

Defense Health Agency

PROCEDURAL INSTRUCTION

NUMBER 6465.01 February 17, 2023

DAD-MA

SUBJECT: Anatomic Gifts and Tissue Donation

References: See Enclosure 1.

- 1. <u>PURPOSE</u>. This Defense Health Agency-Procedural Instruction (DHA-PI), based on the authority of References (a) and (b), and in accordance with the guidance of References (c) through (v), establishes the Defense Health Agency's (DHA) procedures for organ and tissue donation. This applies to the donation of human organs and tissues, for transplantation, therapy, research, or education, pursuant to Section 1109(b) of Reference (l).
- 2. <u>APPLICABILITY</u>. This DHA-PI applies to the DHA Enterprise (components and activities under the authority, direction, and control of DHA) to include: assigned, attached, allotted, or detailed personnel. Additionally, this DHA-PI applies to the Military Departments (MILDEPS), Combatant Commands, Office of the Chairman of the Joint Staff and the Joint Staff.
- 3. <u>POLICY IMPLEMENTATION</u>. It is DHA's instruction, pursuant to References (d) through (v), to:
- a. Establish procedures with a convenient mechanism for Service members, Department of Defense (DoD) beneficiaries, and DoD civilian employees to donate organs and tissues.
- b. Establish how the DoD identification (ID) card will serve as an indicator of donor election in the Military Health System (MHS) and in accordance with Volume 1 of Reference (e).
- c. Establish how the MHS will support the DoD Organ and Tissue Donation Program to obtain and record donor consent for organ and tissue use in transplantation, therapy, research, and education.
- d. Establish how organ and tissue donation, for the purposes of research, will be compliant with Reference (e), Reference (n), and applicable State law applying the Uniform Anatomical Gift Act (UAGA; Reference (v)) that is consistent with federal law and DoD policy.

- 4. RESPONSIBILITIES. See Enclosure 2.
- 5. PROCEDURES. See Enclosure 3.
- 6. <u>PROPONENT AND WAIVERS</u>. The proponent for this publication is the Deputy Assistant Director (DAD), Medical Affairs (MA). When Activities are unable to comply with this publication the activity may request a waiver that must include a justification, to include an analysis of the risk associated with not granting the waiver. The activity director or senior leader will submit the waiver request through their supervisory chain to the DHA DAD-MA to determine if the waiver may be granted by the Director, DHA or their designee.
- 7. <u>RELEASABILITY</u>. **Cleared for public release**. This DHA-PI is available on the Internet from the Health.mil site at: https://health.mil/Reference-Center/Policies and is also available to authorized users from the DHA SharePoint site at: https://info.health.mil/cos/admin/pubs/SitePages/Home.aspx.
- 8. EFFECTIVE DATE. This DHA-PI:
 - a. Is effective upon signature.
- b. Will expire 10 years from the date of signature if it has not been reissued or cancelled before this date in accordance with Reference (c).
- 9. FORMS.
- a. The DD Form 2731, Organ and Tissue Donor Card is available at: https://www.esd.whs.mil/Portals/54/Documents/DD/forms/dd/dd2731.pdf.
- b. The DD Form 2807-1, Report of Medical History is available at: https://www.esd.whs.mil/Directives/forms/dd2500_2999/.
- c. The DD Form 2808, Report of Medical Examination is available at: https://www.esd.whs.mil/Directives/forms/dd2500 2999/.

