



DoD INSTRUCTION 6465.03

ANATOMIC GIFTS AND TISSUE DONATION

Originating Component:	Office of the Under Secretary of Defense for Personnel and Readiness
Effective:	June 8, 2016
Releasability:	Cleared for public release. Available on the Internet from the DoD Issuances Website at http://www.dtic.mil/whs/directives .
Reissues and Cancels:	DoD Directive 6465.03, "Organ and Tissue Donation," May 4, 2004
Approved by:	Peter Levine, Acting Under Secretary of Defense for Personnel and Readiness

Purpose: This issuance:

- Reissues DoD Directive 6465.3 as a DoD instruction.
- Establishes policy and assigns responsibilities for organ and tissue donation, including the donation of human organs and tissues for transplantation, therapy, research, or education, pursuant to section 1109 of Title 10, United States Code (U.S.C.).

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SECTION 1: GENERAL ISSUANCE INFORMATION

1.1. APPLICABILITY. This issuance applies to OSD, the Military Departments, the Office of the Chairman of the Joint Chiefs of Staff and the Joint Staff, the Combatant Commands, the Office of the Inspector General of the Department of Defense, the Defense Agencies, the DoD Field Activities, and all other organizational entities within the DoD.

1.2. POLICY. It is DoD policy that:

a. Without coercion, Service members, DoD beneficiaries, and DoD civilian employees are afforded the opportunity and provided a convenient mechanism to donate organs and tissues.

b. The DoD identification (ID) card serves as an indicator of donor election, in accordance with Volume 1 of DoD Manual 1000.13.

c. The Military Health System (MHS) will support the DoD Organ and Tissue Donation Program, as established in this instruction, to obtain and record donor consent for organ and tissue use in transplantation, therapy, research, and education, as established in this issuance.

d. Organ and tissue donation for the purposes of research must be compliant with DoD Instruction (DoDI) 3216.02, Part 219 of Title 32 Code of Federal Regulations (CFR), and applicable State law applying the Uniform Anatomical Gift Act. This issuance applies only to the use of the DoD Organ and Tissue Donation Program to help identify potential donations for research and does not govern other research programs or procedures.

1.3. INFORMATION COLLECTIONS. The Defense Enrollment Eligibility Reporting System (DEERS), referred to in Paragraph 2.4 and 3.1, has been assigned Office of Management and Budget Control Number 0704-0415 and is prescribed in Volumes 1 and 2 of DoD Manual 1000.13. The expiration date of this information collection is listed on the Office of Management and Budget website at <http://www.reginfo.gov/public/jsp/PRA/prDashboard.jsp>

SECTION 2: RESPONSIBILITIES

2.1. UNDER SECRETARY OF DEFENSE FOR PERSONNEL AND READINESS

(USD(P&R)). The USD(P&R) oversees compliance with this issuance and provides guidance, as necessary, for its implementation.

2.2. ASD(HA).

Under the authority, direction, and control of the USD(P&R), the ASD(HA):

a. Establishes and maintains an information program and appropriate educational materials to inform Service members, DoD beneficiaries, and DoD civilian employees of the importance of organ and tissue donation and of the DoD Organ and Tissue Donation Program as described in this issuance.

b. Provides executive oversight of the DoD Organ and Tissue Donation Committee, as established in this instruction.

c. Approves recommendations of the DoD Organ and Tissue Donation Committee for research partnerships to employ the DoD ID Card election to identify potential donors. All such partnerships must include an established DoD research organization, for example the Uniformed Services University of the Health Sciences Center for Neuroscience and Regenerative Medicine.

2.3. DIRECTOR, DEFENSE HEALTH AGENCY (DHA).

Under the authority, direction, and control of the USD(P&R), through the ASD(HA), the Director, DHA:

a. Develops and coordinates procedural guidance, in coordination with the Military Departments, to implement this issuance. The procedural guidance will comply with local and State law applying the Uniform Anatomical Gift Act requirements.

b. In coordination with the Surgeons General, establishes and maintains a DoD Organ and Tissue Donation Committee to develop and coordinate best practices and assist the organ and tissue donation programs of the MHS. The DoD Organ and Tissue Donation Committee will include senior military and civilian personnel of the MHS and advisory members representing other DoD stakeholders, to include the Uniformed Services University of the Health Sciences and the Armed Forces Medical Examiner System.

c. Establishes and maintains an information program and appropriate educational materials to inform Service members, DoD beneficiaries, and DoD civilian employees of the importance of organ and tissue donation and of the DoD Organ and Tissue Donation Program.

d. Ensures that any support required of the Armed Forces Medical Examiner System (AFMES) to facilitate the implementation of this issuance does not conflict with its primary mission as described in DoD Instruction 5154.30, Armed Forces Medical Examiner System Operations.

e. Directs compliance with this issuance by the medical treatment facilities (MTFs) within the National Capital Region that are assigned to the DHA.

