

American Association of Clinical Anatomists

***Best Practices Guide for Donation
Programs***

2nd Edition

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AACA
Best Practices Guide for Donation Programs

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1. INTRODUCTION

This document was created by the Anatomical Services Committee (ASC) of the American Association of Clinical Anatomists (AACA) and is intended to outline best practices for administering whole body donation programs associated with academic institutions. The best practices contained herein apply specifically to anatomical materials donated for use in research and education (i.e. not for use in patient therapy or transplantation).

2. DOCUMENT OF GIFT

- The donation of anatomical material shall conform to local and state law—only those with the legal authority to donate anatomical material may sign documentation of gift forms. Institutions may impose stricter regulations but should not be less stringent than local and state law.
- Document of gift forms shall be properly executed according to state and local laws and shall be witnessed accordingly.
- Document of gift forms should include the following:
 - a. Written documentation
 - i. Should adhere to reasonable standards of readability
 - ii. Should include disclosures containing the following:
 1. Entity receiving the donation
 2. Donation purpose/uses
(research/education/plastination/display/training)
 3. End users of anatomical materials
 4. Use location (off campus/out of state) and possibility of transfer
 5. Donation time frame (including permanent teaching collections)
 6. Disposition of remains after donation (cremation, alkaline hydrolysis, burial, scattering)
 7. Images (acquisition/use)
 8. Applicable fees, if any
 9. Serology testing/disclosure of test results
 10. Medical records/information gathering/release practices
 11. Results/rights to direct donation/release of information
 12. Preparation methodologies (recovery, disarticulation, embalming, plastination, etc.)
 13. Age/competency status/ classes of the donor or the person signing the forms on behalf of the donor if they are unable to self register

14. Possibility of decline of the donation during the registration process or time of death and the potential reasons for decline
- iii. Signatures:
 1. Disinterested witness (before death donations made on behalf of another person only)
 2. Two witnesses

3. INSTITUTIONAL OVERSIGHT

- Primary institutions should require oversight of donor programs. Oversight should include a well- defined reporting structure and a governing body.
- The governing body should hold a person or committee accountable in knowing and following the laws of that state.
- The governing body should include or receive guidance from an advisory group of subject matter experts (SME's) in topics relevant to donor program operations and the institution's education and research goals. SME's may include legal, ethical, financial, compliance and health & safety personnel.
- Donation programs should include a designated individual who is responsible for administration and management of program operations.
- Donation program staffing levels should be sufficient to allow for appropriate separation of duties.
- Donation programs should be subject to institutional review on a regular basis.
- Primary institutions should create policies for acquisition, use and final disposition of anatomical materials.
- Primary institutions should implement a training program for faculty, staff and students who require anatomical materials from donation programs.
- Primary institutions should ensure that the donation program staff maintains an up-to-date Standard Operation Procedures Manual (SOPM).
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4. MEDICAL SUITABILITY/TRANSFER/ALLOCATION/USE

- Screening procedures should be put in place to mitigate potentially infectious cases from being accepted into donation programs.
- Priority of use should be established to serve the primary institution's needs as well as that of key educational/research affiliates.
- Institutions that transfer anatomical materials should require that end users meet donation program requirements.

- Use of anatomical materials should be defined by the donation program's governing body and agreed to, in writing with an end user agreement, between the respective parties.
- The end user agreement should be detailed and should include the person requesting anatomical materials, their supervisor or department chair, a financial contact, where the anatomical material will be used and stored and a thorough description of intended use, including any images that may be taken.
- End users who will use anatomical materials should be trained in blood-borne pathogens and chemical safety requirements.
- Documentation as required by state and local law shall accompany all anatomical materials. Documentation should include chain of custody through final disposition.
- End users should not transfer anatomical material without the authorization of the original donation program. It is the responsibility of the end user to notify the donation program and request permission for reallocation of anatomical materials
- Anatomical materials may not be retained by an end user without authorization from the donation program.