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Director

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ENCLOSURE 1

REFERENCES

- (a) DoD Directive 5136.01, "Assistant Secretary of Defense for Health Affairs (ASD(HA))," September 30, 2013, as amended
- (b) DoD Directive 5136.13, "Defense Health Agency (DHA)," September 30, 2013, as amended
- (c) DHA-Procedural Instruction 5025.01, "Publication System," April 1, 2022
- (d) DoD Instruction 6465.03, "Anatomic Gifts and Tissue Donation," June 8, 2016
- (e) DoD Manual 1000.13, Volume 1, "DoD Identification (ID) Cards: ID Card Life-Cycle," January 23, 2014, as amended
- (f) DoD Instruction 3216.02, "Protection of Human Subjects and Adherence to Ethical Standards in DoD-Conducted and -Supported Research," April 15, 2020
- (g) 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, as amended
- (h) DoD Instruction 5154.30, "Armed Forces Medical Examiner System (AFMES) Operations," December 29, 2015, as amended
- (i) DoD Instruction 5400.11, "DoD Privacy and Civil Liberties Programs," January 29, 2019, as amended
- (j) DoD 5400.11-R, "Department of Defense Privacy Program," May 14, 2007
- (k) DoD Instruction 8580.02, "Security of Individually Identifiable Health Information in DoD Health Care Programs," August 12, 2015.
- (l) United States Code, Title 10, Section 1109(b)
- (m) DoD Instruction 6025.18, "Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule Compliance in DoD Health Care Programs," March 13, 2019
- (n) DoD Manual 6025.18, "Implementation of the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule in DoD Health Care Programs," March 13, 2019
- (o) Code of Federal Regulations, Title 32, Part 219
- (p) DoD Instruction 1300.18, "Department of Defense (DoD) Personnel Casualty Matters, Policies, and Procedures," January 8, 2008, as amended
- (q) Public Law 104-191, "Health Insurance Portability and Accountability Act of 1996," August 21, 1996
- (r) United States Code, Title 42, Sections 273 and 274
- (s) DHA Administrative Instruction 74, "Workforce Training Pursuant to the Requirements of the Privacy Act and the Health Insurance Portability and Accountability Act," December 2, 2014
- (t) DoD Instruction 4000.19, "Support Agreements," December 16, 2020

- (u) The Joint Commission on Accreditation of Healthcare Organizations, & Joint Commission Resources, Inc. (2022), Chapter on Transplant Safety¹
- (v) National Conference of Commissioners of Uniform State Laws, "Revised Uniform Anatomical Gift Act 2006," January 2003, as amended

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¹ This reference can be found at:

ENCLOSURE 2

RESPONSIBILITIES

1. <u>DIRECTOR</u>, <u>DHA</u>. The Director, DHA, will:

- a. Oversee implementation of this DHA-PI. This procedural guidance will comply with applicable federal laws and policies and, as long as they are consistent with federal law and DoD policy, applicable State law applying the UAGA requirements (Reference (v)).
- b. Support the DHA Components by ensuring systems and standard processes are in place to collect data and measure compliance with this DHA-PI.

2. <u>AD-HCA</u>. The AD-HCA must:

- a. Establish and maintain a DoD Organ and Tissue Donation Committee, pursuant to Reference (d), in coordination with the MILDEP Surgeons General (SG), 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 (AFMES).
- b. Provide coordination required for ASD(HA) approval regarding research partnerships recommended by DoD Organ and Tissue Donation Committee.
- c. Establish and maintain an information program and a process to provide appropriate educational materials to Service members, DoD beneficiaries, and DoD civilian employees to inform them of the importance of organ and tissue donation and of the DoD Organ and Tissue Donation Program.
- d. Ensure any support required for the AFMES to facilitate implementation of this DHA-PI does not conflict with its primary mission as described in Reference (h).
 - e. Ensure compliance, as directed here within, by the DHA Components.

3. DAD-MA. The DAD-MA must:

a. Maintain overall responsibility for providing recommendations, secondary to the requirements in this DHA-PI, to AD-HCA.

- b. Coordinate with the DAD, Health Care Operations (HCO) on healthcare operations implementation activities in support of this DHA-PI and to ensure compliance with the instructions in this DHA-PI.
- c. Monitor compliance with the guidance outlined in this DHA-PI through the DoD Tissue and Organ Donation Committee.
- d. Develop a process to update the policy guidance and procedures as needed. All updated guidance and procedures are sent to OSD, the MILDEPs, DHA, or TRICARE stakeholders, as required.
- e. Provide oversight of the DoD Organ and Tissue Donation Committee that will be responsible for assisting organ and tissue donation programs of the MHS and communicate best practices.

