disposition

After the donor has been used for education or research, their remains should be given a respectful disposition that conforms to the donor's wishes and commitments made by the BDP in the donation consent. Disposition following donation is often by cremation, although other methods are used (e.g., earth burial or entombment, alkaline hydrolysis, aka resomation, biocremation). This should occur within the timeframe specified in the donation agreement.

13.1 Disclosure of Details of Disposition

Body donation programs should disclose to the donor and family what will happen after the cremation or at the time of disposition. The remains of the donors may be returned to their loved ones, if requested, or should be respectfully interred or scattered in accordance with applicable regulations. In certain cases, when requested by the donor or their loved ones, the donor's body may be returned without cremation for a private interment. As a best practice, the loved ones or designated contact of the donor should be provided with the details of the disposition, such as the date, time, and / or location.

13.2 Cremation

Body donation programs should determine and clearly state how cremated remains will be handled following cremation. Options may include return of cremated remains to the donor's family or designee, interment in an ossuary or mausoleum, or scattering, as permitted under local laws. The donor is not considered "at rest" until one of these final steps has occurred. Programs should have a clearly stated policy regarding how they handle unclaimed cremated remains, although the use of unclaimed or unidentified remains is not considered a best practice. States vary greatly in the amount of time that an organization is required to hold cremated remains that a family has not taken into their custody (Fritch and Altieri, 2015), so programs should consult state and local laws. BDPs should maintain disposition records according to the applicable record retention policy that indicates how records will be archived and for how long.

14. Services of Gratitude and Memorial Sites

Many BDPs and end users hold services of gratitude, provide memorialization gifts or mementos and / or erect memorials as a way for the users, faculty, and staff to express their gratitude to the donors and honor their memory. Some BDPs invite families of the donors to these services. Some maintain permanent memorial sites. Some institutions hold services at final disposition of remains (Strakalj and Pather, 2017). The appropriate performance of these services and display of these memorials has implications for:

- The families of the donated individuals
- The faculty, researchers, staff and students who participate in education or research using donors
- The institutions and organizations in which those studies are performed
- The broader education and research communities across the United States
- Body donation organizations throughout the United States
- The public at large

To protect the interests of all, it is recommended that procedures for the development of memorials and ceremonies include the following topics.

14.1 Preparation

An organizing committee may be student-led with mentor oversight. To maintain continuity in culture and practice of the service, it is helpful for organizers from previous years to be involved in the planning of the service. BDP staff, who are often licensed funeral professionals, typically have experience and expertise in planning services. Students, faculty, and staff should be prepared for the event by presentation and discussion of guidelines prior to the event.

14.2 Invitations

An invitation to a memorial ceremony should be sent to donor loved ones, members of the body donation program institutional leadership, and those students, faculty, researchers and staff who used the donors. The invitation should include contact information of the organizers of the service and officials of the institution. It should specify if there will be press at the service, and if so, remind invitees that they are not obliged to speak to the press. It may request pictures of donors to be voluntarily submitted by families, if desired, and include wording reserving the right to determine which images, if any, are included.

The following individuals may be appropriate to be invited to a memorial ceremony: teaching and administrative faculty and staff of the health sciences school and university; faculty or students from other schools; clinicians, researchers and other beneficiaries or stakeholders; communications staff responsible for community outreach; and / or the press.

Students, faculty, and staff members should be encouraged to attend the service. Speaking with the press is voluntary.

14.3 Characteristics of the Memorial Ceremony

Memorial ceremonies should be held in an accessible space and not a laboratory or classroom. It should aim to be welcoming, respectful, polite, grateful, and professional. It should not convey a sense that students are mourning the donors, but rather that they are honoring the donors for their altruism and commitment to advance education and research

Donor anonymity and privacy, per the donation consent should be adhered to during memorial services. Students should not be identified to families of a specific donor (e.g., whom they dissected). No health information or Personal Identifying Information (PII) or Protected Health Information (PHI) or other personal information should be provided. Images or history provided by families should be presented respectfully and voluntarily.