5. FACILITY REQUIREMENTS

- All anatomical materials should be used in an approved facility such as a laboratory or other scientific venue. The facility shall comply with federal, state and local laws and regulations governing biological, pathological and chemical laboratory requirements in addition to public health and safety provisions.
- Facilities where anatomical material will be used should be secured from unauthorized access.
- Facilities that use anatomical materials should monitor/approve persons entering such facility i.e. housekeeping, maintenance, visitors, vendors.
- A site visit should be conducted to ensure the end user's facility is in compliance with the donor program's requirements. Additional site visits may be conducted on an annual basis or as the transferring program deems necessary.

6. TRACKING

- Tracking processes should include all applicable activities including; an initial evaluation of the donor, serology testing results, preparation methodologies,

storage locations, allocation/transfer and subsequent use, transportation, return and final disposition.

- The tracking process begins upon the initial acquisition of the anatomical material. Tracking ends when final disposition is completed in its entirety.
- Electronic and/or hard copy tracking methodologies should be employed to ensure that the location of each portion of anatomical material is known, documented, and retrievable.
- A records retention policy should be established and shall follow institutional, state, and local laws. As a matter of policy, certain institutions may consider donor records part of their official university archive so it is imperative that the donation program consult their institution for guidance on this matter.
- All records for donors currently in use should be retained and updated. Records for individuals who pre-registered but were not donors should be retained according to the primary institution's records management schedule.
- Anatomical material should be allocated utilizing a system of identification that displays the specimen number, type and description or other identifiers.
- An identification tag or device should be affixed or attached to the anatomical material and its container or wrapping and should remain with the anatomical material throughout its use and its return to the donation program.

7. TRANSPORTATION

- Transportation or shipment of anatomical materials and cremated remains shall occur in accordance with international, federal, state and local law.
- A contract for services should be initiated by the primary institution and agreed upon by the transporter.
- The transferring institution should determine the appropriate method of transportation.
- Donation programs shall provide a full disclosure of contents to shipper and adhere to the shippers' protocol and International Air Transportation Authority (IATA) requirements.
- Paperwork should accompany all anatomical material in transit.

8. FINAL DISPOSITION

- Final disposition should be determined by the donation program and shall be in compliance with federal, state, and local regulations for disposal of human remains, implanted medical materials, or other applicable regulations, and per the directives listed on the document of gift.

- Details of the final disposition should be communicated such that potential donors or other persons legally authorized to make a donation decision on another's behalf are aware of the method of disposition, advanced handling options of cremated or hydrolyzed remains, the possibility of comingled buried, cremated or hydrolyzed remains, and the expected time between donation and final disposition.
- Proper documentation of the final disposition should be included in the donor record.

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A. DEFINITIONS

ACQUISITION: Taking possession of anatomical material, either directly or through a third party acting on behalf of the primary institution, in reference to an anatomical gift.

ALLOCATION: The lending of anatomical materials from the primary institution to an approved end user.

ANATOMICAL GIFT: A donation of all or part of a human body to take effect after the donor's death for the purpose of, research, or education.

AKA: ANATOMICAL DONATION

ANATOMICAL MATERIAL: Whole or partial human specimens, including whole bodies, limbs, organs, bones and tissue, not including: urine, feces, semen, or other bodily fluids, microscopic tissue samples, human cells, hair, nails, teeth, paraffin blocks, or tissue slides.

AKA: MATERIALS, SPECIMENS, BODY PARTS, PARTS, ANATOMICAL SPECIMENS, CADAVER, DONOR, DECEDENT

BLOOD-BORNE PATHOGENS: Microscopic organisms or germs that live in human blood and body fluids that have the ability to cause disease in humans.

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.

COMINGLED: Referring to the irreversible mixing of cremated or hydrolyzed remains from more than one donor.

COMPETENCY STATUS: An assessment of whether a person has the mental capacity to make decisions in accordance with one's goals, concerns, and values.

AKA: DECISION-MAKING CAPACITY, COMPETENCE

CONTRACT FOR SERVICES: Agreement between the primary institution and the individual/company/funeral home providing transportation.

