

Systemwide Policy on the Donated Body Programs of the University of California

I. Introduction

The University of California relies on the support and generosity of its community for help in fulfilling its mission in academics and health-care. Each year nearly a thousand Californians make an extraordinary gift to the University by donating their bodies to support the education of health professionals and to further scientific research. The University recognizes the value and importance of these donations and is committed to ensuring that the gifts are stored, used, and disposed of with care and respect.

Donated human remains are utilized in a wide range of educational, research, and clinical purposes, including organ transplantation, pathological examination, skin grafting, stem cell research, reproductive therapy, gross anatomy instruction, neurological, anatomical, and physiological research. Those that are received by the University's Donated Body Programs (hereafter referred to as "Program") through donation, provide human anatomical materials for study and research. These anatomical materials (also referred to as willed or donated bodies, cadavers, and/or human or anatomical specimens) are also used for surgical procedural training, allied health education, forensic research and training, mortuary science education, and the development and testing of new medical devices.

Anatomical materials utilized by the University's Donated Body Programs are defined as body parts that are clearly identifiable and commonly recognizable to a layperson without the use of any specialized methods of identification.

- This policy document applies specifically to uses of anatomical material donated to the University's Programs for use in non-clinical research and education. (e.g., anatomical materials which are not intended for such purposes as transplant or clinical therapy).
- The Programs at the Schools of Medicine at Davis, Irvine, Los Angeles, San Diego, and San Francisco are the sole authorized custodians of the anatomical materials described herein.

II. Use of Human Anatomical Material

Each of the University's five Schools of Medicine has a Program that serves as the collection and preparation point for donated bodies. These donated anatomical materials are studied either immediately as fresh tissue, or at a later date as fresh frozen material, or as specially preserved tissue for use in anatomical preparations, including dissections. Skeletal remains are also used for study.

The University supports appropriate use of anatomical materials by faculty, students, and residents in training at UC health sciences schools, other campus departments, qualified researchers (both non-profit and commercial), affiliated educational institutions such as California State University, California community colleges, and continuing medical education programs. The allocation of specimens by each on-campus UC program shall be prioritized according to the hierarchy outlined below:

1. UC students and researchers who are enrolled or working at or on the same campus
2. UC students and researchers on other UC campuses
3. External non-commercial research and education
4. Commercial research and commercially sponsored educational programs

All anatomical materials available to UC campuses will be prioritized to ensure that the educational and research needs of UC faculty, undergraduate and post-graduate students are met before any external requests are addressed. To ensure that these needs are met, the University encourages sharing and transfer of anatomical material between campus Programs to minimize the need for acquisition of such materials from outside the UC system in order to meet UC program needs.

III. Governance and Oversight

The University shall provide responsible oversight of its Programs by establishing a defined reporting structure, as described in Appendix I. A dual local or systemwide reporting process will be implemented to reflect the important roles of both campus and the Office of the President in ensuring the proper management of the Program.

University of California Office of the President (UCOP)

Systemwide Anatomical Materials Review Committee (SAMRC)

- A Systemwide Anatomical Materials Review Committee (SAMRC) shall serve in an advisory capacity to the Vice President of Health Affairs or to a senior executive designated by the President of the University of California. SAMRC membership shall include a senior manager designated by the Vice President, the systemwide Director, representatives from the Office of the General Counsel, the University Auditor, and campus representatives who will comprise the campus Anatomic Materials Review Committee (AMRC), to include a Responsible Executive Officer (REO), the campus Program Director, and the faculty Advisor from each of the five medical schools. Other members may be appointed to the SAMRC by the Vice President.
- SAMRC shall recommend guidelines, policies and procedures for adoption by all UC Programs.

- SAMRC shall meet no less than three-times per year and whenever possible quarterly.