14.4 Participant Behavior

Participants in the memorial ceremony should adhere to respectful behavior and dress. Students, faculty and staff should be dressed in professional or white coat attire. Invitees should be welcomed. Students, faculty, and staff may present using any non-denominational creative expression, including the spoken word, music, song, dance, paintings or other visual arts, photos or other performance. Participants may talk about the impact of the dissection or donor use experience on them personally and professionally; this can include expressions of gratitude. Participants should not talk about specifics such as dissection practices, details about individual donors, or the location of laboratories or morgues (e.g., “in that building on the top floor”).

14.5 Press and Publicity

The university and / or school communications office responsible for controlling institutional communications should be consulted if press or media are to be invited or wish to attend a memorial service. Families and other attendees should be notified that press will be present and advised that they do not need to speak to them. The press should be provided with a press packet giving background on the event and guidelines for their attendance. The press should be made easily identifiable by wearing proper credentials. Recording by the organizers is appropriate for limited sharing with families and for planning future events. It is not appropriate for students, faculty, and staff to record the event on personal devices. It may be appropriate for family members to record the service for their own use. If the event is recorded or distributed, emphasis to participants must be put on the appropriate nature of sharing information about donors and maintaining their privacy.

14.6 Permanent Memorial Displays

The design and location of permanent memorial displays should be planned in consultation with committees within the institution responsible for appearance, safety, and design of facilities. Consideration should be given to the following factors: The memorial should be designed so that it communicates the desired message in a way that is inclusive. The memorial should be located such that it is accessible to the people who it is designed to reach and allows the appropriate space for reflection. Supporting text should be provided that describes the goals of the memorial and those who erected it.

III. CONCLUDING REMARKS

With the vast diversity of BDPs in the United States (and internationally), it is important to have standardized foundational guidelines that can lead to a community ethos on the proper and respectful care of the altruistic individuals who donate their bodies for education and research. The Human Body Donation Committee developed these guidelines to provide body donation programs with practical guidance on how to operate their program in an efficient and ethical manner.

While there are no enforcement mechanisms for these guidelines, they can be used to provide both foundational and aspirational means to standardize and improve body donation programs. It is understood that some BDPs may not be able to follow all of these guidelines and therefore they may be aspirational for these programs. These guidelines do, however, provide a 'road map' for programs to follow for the respectful and ethical treatment of their donors.

While these guidelines focus on the appropriate and ethical development and operations of body donation programs, it should be emphasized that body donation programs have an obligation to encourage donations from all stakeholders in a community. Donation programs should not prey on the economically disadvantaged or those in society that are less fortunate. They should strive to have their donor demographics represent the breadth and diversity of their community. This is important for the inclusive moral basis of donor programs and for the ability of these diverse donors to silently teach diversity and inclusion to their end users.

While the Human Body Donation Committee has spent many hours discussing the development and promulgation of these guidelines, they should not be considered as 'cast in stone' requirements nor local legal interpretation or advice. These guidelines are based on the current best practices for operating ethically appropriate BDPs as determined by the experiences of the Committee members. It is assumed that they will evolve as the ethos in the body donation field develops. The Committee wholly supports this evolution.

The Human Body Donation Committee thanks all those who provided support for the development of these guidelines including the American Association for Anatomy staff and leadership. The Human Body Donation Committee especially wants to acknowledge and thank the altruistic donors who are the reason for the existence of body donation programs and who we strive to honor and respect with the development of these guidelines.

IV. BODY DONATION TERMS AND DEFINITIONS

ACQUISITION: Taking possession of anatomical material that was not directly donated to the body donation program or primary institution.

ALLOCATION: The assignment of anatomical materials from the body donation program to an approved end user.

ANATOMICAL GIFT: A donation by an individual or their legally authorized representative of all or part of that individual's body after their death for the purpose of research or education.

ANATOMICAL MATERIAL: Whole or partial human bodies, including limbs, organs, bones, specimens, and tissues.

ANATOMICAL SERVICES: The goods and services component of an anatomical donation program. The provision of Anatomical Materials and staff expertise or services for education and research purposes.

ANATOMICAL SERVICES PROFESSIONAL: An individual who provides anatomical services.