2.4. DIRECTOR, DEPARTMENT OF DEFENSE HUMAN RESOURCES ACTIVITY (DODHRA). Under the authority, direction, and control of the USD(P&R), the Director, DoDHRA, establishes and maintains systems and procedures to enter donor information in DEERS and display intent to donate on the DoD ID card. The DEERS system will include the ability to indicate intention to donate organs and tissue for both therapeutic and research purposes. Information about the donor's election must be accessible through a searchable donor registry by authorized DoD users in order to provide information to United Network for Organ Sharing so that an individual's desires are honored. All searchable donor registries and databases containing personally identifiable information must comply with the Privacy Act of 1974, DoD Directive 5400.11, and DoD 5400.11-R.

2.5. SECRETARIES OF THE MILITARY DEPARTMENTS. The Secretaries of the Military Departments:

- a. Require the MTFs under their authority carry out the functions listed in Paragraph 3.1.c.
- b. Ensure that notification of donation procedures is provided to officer candidates and recruits in accordance with section 1109(b) of Title 10, U.S.C.

SECTION 3: PROCEDURES

3.1. OVERARCHING PROCEDURES FOR ANATOMIC GIFTS AND TISSUE

DONATION. The following procedures will be further detailed and supplemented by DHA procedural instructions.

a. Election to Donate.

(1) The DoD recognizes that where supported by State law, the principle of “first person consent” or “donor designation” places the individual’s desire to donate above the desire of the next of kin or the individual’s designated power of attorney. If an individual with capacity to consent has designated an election to donate organs and tissues, that election will be honored unless prohibited by the State law in the State of organ recovery. The election will include valid consent to donate organs and tissues for transplantation and therapy, and may also include intent to donate for purposes of research and education. Additional consent may be required from next of kin in accordance with State laws.

(2) Each Service member will be given the opportunity to choose to become an organ and tissue donor at the time of DoD or DoD civilian ID card issuance or at any time the Service member or DoD civilian changes his or her desire to donate.

(3) All DoD beneficiaries 18 years of age or older will also be given the opportunity to elect to be organ and tissue donors. These beneficiaries may elect to be organ and tissue donors at the time of DEERS enrollment, DoD ID card issuance, or at any time the DoD beneficiary changes his or her desire to donate.

(4) Each DoD civilian will be given the opportunity to choose to become an organ and tissue donor. A DoD civilian may elect to become an organ and tissue donor at the time he or she is issued a DoD ID card, or at any time the DoD civilian changes his or her desire to donate.

(5) DEERS donor election will be documented as indicated at the time of DoD ID Card issuance in accordance with Volume 1 of DoD Manual 1000.13. All other mechanisms to record or display donor election within the health record systems will be reconciled with DEERS in order to reflect the individual’s desires as recorded in DEERS. The DoD will enable authorized users, in accordance with DoD 6025.18-R and subsequent revisions, to query the data in the DEERS system, establishing a registry-like capability mirroring the form and function of State donor registries based on elections from drivers’ licenses. The procedures for obtaining the consent recorded will be designed to provide informed consent sufficient to allow therapeutic donation to the extent practical and the system will comply with information protection requirements in accordance with DoDI 5400.11. It will enable requisite access for approved officials (military or United Network for Organ Sharing) to fulfill local law enacting the Uniform Anatomical Gift Act (as revised) requirements that all registries provide sufficient access so that an individual’s desires are honored. Election information will include the date of election; the most recent designated desire will take precedence in the case of differences between sources.

(6) Use of donated tissue to support research must comply with DoDI 3216.02 and Part 219 of Title 32, CFR. The donor election procedures and means of recording the donor election in DEERS will provide one mechanism for recording intent to donate for research purposes. Additional mechanisms to obtain informed consent may be required before tissue can be obtained, for example next of kin may augment the consent indicated in the primary donor election. Modifications of the procedures to enable compliance with additional consent requirements must be approved through the Organ and Tissue Donation Committee and coordinated with DEERS to be implemented.

b. Logistical Support.