Systemwide Director of the Program

- The University shall appoint a Systemwide Director of Anatomical Services to provide oversight and coordination of the individual campus Programs.
- The responsibilities of the systemwide Director, with input from the SAMRC, shall include initiating and proposing policies and procedures, setting inventory audit and monitoring procedures, verifying and reporting compliance with policies and procedures, coordinating the development and implementation of ethical standards of conduct and guidelines for the business model. Additionally, the systemwide Director shall participate in the recruitment, selection, and evaluation processes for the campus Directors. Hiring of campus Directors will occur with substantive involvement and concurrence by the systemwide Director.
- The systemwide Director shall receive and review direct standardized reports from each campus regarding all donations, inventories, requests for use, allocations, returns of material, and final dispositions. Additionally, the systemwide Director shall conduct regular reviews, site visits, inventory audits and conferences.
- The systemwide Director shall work under the direction of the Vice President for Health Affairs or a senior executive designated by the President of the University of California.
- To ensure that all campus programs meet high ethical standards and conform to UC policies and procedures, each campus Director is accountable to the systemwide Director with regard to their overall performance and compliance with systemwide policies and standards; simultaneously the REO is accountable for all administrative and operational responsibilities. This represents a dual local/systemwide reporting arrangement. The REO, with input from the faculty Advisor, is responsible for annual (and other periodic) evaluations of the campus Director, and shall receive and consider formal input from the systemwide Director as a regular part of the employee evaluation process.

Campus

- Each medical school administers an on-site Program that will participate in systemwide activities and be subject to systemwide policies applicable to all UC Programs. These programs will have a direct link and systemwide accountability to the Office of the President through the Director, Anatomical Services (systemwide Director) in the Division of Health Affairs.
- The Vice Chancellor or School of Medicine Dean shall serve as Responsible Executive Officer (REO) providing management oversight of the Program. He/she may appoint a senior member of the administration to serve as the REO at his/her discretion.

- Locally, the Program will have a campus Director who shall be responsible for the daily operation of the Program and shall report to the REO.
- Each campus Program shall have an appointed faculty Advisor who shall be afforded sufficient time to provide meaningful participation in Program operations. The faculty Advisor shall provide active operational advice and shall participate in the hiring and evaluation processes of Program employees.
- Each Program shall operate under the direction of an Anatomical Materials Review Committee, a management team with operational expertise, that shall consist of at least the REO, who will serve as Chair, the campus Director, and the faculty Advisor (a senior faculty member with expertise in the use of anatomical materials). The Dean may appoint additional members with relevant qualifications to this committee as desired.
- The AMRC shall meet monthly, or a minimum of ten times per year, to ensure proper daily operation of the program. Designated members of this committee shall review and recommend action on requests for use of anatomical material as necessary.
- Each campus shall establish an Anatomical Advisory Board (AAB) consisting of the REO, faculty, staff, users of anatomical materials and the community. This board shall provide broad input from the community by advising the campus on policy and making recommendations regarding program activities. The Dean of the School of Medicine shall serve as chair of the AAB. The AAB shall meet at least annually or as necessary.

IV. Donor Relations/Intake

A central anatomical services registry shall be maintained by the University. This shall be accomplished via a secure electronic registry that is accessible both at the campus and at UCOP, to ensure that active, real-time transparent controls of the programs are in place, and that standard data elements are gathered from each program. Each campus shall ensure that the Program has secure computing environments and access to systemwide databases.

The central anatomical services registry shall be used to manage and track all stages of donation, anatomical preparation, handling, inventory management, allocation, and disposal of anatomical materials. (See Sections V–VII below). Ceremonies of appreciation may be held annually at each campus; they shall not be donor-specific but may include donor families at the discretion of the campus Program director.

The central anatomical services registry shall be managed by the systemwide Director.

- Donor application requirements and materials, including informed consents, shall be uniform to the extent possible as defined by legal counsel, the systemwide Director, and the SAMRC. Local variation in forms shall be permitted to reflect unique Program features, with input from the SAMRC and approval of the systemwide Director.
- Third party donations of non pre-registered deceased individuals may be initiated according to statute by a spouse, registered domestic partner, or upon presentation of an acceptable and unambiguous durable power of attorney. As determined by the local campus, and with approval of the systemwide Director, third-party donations may also be accepted from individuals who sign the required documentation.
- Donations will be accepted from only those individuals who have waived their rights for the return of their cremated remains as stipulated in California Health and Safety Code 7154 (HSC §§ 7154), unless mandated by court order.
- A systemwide mechanism shall record and relay all death notifications from each campus to the systemwide Director.