4. <u>DAD-HCO</u>. The DAD-HCO must:

- a. Establish standard healthcare operations processes based on this DHA-PI and provide compliance oversight of DHA Components.
- b. Collaborate with DAD-MA to communicate and monitor compliance to the procedures outlined in this DHA-PI to the DHA Components.
- 5. <u>DIRECTOR, HEALTH INFORMATICS</u>. The Director, Health Informatics will provide documentation availability for annotating Service member and beneficiaries' desire to serve as an organ or tissue donor in the electronic health record (EHR).
- 6. <u>DEPUTY ASSISTANT DIRECTOR, DHA RESEARCH AND ENGINEERING (J-9)</u>. The Director, DHA Research and Engineering (J-9) will:
- a. Ensure research using donated organs or tissues complies with DoD guidance on protection of human subjects and adherence to ethical standards in DoD-supported research (Reference (f) and (o)).
- b. Oversee each institutional official's implementation of its organization's Human Research Protection Program.
- 7. <u>DIRECTOR, DOD HUMAN RESOURCES ACTIVITY</u>. The Director, DoD Human Resources Activity, will:
- a. Establish and maintain systems and procedures to enter donor information in Defense Enrollment Eligibility Reporting System (DEERS) and display intent to donate on the DoD ID card. The Defense Enrollment Eligibility Reporting System (DEERS) system will include the

ability to indicate intention to donate organs and tissue for both therapeutic and research purposes.

- b. Develop a process to access the information about the donor's election through a searchable donor registry by authorized DoD users to provide information to United Network for Organ Sharing (UNOS) so an individual's desires are honored.
- c. Perform inspections of donor's election registration and identity management processes and procedures, and report findings to the USD(P&R), as necessary.
- 8. <u>SECRETARIES OF THE MILDEPS AND THE COMMANDANT OF THE COAST GUARD</u>. The Secretaries of the MILDEPs and the Commandant of the Coast Guard, in coordination with the Director, DHA will assist in implementation of this DHA-PI by ensuring:
 - a. Compliance with and execution of the procedures outlined in this DHA-PI.
- b. The respective Surgeon General or Reserve Component Commander reviews all Service member requests to be a living donor of tissue or organ transplant and makes the final determination of approval, taking into consideration the impact of donation may negatively affect a Service member's fitness for AD or future deployability.
- 9. <u>DHA DIRECT REPORTING MARKETS</u>, SSO, THE HAWAII MARKET, AND DHAR <u>DIRECTORS</u>. These Directors will monitor compliance with and execution of procedures in this DHA-PI as outlined in Enclosure 3 for the MTFs in their areas of responsibility, and report compliance to DAD-MA on an annual basis by February 15.

10. MTF DIRECTORS. The MTF Directors must:

- a. Establish and maintain 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 the DoD Organ and Tissue Donation Program.
- b. Provide awareness to MTF personnel on DoD Organ and Tissue Donation Program and procedures.
- c. Ensure awareness of proper handling and coordination with the local Organ Procurement Organization (OPO) for situations where a beneficiary is identified as a donor and eligible to provide immediate organ or tissue donation.
- d. Establish a process to educate unit commanders on risks, benefits, and mission impact of a Service member who has elected to be a living donor. The education must provide an analysis on impact to Service member readiness and anticipated rehabilitation timeline.

- (1) Attending provider educates and provides recommendation on the medical appropriateness for both unit commanders and Service members alike.
- (2) Ensure there is a process established to inform the unit commander about the recommendation regarding medical care. Decision-making authority impacting readiness lies with unit commanders.
- e. Provide recommendations for medically necessary convalescent leave duration for donors from time of admission to a non-military facility through discharge. Final approval of convalescent leave resides with the Service member's immediate unit commander.
- f. Ensure Service members are transferred to a MTF after the medical discharge from a private sector facility for the completion of any required Military Department- specific administrative requirements, such as profiles, assignments, and qualifications for continued service.
 - (1) Continued service is dependent upon military career field.
- (2) Military Department-specific accession, commissioning, retention criteria, and waiver process should be addressed during pre-donation counseling as well as post-donation medical evaluation.
- g. Notify AFMES of all deaths that occur at any DHA MTFs under federal jurisdiction, to include civilian and non-beneficiary deaths. For deaths that occur outside federal jurisdiction, notify the local medicolegal authority. Consult the local servicing DHA Office of General Counsel and law enforcement entities for information and guidance regarding jurisdictional issues, as needed.