ANATOMICAL SPECIMENS: Human body parts donated to by an authorizing human adult or minor (for use in education and research) that are grossly identifiable and commonly recognizable as such to a layperson without the use of any specialized methods of identification. This definition does not include blood, urine, feces, semen, or other bodily fluids, non-organic tissue types, tissue samples, human cells, hair, nails, teeth, paraffin blocks, or tissue slides.

AUTHORIZED TO DONATE: Individual or organization legally empowered to donate an individual or their parts.

BLOOD-BORNE PATHOGENS: Microscopic agents that live in human blood and body fluids that cause disease in humans.

BODY DONATION: General approach to the acquisition of whole bodies or parts for education or research purposes.

BODY DONATION PROGRAM: Institution or organization authorized to receive and allocate an anatomical gift.

BODY PART: A portion of a dead human.

CADAVER: A dead human body. This use of this term in body donation is contested due to its perceived pejorative connotation.

CHAIN OF CUSTODY (COC): The chronological documentation or paper trail following an anatomical gift through its entirety (initial acquisition through final disposition). A COC should be established as part of the tracking process for anatomical materials.

COERCION: The practice of persuading someone to do or not do something by using force or threat.

COMMERCIALIZATION: The offering of anatomical material and/or its byproducts for financial gain - to profit from the sale of these materials.

COMMINGLED: The mixing of cremated remains from more than one anatomical gift.

COMPETENCY STATUS: The capacity of an individual to make decisions in accordance with their goals, concerns, and values.

CONSENT: See INFORMED CONSENT.

CREMATED REMAINS: The materials from the human body that remain after cremation or alkaline hydrolysis.

CUSTODY: The protective care, possession, and control of (in this case) a body donor.

DATA: Information either in physical or digital form generated during the body donation process.

DECEDENT: A deceased individual, including a stillborn infant or fetus.

DECLINATION/DECLINE: The act of refusal of an anatomical gift by a body donation program.

DIGITAL RECORDS: Data stored in an electronic format.

DISCLOSURE: Providing information regarding program policies and practices to inform individuals interested in making an anatomical gift.

DISINTERESTED WITNESS: A witness other than an executor, trustee, guardian, spouse, child, parent, sibling, grandchild, grandparent, or close friend, or another adult who exhibited special care and concern for the individual.

DISPOSITION: The interment of human remains following donation.

DISSECTION (HUMAN): the careful, methodical, and purposeful disassembly of human bodies for education or research.

DOCUMENT OF GIFT: A written or electronic record used to make or memorialize an anatomical gift, including a driver's license, identification card or donor registry.

DONOR: Individual whose body or part is the subject of an anatomical gift.

DONOR ANONYMITY: Non-disclosure of any data that would reveal the identity of a donor or their family.

DONOR REGISTRY: Records, usually in a database format, of anatomical gifts, prospective donors, and other donor information (to include amendments to or revocations of anatomical gifts) that are maintained in accordance with applicable law.

EDUCATIONAL OR RESEARCH INSTITUTION (ERI): Organization that delivers courses or runs research programs that use body donors; and governs operations in BDPs.

EMBALMING: Preservation, disinfection, and preparation of a human body for use or disposition.

END USER: An educator, researcher, student, or other individual who uses anatomical material from a body donation program.

END USER AGREEMENT: Agreement between an end user and an Educational or Research Institution that defines the terms and conditions under which the end user is permitted to use anatomical material.

ENTICEMENT: Act of wrongfully soliciting, persuading, alluring, attracting, coaxing, or seducing a person to do or not do a thing.

EXCLUSIONARY CRITERIA: Characteristics that disqualify individuals from being a body donor.

EXTRACTION: Excision of an organ from a deceased human body.

FOR PROFIT: An entity that operates with the goal of making money.

GENETICS: The scientific study of genes and heredity—of how certain qualities or traits are passed from parents to offspring as a result of changes in DNA sequence. (NIH)

GENOMICS: The study of a person's genes (the genome), including interactions of those genes with each other and with the person's environment. (NIH)

IMAGES: Photographs and video, including digital, film or any other medium, including medical images (radiographs, Computerized Tomography (CT), Magnetic Resonance Imaging (MRI), ultrasound) derived from a body donor (pre or post mortem).