V. Anatomical Material Preparation and Handling, Inventory Management and Tracking

All anatomical materials shall be tested for infectious diseases, including but not limited to HIV, Hepatitis B, and Hepatitis C, upon receipt. In general, infected anatomical material is not acceptable for use at the University of California and shall not be allocated to any external entity. External entities wishing to utilize untested or reactive material(s) must be approved by the AMRC and they shall indemnify the University, in writing, for all associated risks.

In order to manage the University's collection of human anatomical material more efficiently, human anatomical specimens shall be defined in a master specimen list (Appendix II).

- This common set of definitions shall be reflected in a standard University coding system.
- Standardized specimen tagging and tracking by means of a suitable technology shall be developed by the SAMRC and utilized by the local campus. It is expected that this tagging system will be in place by February 1, 2006.
- The tagging system shall be integrated with the central anatomical services registry, which will permit seamless data management from the preparation laboratory to UCOP.
- Complete inventories shall be validated on a monthly basis.
- Campus Programs shall establish a schedule for physical inventory of their collections to occur no less than annually. Discrepancies shall indicate the need for more frequent inventories. Upon request of the systemwide Director, inventories shall be conducted at random or for cause.

- Campus audit services shall conduct unscheduled inventory and financial audits of local Programs. Audits may be initiated by the systemwide Director.

VI. Anatomical Material Request and Fulfillment

- Local campus Programs shall use a well-documented, standardized specimen requisition process that identifies the custodian of the material, the intended users, and describes in appropriate detail the purpose of the request and duration of usage, research protocol or course of study, if applicable.
- Allocation decisions shall be made by the campus AMRC with general guidance on allocation policy from its AAB.
- University policy shall prohibit the transfer of anatomical materials to third-party brokers or intermediaries. Anatomical materials may only be transferred directly from the University as the provider to an approved end-user for purposes of teaching or research.
- All end-user facilities that request and receive anatomical materials must have prior approval by the Program, and thereafter undergo routine inspection by the local Program Director or his/her designee; the systemwide Director may also inspect facilities.
- Data on all users for all purposes shall be included in the central anatomical services registry.
- Loan duration shall be specified in the initial user application.
- Campus Programs may maintain permanent teaching collections such as skeletal or plastinated collections whose loan duration may be considered indefinite.

VII. Anatomical Material Return and Disposition

- All materials shall be returned to the Program to which they were originally donated. In exceptional circumstances, alternate disposition arrangements may be approved by the REO; prior to final disposition, Program staff shall verify that records and materials for disposal match.
- Return and final disposition of materials to Programs shall be recorded in the central anatomical services registry and reported to the systemwide Director.
- The University assures and provides appropriate disposition of anatomical materials through cremation and scattering at sea or by legal methods of disposition according to California Health and Safety Code.

- Anatomical materials that are not tracked include blood, urine, feces, semen, or other bodily fluids, microscopic tissue samples, human cells, hair, nails, teeth, paraffin blocks or tissue slides. These materials are generally regarded as bio-hazardous or medical waste and are disposed of in accordance with standards defined by the California Health and Safety Code.

VIII. Financial Management

The University shall, to the extent practical, seek to recover costs for material acquisition, preservation and storage, and costs for the management of the program from all users of anatomical materials, both internal and external, educational and commercial.

- Preparation fees shall be determined locally based on a master charge description, to be developed by the SAMRC. The master charge description shall be relevant to actual program costs in accordance with UC policies and procedures.
- Fees for use of anatomical material shall follow all UC regulations regarding collection of indirect costs according to university financial guidelines.