ENCLOSURE 3

PROCEDURES

1. ELECTION TO DONATE

- a. The DoD provides opportunities for Service members and beneficiaries to make organ and tissue donations. Coercion or appearance of coercion of donors, their next of kin (NOK), or a legally authorized representative will not be tolerated. The NOK or legally authorized representative is the person, under applicable law, recognized to make decisions on behalf of a patient when the patient is unable to do so. Donations from minors will be accepted only with appropriately informed parental or legally authorized representative consent.
- b. DoD recognizes that where supported by State law, the principle of "first person next consent" or "donor designation" places the individual's desire to donate above the desire of the NOK. If an individual with capacity to consent has designated an election to donate organs and tissues, that election will be honored unless prohibited by 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 the NOK in accordance with State laws, when consistent with federal law and DoD policy.
- c. Each Service member, DoD beneficiaries 18 years of age or older, and DoD civilian will be given the opportunity to choose to become an organ and tissue donor. Guidance on documentation of donor election in DEERS is outlined in reference (d) and (g).
- d. Where State law (when consistent with federal law and DoD policy) makes an organ or tissue donation election irrevocable and precludes countermand by the NOK, DoD medical system personnel must comply with the donor's election, if the donor's election is valid and documented in accordance with State law (e.g., driver's license designation). Most states have donor designation or "first person consent" that obviates OPOs from obtaining consent from NOK.
- e. Use of donated tissue to support research must comply with References (d), (i), (j), (m), (n), (o), and (q). The donor election procedures and means of recording the donor election in DEERS will provide the primary mechanism for recording intent to donate for research purposes. There will be an approved human research protocol that has been reviewed by an appropriately constituted human research protections body. NOK 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 DoD Organ and Tissue Donation Committee and coordinated with DEERS to be implemented.
- f. There is no prohibition against Service members executing a declaration of intent, while they are alive, to donate organs or tissues after their death, under the UAGA (Reference (v)) and State laws that implement UAGA.

- g. Active Duty and Reserve Component Service Members as Donors (Living): Service members may serve as living donors. When donation involves required absence from duty for more than one day or may negatively impact a Service member's fitness for AD or future deployability, procedures outlined in reference (d) will be followed in addition to the following:
- (1) The Service member's local chain of command, along with the office of the respective Surgeon General or Reserve Component commander, must approve the Service member's request to donate organs, tissues, or bone marrow to avoid any negative impact on mission.
 - (2) Clinical and administrative process for Service members must include the following:
- (a) Evaluation by their Primary Care provider before and six weeks after donation, to assess the Service member's fitness for duty, in accordance with the living donor member's Military Department applicable policy.
- (b) Counseling in writing prior to becoming a living donor by their immediate commander with follow-on counseling by a medical officer, preferably an internist, who can review preliminary results as well. The counseling sessions must ensure the Service member understands any surgery or procedure, including organ or tissue donation, may result in the member being found unfit for duty and impact continued service.
- (3) Evaluation of living donor patients for organ or tissue transplantation are performed by medical providers who coordinate with either military or non-military transplant centers in compliance with UNOS standards.
- (4) Request packages must be encrypted when delivered electronically (see appendix 4) and include:
- (a) Prospective donor name, rank, grade, DoD ID, work phone, home phone, military unit, and location.
 - (b) Recipient's name and relationship to donor, if known or available.
 - (c) Recipient's primary diagnosis and prognosis, if known or available.
 - (d) Recipient's physician and place of transplant, if known or available.
- (e) Signed statement from prospective donor that provides acknowledgement of (see appendix 2):
 - 1. Counseling by a medical provider.
- <u>2.</u> Costs for services associated with a transplant performed in a private sector facility are not the responsibility of DoD unless the recipient is a TRICARE beneficiary.