INFORMED CONSENT: The voluntary agreement by a person with the capacity to make a decision to a proposed course of conduct after communication of adequate information and explanation of the expected benefits and material risks of and reasonably available alternatives to the proposed course of conduct.

LEGACY MATERIAL: Human anatomical material in the possession of educational or scientific institutions for which records regarding identity and/or consent may be missing or incomplete.

LEGALLY AUTHORIZED REPRESENTATIVE: Any individual authorized by law to make an anatomical gift.

MEDICAL HISTORY: Health related information about the donor provided by the donor or the authorized representative.

MEDICAL RECORD: Any item, collection, or grouping of information that includes personal health information and is maintained, collected, used, or disseminated by or for a BDP or another covered entity. (HIPAA)

NONPROFIT: An entity that functions to benefit the public good and that uses any profits to further any purpose exempt from taxation under sections 501(c) or 501(d) of the United States Internal Revenue Code, now in effect or hereafter amended

NOT FOR PROFIT: organizations whose operations function to further the owners' organizational objectives, who do not have a goal of generating revenue

OVERSIGHT COMMITTEE: The group of individuals who are responsible for decision-making and/or advising on the policies and procedures of a body donation program in partnership with the anatomical services professionals.

PERMANENT DONATION: Anatomical material that is kept in perpetuity, presumably after receiving consent from the donor.

PERSONALLY IDENTIFIABLE INFORMATION (PII): Any information that permits the identity of an individual to be determined either directly or indirectly. (Dept. of Labor)

PLASTINATION: Replacing the water content of an embalmed human body or body part with a polymer.

PREPARATION: Physical or chemical procedures to ready a deceased human body for research or education.

PROTECTED HEALTH INFORMATION (PHI): Individually identifiable health information that is transmitted or maintained in any form or medium (electronic, oral, or paper) by a covered entity or its business associates, excluding certain educational and employment records. (HHS)

RECORD: Information that is stored in an electronic or other medium and is retrievable.

RECORD RETENTION: The holding, maintaining, safeguarding and/or destruction of records.

REGISTERED BODY DONOR: A person who has consented to the anatomical gift of their body for education and/or research after death.

RESPONSIBLE PARTY: Individual(s) employed and trained by an educational or research institution to oversee and uphold requirements and, end user agreements for use of anatomical material.

SEPARATION: Dismemberment, severance, or dissection of a deceased human body into regions or parts.

SITE VISIT: A physical inspection of a facility performed by an accrediting, licensing, or body donation program in order to confirm that the facility is in compliance.

STORAGE: Process of holding donors and donor specimens.

SUBJECT MATTER EXPERTS (SME): A person who is an authority in a particular area or topic.

TEACHING AND RESEARCH FACILITIES: physical spaces where teaching and research activities take place that involve use and storage of human donor material.

TEACHING COLLECTION: Anatomical material used for education.

TERMS AND CONDITIONS AGREEMENTS: Contract between BDPs and educational or research institutions specifying responsibilities of these institutions while donor material is in their custody.

TRANSFER: The act of moving anatomical material between approved facilities that is memorialized as part of a chain of custody process and reflected in appropriate documentation.

TRANSPARENCY: Operating in such a way that it is easy for others to see what has been performed and/or what is expected.

UNAFFILIATED ANATOMICAL MATERIAL: Human remains for which evidence of cultural identity is missing.

UNCLAIMED ANATOMICAL MATERIAL: Human remains which may be identifiable but have not been claimed by any legally authorized representative.

UNIDENTIFIED ANATOMICAL MATERIAL: Human remains for which documentation of individual identity is missing.

V. REFERENCES

Links and References for Definitions

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VI. APPENDICES
APPENDIX
Consent Form Guidelines

The guidelines provided below are from Johnson et al., (2023). The recommendations are categorized into eight themes the authors found when reviewing documents of gift for their content. The text has been amended to provide description of the categories.