IX. Security

All Programs shall provide a high level of security that will facilitate authorized access only by personnel approved by the AMRC, ensuring that donated materials are protected from misuse.

- Individual coded entry privileges shall be utilized.
- Campus security systems include alarm systems, card-key access, and video cameras as determined by facility needs.

X. Human Resources

- All Program employees shall be hired according to University policies and procedures. Hiring procedures shall include financial and criminal background checks, in accordance with applicable Human Resources policies and California law.
- Job descriptions shall designate positions in Donated Body Programs as critical.
- Standardized job descriptions and classifications shall be established for campus Directors and key staff. Pay scales shall be regularly reviewed by the SAMRC for appropriateness to the level of responsibility for management of the program. All employees shall have a completed background check on file.
- Campus Directors shall be hired or reclassified to at least the MSP-I level.

XI. Physical Plant

Programs shall have sufficient space to permit appropriate storage of anatomical materials and work areas that allow faculty, staff and students to operate in a safe and secure environment. Program work areas will include spaces appropriate for anatomical preparation, dissection and storage of frozen and embalmed tissues as well as whole cadavers.

MASTER SPECIMEN LISTWhole Cadaver

Whole Un-embalmed Cadaver (WC-UN)
 Whole Embalmed Cadaver (WC-EM)

Cephalus

Whole Cephalus (C-HD)
 Skull (C-BS)
 R Temporal (C-BTR)
 L Temporal (C-BTL)
 Mandible (C-BMR)
 Maxilla (C-BML)
 Whole Brain (C-WB)
 Half Brain (C-HB)
 Cephalus Tissue (C-T) (specify)

Torso

Whole Torso (T-W)
 Thorax (T-TRX)
 Whole Spine (T-SW)
 Cervical Spine (T-SCV)
 Thoracic Spine (T-STH)
 Lumbar Spine (T-SLU)
 Sacral Spine (T-SS)
 Spinal cord (T-SCD)
 Abdomen (T-ABD)
 Pelvis (T-PW)
 R Hemi Pelvis (T-PHR)
 L Hemi Pelvis (T-PHL)
 Organ (individual or Paired) (T-ORG)
 (specify)
 Tissue (T-T) (specify)

Upper Limb

R Upper limb with Shoulder (UL-WR)
 L Upper limb with Shoulder (UL-WL)
 R Shoulder (UL-SR)
 L Shoulder (UL-SL)
 R at Mid Humerus (UL-MR)
 L at Mid Humerus (UL-ML)
 R Elbow (UL-ER)
 L Elbow (UL-EL)
 R Forearm (UL-FR)
 L Forearm (UL-FL)
 R Hand (UL-HR)
 L Hand (UL-HL)
 R Humerus (UL-BHR)
 L Humerus (UL-BHL)
 R Radius (UL-BRR)
 L Radius (UL-BRL)
 L Ulna (UL-BUR)
 L Ulna (UL-BUL)
 Upper Limb Tissue (UL-T) (specify)

Lower Limb

R Lower with Hemi Pelvis (LL-HPR)
 L Lower with Hemi Pelvis (LL-HPL)
 R Lower with Full Femur (LL-WR)
 L Lower with Full Femur (LL-WL)
 R Lower at Mid Femur (LL-MR)
 L Lower at Mid Femur (LL-ML)
 R Knee (LL-KR)
 L Knee (LL-KL)
 R Foot (L-LFR)
 L Foot (LL-FL)
 R Femur (LL-BFMR)
 L Femur (LL-BFML)
 R Tibia (LL-BTR)
 L Tibia (LL-BTL)
 R Fibula (LL-BFR)
 L Fibula (LL-BFL)
 Tissue (LL-T) (specify)

UNIVERSITY OF CALIFORNIA, ____ (campus) _____
DONATED BODY PROGRAM
DONATION AGREEMENT

1. INFORMATION ON THE DONATED BODY PROGRAM

The Donated Body Program (“PROGRAM”) operates for the following purposes and under the following principles:

The Program accepts donations of human bodies for use by various individuals and institutions in connection with education and research. In doing so, the Program’s goals are: (1) assisting in the education and continuing education of current and future health care practitioners, anatomists, forensic scientists, and mortuary technicians; and (2) biomedical, forensic, and other scientific research that will assist in the development of procedures and/or products with the general intent of improving the human condition.