CREMATED REMAINS: The remaining materials from the human body that still exist after cremation or alkaline hydrolysis. Often includes foreign materials including implanted medical devices.

AKA: CREMAINS, ASHES, HYDROLYZED REMAINS, REMAINS

DECLINE: The act of refusal of an anatomical gift by an anatomical donation program.

DISARTICULATION: The separation of bones at their joints.

AKA: AMPUTATION

DISCLOSURE: The act of releasing information for the purpose of performing duties related to a donation program or to inform individuals interested in making an anatomical gift of program policies and practices.

DISINTERESTED WITNESS: A witness other than the spouse, child, parent, sibling, grandchild, grandparent, or guardian of the individual who makes, amends, revokes, or refuses to make an anatomical gift, or another adult who exhibited special care and concern for the individual. The term does not apply to a person to which an anatomical gift could pass.

DOCUMENT OF GIFT: A record used to make an anatomical gift.

AKA: DONATION FORMS, DONOR FORMS, , CONSENT FORMS, REGISTRATION FORMS

DONATION PROGRAM: Any program with the the legal and ethical ability to acquire, track, prepare, store and maintain anatomical materials for education and research in a ecured and appropriate environment.

AKA: ANATOMICAL GIFT PROGRAM, ANATOMICAL MATERIALS PROGRAM, DONATED BODY PROGRAM, BODY DONATION PROGRAM, WILLED BODY PROGRAM, BODY BEQUEST PROGRAM, DONOR PROGRAM

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

AKA: DECEDENT, CADAVER

DONOR REGISTRY: Records, usually residing in a database format, of anatomical gifts, prospective donors, and other donor information (to include amendments to or revocations of anatomical gifts) that is maintained and secured by the primary institution.

AKA: PREREGISTERED DONOR LIST, DATABASE, DOCUMENT OF GIFT

EMBALMING: A method of preparing a human body for scientific study that usually involves the arterial injection of a chemical which serves to forestall decomposition.

AKA: PREPARATION, PREPARATION METHODS, FIXING

END USER: An educator, researcher, student, or other user, that requests, receives and uses a loan of anatomical materials from a donation program.

END USER AGREEMENT: The agreement entered into between an external end user and a primary institution that defines the terms and conditions by which the end user is permitted to use anatomical materials.

AKA: END-USER CONTRACT, CADAVER CONTRACT, SPECIMEN CONTRACT, CADAVER REQUEST, BODY REQUEST

FACILITY: A location for storage and or use of anatomical materials.

FINAL DISPOSITION: Final disposition refers to following donation and may include: cremation, earth burial, entombment, or alkaline hydrolysis. Final disposition also refers to advanced handling options regarding cremated or hydrolyzed remains including the return or burial of cremated or hydrolyzed remains, or scattering at sea or other location. **AKA:** DISPOSITION

GOVERNING BODY: The group of individuals who are responsible for formulating the policy and directing the affairs of an donation program in partnership with the program management.

MAY: A verb used to express possibility, advisability, used to express opportunity or permission, and to express contingency.

AKA: MIGHT

PART: An organ, eye, extremity, , bone, or tissue of a human being. The term does not include the whole body.

PLASTINATION: A method of preparing a human body or body part for scientific study. Usually involves displacing the water content within the human tissue with a polymer while under vacuum pressure and serves to forestall decomposition.

PREPARATION: Procedures undertaken to make a human body ready for scientific study. Includes various methodologies such as embalming, plastination, and recovery.

PRIMARY INSTITUTION: The university, college or entity to which the donors are gifted by the donor or other legally authorized person. This term refers to the main entity that requires the anatomical materials for educational or research benefit for their own or an end user's benefit.
AKA: TRANSFERRING INSTITUTION

RECORD: Information that is inscribed on a tangible medium or that is stored in an electronic or other medium and is retrievable in perceivable form.

AKA: DONOR RECORD

RECOVERY: The removal, via dissection or another method, of an anatomical material.

SEPARATION OF DUTIES: Clear description and assignment of specific job duties and responsibilities within a donation program.