(1) Military Department Secretaries are required to ensure that appropriate training will be provided to enlisted and officer medical personnel and logistical support personnel to ease the operation of organ and tissue donation activities under garrison conditions and, to the extent possible, under operational conditions. Under garrison conditions, this training should involve the local hospital-affiliated organ procurement organization's (OPO) participation. Training must include when to call the OPO about a potential donor and how to respect the sensitivities of potential donor families, the concept of "donor designation," and that, in general, it is best to defer to the professional OPO coordinators when approaching the families. More specific guidance may be provided by DHA and Service implementation and procedural instructions.

(2) Active duty and Reserve Component Service members may serve as living donors. When donation involves required absence from duty for more than 1 day or may negatively impact a member's fitness for active duty or future deployability, the following procedures apply:

(a) The local chain of command must approve the Service member's request to donate organs to avoid any negative impact on mission.

(b) The office of the respective Surgeon General or Reserve Component commander must approve the surgery to proceed.

(c) The Service member must:

1. Be seen by his or her primary care provider before, and 6 weeks after, donation to assess the member's fitness for duty in accordance with respective Service guidance.

2. Understand that any surgery, including organ donation, may result in the member being found unfit for duty and impact continued service.

(d) Any questions about organ donation may be directed to the Service branch subject matter expert (SME). In addition, the Army-Navy Transplant Service can assist the branch SMEs as needed.

(3) Other DoD beneficiaries' participation as living donors is governed by State law, with benefits as determined by the TRICARE operations manual.

(4) Medical logistical activities will support an effective organ and tissue donation program as much as possible without jeopardizing operational requirements.

(5) The MHS will participate with the Organ Procurement and Transplantation Network established in accordance with sections 273 and 274 of Title 42, U.S.C. that facilitates and coordinates the donation, recovery, allocation, and distribution of organs and tissues.

(6) Each MTF hospital will have an appropriate memorandum of agreement between the MTF hospital and the local OPO granting the OPO access to the MTF hospital. Standards for these memorandums of agreement will be established by the DoD Organ and Tissue Donation Committee.

c. MTF Hospital Responsibilities.

(1) MTF hospitals will comply with the guidelines of The Joint Commission on recovering and donating organs, eyes, and other tissues, in accordance with the Comprehensive Accreditation Manual for Hospitals.

(2) MTF hospitals will follow this issuance and specific procedural instructions published by the DHA when determining the validity of an anatomical gift or amendment to, revocation, or refusal to make a gift.

(3) MTF hospitals will comply with DoD 6025.18-R procedures related to uses and disclosures of protected health information concerning transplantation.

(4) MTF hospitals will have a written, established procedure for contacting the local OPO about a potentially available organ or tissue donor and provide opportunity for the OPO to educate nursing and medical staffs regarding which donors or potential donors should warrant a call to the OPO.

d. AFMES Responsibilities.

(1) The AFMES will follow this issuance and specific procedural instructions published by the DHA when facilitating an anatomical gift in response to an authorized request.

(2) The AFMES will comply with DoD 6025.18-R procedures related to uses and disclosures of protected health information concerning transplantation.

(3) The AFMES will coordinate with the Organ and Tissue Donation Committee to establish and update procedural instructions and will, in accordance with those instructions, assist with facilitating the procurement of specified organs and tissues from donors identified through their DEERS recorded intent to donate under procedures approved by the ASD(HA), when doing so does not compromise its forensic pathology investigation.

(a) The approved procedures, which may include arrangements with an appropriate entity, will be responsible for identifying potential donors and, in the case of donations for research purposes, for compliance with DoDI 3016.02, Part 219 of Title 32 CFR, and applicable

State laws, to include obtaining Institutional Review Board approval and ensuring that the ID card election is augmented as may be necessary to establish informed consent.

(b) The AFMES will provide any information required to a procuring OPO when requested and when procurement documentation compliant with this issuance and published procedural guidance is presented. The release of any information will be dependent on the suitability of its release in relation to security concerns.

(c) When responding to an OPO request, the AFMES will inform the OPO when any determination of the cause of death differs from the cause of death listed on the procurement documentation.

GLOSSARY

G.1. ACRONYMS.