A donated body will be used by the Program and others in a manner to be determined exclusively by the Program, pursuant to the policies and procedures that are in effect at the time of a donor’s death or as they may be revised thereafter.

Upon proper completion of this donation agreement (AGREEMENT) as well as the vital statistics sheet and the Department of Health Race Identification worksheet, and upon subsequent registration in the Program, donors will be provided with a Donor Card that contains the information necessary to assist in contacting the Program at the time of death. Donations are confidential. Once a donor’s remains have been accepted into the Program and an acknowledgement has been sent to the person a donor may designate in this form, the Program will not provide any further information concerning the use and/or disposition of a donor body.

When a donor signs this form, he/she specifically waives the provisions of California Health & Safety Code Section 7153.5(D) that provides for the return of cremated remains to certain individuals. Due to the nature and variability of uses for scientific research and education, cremated remains WILL NOT be returned.

Initials _____

2. INSTRUCTIONS FOR SURVIVORS (RESPONSIBLE PARTY)

Upon death, a donor must be delivered to the Donated Body Program as follows:

1. The Program is to be notified of the death immediately, as a delay can result in rendering the remains unusable to the Program.
2. The body is to be un-embalmed or otherwise unprepared for disposition.
3. Every effort will be made to accept a donor body; however, the Program may, at its sole discretion, reject a donation at the time of death. If this situation arises, the designated survivor/responsible party will be required to make alternative arrangements for the disposition of the remains.

[**NOTE:** sections 4 and 5 will contain campus-specific criteria for transportation when all other amendments have been made and approved.]

4. If death occurs within ___ miles of the University of California, _____, the Program will arrange for and pay for the cost of transporting the body.
5. If death occurs more than ___ miles from the University of California, _____, the Program shall have the option of: (1) accepting the donation upon confirmed payment arrangement by the next of kin or estate for the cost of transporting the body to the Program, via use of a transportation provider approved by the Program; (2) arranging for the body to be accepted by another University of California Donated Body Program closer to the place of death; or (3) declining to accept the donation of the body.
6. The Program will have an original certificate of death filed with the county where death occurs by means acceptable to the Registrar of Births and Deaths. It will be the responsibility of the survivor/responsible party to obtain all necessary copies of the certificate.
7. As determined by the local campus, third party donations (eg. adult children, adult siblings, grandparents) may also be accepted. Individuals making third party donations must sign the required documentation specifying that they are compliant with the criteria defined in the California Health and Safety Code. (HSC §§ 7100)
http://www.cfb.ca.gov/crd_booklet.pdf

I, _____, hereby designate the following individual to receive acknowledgement of my donation upon my death.

Name _____

Address _____

City/state/zip code _____

Phone number/E-mail _____

OR

I elect not to name a recipient: _____

Initials _____

3. USE OF DONATED BODIES

Whole body donors may be accepted by the Donated Body Program and used in the following manner:

1. Upon receipt of the body, the Program will use the information furnished in this Agreement to send an acknowledgement notice to the person designated, if any, in the previous section. That notice will include the address of the appropriate county Department of Health where survivors can obtain certified copies of the death certificate. The notice as well as any future communications will not provide any specific information concerning the use, location, analysis or disposition of the body, or any part of the body.
2. Once received, if it is determined that, for any reason, a body cannot be used by the Program, or by any person or entity approved for use of anatomic material donated to the Program as described hereafter, it will be cremated and the cremated remains will be disposed of in any manner consistent with then-existing California law.
3. Donor bodies may be tested for Hepatitis B, Hepatitis, C and HIV upon receipt in the program. Results of tests will not be disclosed to the donor's responsible party but may be reported to the California Department of Health Services if mandated by law.
4. A donated body may be, but need not be, embalmed by the Program or may be used in an un-embalmed state as anatomical material.
5. A donor body may be dissected, examined, studied, preserved for a substantial period of time, and used for more than one purpose. Parts of the body such as organs or limbs may be removed and separated from the whole. Removed body parts may be disposed of at different times and at different places. Bodily fluids and tissues may be analyzed and destroyed.
6. A donor body and/or part of the body may be provided to educators, students, researchers, etc. at other University of California campuses, as well as to non-UC educational institutions, researchers (both UC employees and non-UC employees), non-profit entities and for-profit entities. When making a donation, donors, survivors and/or responsible parties cannot designate the uses to which the body will be put nor the persons or entities that will use the same.
7. If a donated body, or parts thereof, are used by persons and/or entities not associated with the University of California campus at which the body is housed, the Program shall be entitled to recover all of its acquisition, preservation, storage, transportation and related costs (both fixed and non-fixed) from the end user as it sees fit.

Initials _____

4. DISPOSITION OF DONATED BODIES

The following applies to the ultimate disposition of donor bodies by the Program. By signing this agreement, a donor or his/her responsible party authorizes the Program and its agents to dispose of the donation by cremation or by other legal manner that may be approved at the time of death:

1. Because parts of the body may be removed during its use, these parts may be disposed of at different times and at different locations.
 - Upon completion of the use of a body, or any part of a body, the material may be cremated and/or otherwise disposed of by any means permitted under California law in effect at the time.
2. Under certain circumstances, body parts, tissue, fluids, etc., may undergo disposition with such material from other donors, with the resulting cremated remains being co-mingled.
3. Survivors/responsible parties will not be notified of the time, place or manner of the disposition of a body or any part of a body, or of the final disposition of the remains. The cremation of some parts of the body may not result in the creation of any remains for disposition due to the composition of those body parts.
4. The donor expressly waives the provisions of California Health & Safety Code Section 7153.5(D) that provide for the return of cremated remains to certain individuals. Due to the nature and variability of uses for scientific research and education, cremated remains **WILL NOT** be returned.
5. The Program undertakes no duty to survivors of the donor with respect to the handling, disposition, disposal, or return of the donor's remains.

Initials _____

5. THE RIGHTS OF A DONOR

1. A donor can revoke this donation at any time prior to death. After death, this donation cannot be revoked by survivors/responsible parties and survivors/responsible parties cannot change any term or condition of this gift. By signing this agreement a donor intends for the Regents of the University of California to have the exclusive right to control the use and disposition of their body upon death.

Initials _____

I, _____, hereby donate my body upon my death to the Donated Body Program referenced above. It is my wish and my specific instruction that, upon my death, my body is to be donated to the Program pursuant to the terms and conditions set forth herein. I am at least 18 years of age. I adopt these descriptive and declarative terms and conditions as my own and make them my instructions as to the disposition of my body upon my death. I have read and considered all of the information contained in this Donation Agreement. I have initialed each section of the agreement indicating my understanding of the information and my desire to donate my body pursuant to this agreement.

Signature

Date

Print Name

Address:

City/state/zip/code

Phone/E-mail

WITNESSES

We, the undersigned, have witnessed the signing of this document by the donor.

Signature

Signature

Print Name

Print Name

Address

Address

City/State/Zip

City/State/Zip

I have read and fully understood the policies set forth in this document. As the legally responsible party under this section for _____ (name of deceased) I wish to donate his/her remains to the _____ (UC campus) Donated Body Program. I accept all terms and conditions set forth in this document.

____ I am the spouse of the deceased donor.

____ I am the registered domestic partner.

____ I am the agent for the deceased donor with power of attorney for health care and I have the right and duty of disposition under Division 4.7 (commencing with Section 4600) of the Probate Code.

Signature Relationship to Decedent Date

Print Name

Address

City/State/Zip

We the undersigned have witnessed the signing of this document by the third-party donor.

Witness

Witness

Print Name

Print Name

Address

Address

City/State/Zip

City/State/Zip