SHALL: Expressing an instruction, command, strong assertion, intention, or obligation.

AKA: SHOULD, MUST, OUGHT

SHOULD: Simple past tense of "shall". Expressing an instruction, command, strong assertion, intention, or obligation.

AKA: SHALL, MUST, OUGHT

SITE VISIT: A physical inspection of an end user's facility performed by the primary institution in order to confirm the agreements between the primary institution and the end-user are in compliance.

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

TEACHING COLLECTION: Bones, embalmed or plastinated anatomical material allocated to a specific educator for an extended period of time.

TRANSFER: The act of officially moving a donor from one institution to another approved facility for the purpose of education and/or research that is accompanied by a chain of custody and appropriate approvals and documentation.

USE: Refers to the appropriate use of anatomical materials as defined by the donor program's governing body.

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Institutional Checklist for Self-Review of an Anatomical Donation Program

This completed form will describe your program practices and offer a transparent look at your program's current functions. Consider asking your staff, faculty, Institutional Oversight Committee, and/or attorneys to complete a copy of this checklist. Their responses may vary from yours which is not unusual and will foster a better mutual understanding of the internal workings of your program.

Name of Program

Affiliated Institution

Person Conducting Self-Review

Title

Date

Program Mission Statement

Staff, Title, and Job Description

Institutional Oversight

Have you identified potential members of an Intuition Oversight Committee (IOC) to include subject matter experts (SME)? Yes No

Have you identified and contacted the following SME to form your program's IOC?

Legal SME _____

Ethics SME _____

Finance SME _____

Compliance SME _____

Health and Safety SME _____

Outside Institution SME _____

Other: _____

Do you have a defined organization structure? Yes No

Is there a clear reporting structure and delineation of duties? Yes No

Have you identified the person or committee responsible for knowing and following the applicable federal, state and local laws? Yes No

Have you identified the means of holding responsible the person or committee tasked with knowing and following the applicable federal, state and local laws? Yes No

Have you established a means of annual institutional review of your program? Yes No

Have you determined a date and/or scheduled a time for annual institutional reviews? Yes No

Standard Operation Procedures Manual (SOPM)

Do you have a SOPM for your program? Yes No

Is the SOPM an institutional or departmental document? _____

Has your SOPM been reviewed by your IOC? Yes No

Were recommendations for changes offered and implemented? Yes No _____

Has your SOPM been reviewed by your institution's legal council? Yes No

Is your SOPM legally sound? Yes No

Does your SOPM contain policies for acquisition, use and disposition of anatomical material? Yes No

Does your SOPM include templates of donation forms, personal data forms, donor contact form letters, donor cards and other documents regularly used to correspond to the donor or potential donor? Yes No

Does your SOPM include standard operating procedure (SOP) protocols detailing the various preparation methods used to prepare donors? Yes No

Does your SOPM include a detailed SOP protocol regarding the use of personal protective equipment that is to be worn during donor preparations? Yes No

Does the SOPM have a detailed SOP protocol regarding chemical or body fluid spills? Yes No

Does your program have a detailed Injury, Illness and Prevention Program (IIPP) in place? Yes No

Is the IIPP included in the SOPM? Yes No

Does your SOPM include a detailed specimen code list for the different types of specimens that are utilized within your program? Yes No

Have you developed a plan to ensure that program staff maintains the SOPM by establishing regular internal reviews of the SOPM materials? Yes No

Program Management and Staff

Have you designated an individual to be responsible for administration and management of program operation? Yes No

Have you identified program staff needs and appointed staff members? Yes No

Have you made a determination as to whether your program staff is sufficient to allow of separation of duties? Yes No

Have you implemented a training program for program staff as well as faculty and students to ensure their understanding and compliance with the SOPM and established facility and program rules? Yes No

Staff and Donor Relations

Do you have standard communication preferences or scripts? Yes No

Do you maintain staff and donor confidentiality? Yes No

Do you have a detailed scope of program representation? Yes No

Have you established a return time for phone calls and emails? Yes No

Do you record all correspondences with donors and potential donors and those related to donors? Yes No