AFMES	Armed Forces Medical Examiner System
ASD(HA)	Assistant Secretary of Defense for Health Affairs
CFR	Code of Federal Regulations
DEERS	Defense Enrollment Eligibility Reporting System
DHA	Defense Health Agency
DoDHRA	Department of Defense Human Resources Activity
ID	identification
MHS	Military Health System
MTF	medical treatment facility
OPO	organ procurement organization
SME	subject matter expert
U.S.C.	United States Code
USD(P&R)	Under Secretary of Defense for Personnel and Readiness
USUHS	Uniformed Services University of the Health Sciences

G.2. DEFINITIONS. Unless otherwise noted, these terms and their definitions are for the purpose of this issuance.

DoD beneficiaries. Individuals who have been determined to be entitled to or eligible for medical benefits and therefore authorized treatment in an MTF or under DoD auspices.

DoD civilians. Individuals who are civilian employees of the DoD who possess a DoD ID card in accordance with Volume 1 of DoD Manual 1000.13.

DoD ID Card. Identification issued to uniformed service members, their dependents, and other eligible individuals in accordance with DoD Manual 1000.13, Volume 1, that will be used as proof of identity and DoD affiliation, and to facilitate access to military service benefits or privileges in accordance with Volume 2 of DoD Manual 1000.13.

DoD recipients. DoD beneficiaries who are eligible to receive organ, eye, and tissue donations.

donor. An individual who makes a gift of all or part of his or her body for specific purposes.

garrison conditions. Routine operational environment at a fixed health care facility with an established scope of service, standard operating procedures, and permanent staff.

next of kin. The person most closely related to the donor, designated according to the established order of priority in DoDI 1300.18.

operating conditions. The dynamic operational environment of a health care facility supporting and maintaining a specific military mission.

organ. The heart, lung, liver, kidney, pancreas, or any other self-contained biological structure or portion thereof that is currently or will be suitable for transplantation and that requires active biological patient support to ensure viability prior to removal.

OPO. A formal civilian organization that, within a designated area, coordinates activities related to the recovery of organs, eyes, and tissues for a specific type of transplantation. OPOs evaluate potential donors, discuss donation with surviving family members, arrange for the surgical removal and transplantation of donated organs, and educate the public about the need for organ and tissue donation.

personally identifiable information. Defined in DoD Directive 5400.11.

Reserve Components. Any of the Reserve or National Guard units eligible to be called into active duty service by a Military Department.

Surgeons General. Surgeons General of the Military Departments.

tissue. The cornea, eye, skin, bone, bone marrow, dura, blood vessel, fascia, brain or any other distinct type of material that is currently or will be suitable for medical therapeutics or scientific research that does not require ongoing biological patient support (active perfusion) at the time of harvest.

REFERENCES

- Code of Federal Regulations, Title 32, Part 219
- DoD 5400.11-R, "Department of Defense Privacy Program," May 12, 2007
- DoD 6025.18-R, "DoD Health Information Procedures Regulation,"
- DoD Directive 1322.16, "Montgomery GI Bill (MGIB) Program," June 18, 2002
- DoD Directive 1341.3, "Defense Enrollment Eligibility Reporting System (DEERS) Procedures," March 19, 1999
- DoD Directive 5124.02, "Under Secretary of Defense for Personnel and Readiness (USD(P&R))," June 23, 2008
- DoD Directive 5400.11, "DoD Privacy Program," October 29, 2014
- DoD Instruction 1300.18, "Department of Defense (DoD) Personnel Casualty Matters, Policies, and Procedures," January 8, 2008, as amended
- DoD Instruction 3216.02, "Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research," November 8, 2011
- DoD Instruction 5154.30, "Armed Forces Medical Examiner System (AFMES) Operations," December 29, 2015.
- DoD Manual 1000.13, Volume 1, "DoD Identification (ID) Cards: ID Card Life-Cycle," January 23, 2014
- DoD Manual 1000.13, Volume 2, "DoD Identification (ID) Cards: Benefits for Members of the Uniformed Services, Their Dependents, and Other Eligible Individuals," January 23, 2014
- Joint Commission, "Comprehensive Accreditation Manual for Hospitals," most current edition¹
- National Conference of Commissioners of Uniform State Laws, "Uniform Anatomical Gift Act 2006," July 2006, current version
- United States Code, Title 5, Section 552a (also known as the "Privacy Act of 1974 as amended")
- United States Code, Title 10
- United States Code, Title 42, Section 273

¹ Copies may be obtained from the Internet at <http://www.jcrinc.com/store/publications/manuals/>