1. Communication - This theme accounted for general information about the program, and who, when, and how communication should occur between relevant parties.
    1. Description of the body donation program, including a statement of purpose and benefit of the donation, any affiliations to other programs, and how donors will be memorialized
    2. Who the donor should talk to about their decision such as family, loved ones, spiritual leaders, health care providers and others involved with their estate planning
    3. How and when the donation can be revoked by the donor or another
    4. Why personal information of the donor, including medical history, will be requested, how it will be used, and who it will be disclosed to
2. Eligibility - This theme accounted for the ways in which donors are eligible (or not) to donate their body to a given program.
    1. Description of who can make the donation (self-authorizing only), including competency status (age and sound mind) as well as other forms of vulnerability such as minors or the incarcerated
    2. A clear statement that the program has the right to decline the donation at the time of death, including the determining factors for the decision -
        i. Suitability of the condition of the body; the presence of communicable diseases; recent major traumas or surgeries; amputation or other organ removals; length of time between death and receipt of the body; and similar concerns
        ii. Geographic limitations on who can donate and the implications of death occurring outside a radius should be included; if the program closes for specific times or if there are capacity limitations
3. Logistics - This theme accounted for the logistical actions needed to be taken at the time of death of the donor to enact the donation.
    1. Descriptions of what to do at the time of death to enact donation, and what, if any, types of additional documents are necessary for donating, or if there are other documents available for informational purposes, and where to find them
    2. Any source of additional information for the consent must be specifically laid out in the DG
    3. Which actions need to be taken by the donor representative to enact the donation
    4. How and when last rites or blessings can be administered with the donor present

5. What will occur with any personal property of the donor recovered by the program

4. Terms of Use - This theme accounted for the ways in which donors may or may not be used during their time in the program.
    1. Accurate descriptions of donor use that are sufficiently broad to represent the range of program activities but specific enough to describe the preparations and conditions a donor body may be subject to; an umbrella use statement "for education and research" is not sufficient
        i. Provide information on donor preparation methods such as embalming, skeletonization, plastination, segmentation, dissection, and disarticulation
        ii. Provide information on additional use concepts including retention of anatomical material, acquisition, use and retention of images, and whether commingling of body parts occurs (in storage or disposition)
        iii. The type of end-users should be identified including whether the transfer of the donor can occur and, if so, the conditions for the transfer and return or disposition; also, the information about the donor that the end users may be provided
        iv. How donors are treated with respect and dignity in the program, and whether or not a donor can direct their donation in any specific way
        v. A description of the unknown future direction of education and research that could lead to uses of the donor's body outside the scope of what is understood today
        vi. Information on the discretion of the program to revise its policies and the presence or absence of a re-consent process
    1. Practices for reporting information about a donor including mandatory and voluntary types such as personally identifiable information for death certification, if disease test results are reported, and to where/whom, and what type of information, if any, will be reported to the donor representatives or governmental agencies
5. Legal References - This theme accounted for statements relating to laws, governmental entities, and similar relating to the donation.
    1. The state's amended version of the UAGA should be referenced with information on how to access the law's text
    2. The governmental entities that may receive or give relevant information should be included
    3. Applicable privacy laws should be referenced
6. Financials - This theme accounted for financial transactions related to the acceptance or the declination of the donation
    1. Whether there are fees assessed to the donor or estate for donation
    2. The types of entities assessing and receiving fees, for example, a funeral home, vital records office, or the donor program itself
    3. Whether the donor program imposes fees for the use of anatomical material

    4. Whether anatomical material or images and other materials derived from it, can be used for commercialized products (e.g., publications, product development, or training)
7. Final Disposition - This theme accounted for timeframe and what occurs to the body once the donor's time in the program is complete.
    1. Descriptions of the estimated length of time that a donor's remains will be in the program
    2. Whether there will be permanent retention of anatomical material
    3. Processes of the final disposition, such as whether the body will be cremated and under what conditions remains can be returned to the family
8. Signatures - This theme accounted for the relevant signatures needed to enact the document of gift.
    1. Donor
    2. Witnessed or notarized
    3. Two witnesses when legally required, one of which may be a disinterested witness.