Conflict of Interest

Do you maintain an updated database or donor registry? Yes No

Do you offer training for staff to avoid conflict of interest situations? Yes No

Do you have a screening mechanism in place for hiring program staff to prevent conflict of interest? Yes No

Does your SOPM include a policy if a conflict of interest should arise? Yes No

If so, Does it address potential conflicts of interest? Yes No

Donation Forms

Does your donor registration packet, consent forms, and final disposition authorization contain all federal state and local requirements and regulations? Yes No

Do your donation forms disclose the entity receiving the donation? Yes No

Do your donation forms disclose whether the donation may be transferred to another facility? Yes No

Is there consistency and transparency in all of your program related documentation? Yes No

Do your forms fully disclose possible uses, users, and use location? Yes No

Does your consent form include a description of final disposition? Yes No

Does this description of final disposition include:

Means of final disposition Yes No

Expected time between donation and final disposition Yes No

Whether cremated remains are available for return Yes No

Expected time between donation and return of cremated remains Yes No

Disclosure of any applicable fees Yes No

Are all parties (chain of custody) included and in agreement with the donor's final disposition? Yes No

Is the required documentation for final disposition included in the donor files? Yes No

Is there a description of the serology testing policy and testing disclosure policy? Yes No

Do you disclose a description of your program's medical records information gathering and release practices? Yes No

Do your forms include a statement indicating the different methods of donor preparation that may occur? Yes No

Do your forms include a requirement for age and competency status of the potential signer? Yes No

Is there an area for the donor to sign the document? Yes No

Is there an area (and requirement) on the form for two witness signatures? Yes No

Do you state the possibility of refusal of the donation at the time of registration or time of death and the potential reasons for refusal? Yes No

Is the document language reasonably understandable for most people? Yes No

Is there an area for disinterested witnesses to sign (for before death next of kin donations only)? Yes No

Have you submitted your donor registration packet, consent forms, final disposition authorization documents for review by your institutional's legal council? Yes No

Have the above mentioned documents been reviewed by your program's IOC? Yes No

Have you implemented any recommended changes? Yes No

Records Management

Do you have a donor registry? Yes No

Do all program staff have access to the registry? Yes No

Are their restrictions for staff separation of duties in place within the donor registry? Yes No

Do you have a backup system? Yes No

Does your donor registry include fields for tracking purposes? Yes No

Does your donor registry include correspondence and/or form letter? Yes No

Does your donor registry include final disposition? Yes No

Does your donor registry include chain of custody contact information? Yes No

Is your donor registry up-to-date? Yes No

Do you have a policy for updating donor information? Yes No

Is the donor registry program drive or donor requested to update as needed? _____

Is your donor registry designed to track all donors for all uses? Yes No

If not, what is your tracking mechanism from the time of acceptance to final disposition? _____

How are your donors, cadavers, and specimens identified? _____

Is each donor, cadaver or specimen further identified with a barcode or identification tag? Yes No

Tracking

Does your tracking process include the following:

Initial evaluation of the donor Yes No

Serology testing results Yes No

Preparation methodologies Yes No

Storage location Yes No

Allocation, transfer and subsequent use Yes No

Transportation Yes No

Return Yes No

Final Disposition Yes No

Does your tracking process begin when a donor is delivered or when entering the custody of a transportation service, that is acting on behalf of your program, and end when final disposition is completed in its entirety? Yes No

Do you employ electronic and/or hard copy tracking methodologies to ensure the location of every portion of every specimen is known, documented and retrievable? Yes No

Does your program have a records retention policy (RRP)? Yes No

Does your RRP follow institutional, state and local laws? Yes No

Are donor records considered part of the official archive of your institution? Yes No

If so, is your program following the institution's RRP? Yes No

Are all records for in use donors retained and updated? Yes No

How do you handle records for those who are registered as donors but were not received into the donor program? _____

Do you retain the records for a set amount of time? Yes No

Do you retain the records until the potential donor would have been a certain age (e.g., 120 years old)? Yes No

Do you record the reason the donor was not received or declined? Yes No

How are anatomical materials allocated in your program? _____

Is there a system of identification that displays the specimen number, type and description (or other identifiers)? Yes No

Do you affix an identification tag or device to the donor/specimen and the container or wrapping? Yes No

Does the identification tag stay with the donor/specimen throughout its use and its return to the donor program of final means of dispositions? Yes No

Transfer, Allocation, and Use of Anatomical Materials

Has your program formally established the priority of use to serve the needs of the institution as well as any other affiliates? Yes No

Has the donor program's governing body defined the use of anatomical materials? Yes No

Do you have documentation prepared concerning the use of anatomical materials that should be completed and signed by respective parties? Yes No

Does this signed documentation include the donor program's governing body's definition of anatomical use? Yes No

Does it include the person requesting anatomical materials? Yes No

Does it include the requestor's supervisor or department chair? Yes No

Does it include a financial contact? Yes No

Does it include the location where the anatomical material will be used, including a description of security? Yes No

Does it include a thorough description of intended use, including any images that may be taken? Yes No

Does it include language indicating that end users shall not transfer or retain anatomical material without the authorization of the original donor program? Yes No

Do you request documentation that all faculty, staff, students and other individuals who will use anatomical materials are trained in blood borne pathogens and chemical safety requirements? Yes No

Does your transfer documentation include chain of custody through final disposition? Yes No

Does your program ensure that documentation, as required by state and local law, accompany all anatomical materials? Yes No

Has your program put in place a screening procedure to mitigate potentially infections cases from being accepted into your program? Yes No

Is there a description of the testing policy and testing disclosure policy? Yes No

Have you made sure that end users meet donor program requirements prior to transferring anatomical materials? Yes No

Does the end user have facilities such as a laboratory or other scientific venue that complies with federal, state and local laws? Yes No

Is the facility in compliance with all regulations governing biological, pathological and chemical laboratory requirements in addition to public health and safety? Yes No

Is the facility secured from unauthorized access? Yes No

Is the facility monitored such that approval is needed for persons entering (e.g., facilities staff, maintenance, visitors, vendors)? Yes No

Facility Requirements

Does the end using facility have a SOPM (including those programs whose end user is their gross anatomy laboratory)? Yes No

Does the end using facility SOPM include the following:

Privacy and confidentiality policies for use of cameras, cell phones, video equipment and other photographic equipment Yes No

Security; authorized access only Yes No

Written training and lab safety protocols pertaining, but not limited to: chemical and body fluid spills, IIPP, personal protective equipment, use of instruments, disposables, and reporting pregnancies Yes No

Maintenance schedule Yes No

Cadaver storage Yes No

Air quality checks Yes No

OSHA Compliant Yes No

Biohazard waste containers, sharps containers, appropriate hazard signs Yes No

Transportation

Is your transportation policy in compliance with all pertinent laws (federal, state, local)? Yes No

Are full disclosure documents released to appropriate affiliates? Yes No

Does required transit documentation accompany each transfer? Yes No

Has your program determined the appropriate method of transfer? Yes No

Have transport professionals and companies been fully vetted? Yes No

Are there any conflicts of interest with the transport professionals or company? Yes No

Is there a contract for services between the primary institution and the transportation company? Yes No

Do you ship anatomical material, including cremated remains, in accordance with international, federal and state laws and regulations? Yes No

Do you provide full disclosure of contents to the shipper and adhere to their protocol as well as International Air Transportation Authority (IATA) requirements? Yes No

Final Disposition

Have you determined your program's method of final disposition? Yes No

What method of final disposition will your program use? _____

Have you communicated to the interested parties the means and method of final disposition? Yes No

Is your policy concerning final disposition in compliance with all pertinent laws (federal, state, local) and regulations for disposal of human remains, medical materials and other applicable regulations? Yes No

Do you include the proper documentation of the final disposition in the donor record? Yes No

Notes