- 3. Understanding of follow-up medical evaluations by a nephrologist, hepatologist, hematologist/oncologist, or Primary Care provider will be completed 6 to 12 months after donation. The evaluation must include a routine medical examination and labs. UNOS requires living donors to be followed for a specified period of time, usually two years. The center that performed the operation should report this data.
- (f) A complete history and physical examination evaluation report using DD Form 2808, Report of Medical Examination, and DD Form 2807-1, Report of Medical History.
- (g) Diagnostic testing: human immunodeficiency virus, hepatitis B and C, urinalysis, complete blood count, blood urine nitrogen, creatinine, serum electrolytes, fasting glucose, and blood type with compatibility testing (to be performed at transplant institution). Liver donors must include record of liver function tests; if over 45 years of age, cardiac risk assessment is needed, preferably including a graded exercise test.
 - (h) Signed statement from the unit commander approving the donation request.
- (i) Signed statement from attending physician associated with the transplant facility providing the recipient's diagnosis, prognosis, and verification that no other donor is available.
 - (j) Name and address of intended operating facility.
- (k) An organ donor label or ID must be placed in the EHR or on the physical record jacket alerting both physicians and nursing staff that patient is an organ donor.
 - (1) Name and signature of translator should be included if used.
- (5) Service members approved for organ donation will be placed on convalescent leave IAW MILDEP policy. Convalescent leave must be approved by the member's unit commander, commanding officer, or officer in charge. Any absence from duty before hospital admission not associated with the living donation program processes will be charged as regular leave.
- (6) After an organ donation in a private sector medical facility, Service members will be required to be medically evaluated immediately upon discharge by DHA providers. The purpose of this evaluation is to determine future profile, assignments, and qualification for continued service.
- (7) There is no requirement that a solid organ donor be separated from the Military Department or denied the opportunity to reenlist. The donation of a kidney or partial liver, without complications and resulting in normal functioning of the remaining kidney or partial liver, normally would cause no disruption in the career of the Service member.
- (8) Each Military Department has restrictions placed on certain career fields associated with donating, past donation, or reception of an organ; however, waivers for accession into the military or specific career field can be considered where process exists for waivers to be granted.

Specialists may evaluate members who have donated an organ, are considering donation, or who have received an organ, on a case-by-case basis.

h. Other DoD beneficiaries' participation as living donors is governed by applicable law.

2. LOGISTICAL SUPPORT

- a. Education and training about organ and tissue donation is to be facilitated by the MTF leadership in coordination with the local OPO. MTF leadership will ensure appropriate training will be provided to medical personnel and logistical support personnel to ease the procedures for organ and tissue donation activities under garrison conditions and, to the extent possible, under operational conditions. Under garrison conditions, this training should involve local hospital-affiliated OPO participation. Training must include when to call the OPO about a potential donor, how to respect sensitivities of potential donor families, the concept of "donor designation," and in general, it is best to defer to the professional OPO coordinators when approaching the families.
- b. Medical logistical activities will support an effective organ and tissue donation program as much as possible without jeopardizing operational requirements.
- c. The MHS will participate with the Organ Procurement and Transplantation Network (OPTN) established in accordance with Reference (r) that facilitates and coordinates the donation, recovery, allocation, and distribution of organs and tissues.
- d. Walter Reed National Military Medical Center has the DHA Transplant Service that complies with all applicable laws and transplants organs (typically kidneys) into MHS-affiliated beneficiaries who are on the national organ transplant registry. This organ transplant program is colloquially called the "Military Share Program." Such transplants occur only after the local OPO notifies the DHA Transplant Service that a donor or donor family made a directed donation to a specific MHS-affiliated beneficiary who is on the national organ transplant registry. The policy of the Organ Procurement and Transplant Network (OPTN), operated by the United Network for Organ Sharing (UNOS), recognizes directed donation as long as the agencies involved take steps to verify the medical suitability of the organ offered for the specific recipient, which occurs at the DHA Transplant Service. Further, the OPTN provided that the directed donation practice is legally authorized by the Uniform Anatomical Gift Act (UAGA) and by most state anatomical gift laws, which use the UAGA as a guide. The OPO takes credit for a directed donation upon all statistical reports to UNOS, as well as any others as required. The DHA Transplant Service assumes responsibility of standard acquisition charges for retrieval of the kidney and/or other organs that the OPO makes available to the DHA Transplant Service. DHA Transplant Service personnel perform all required evaluation before performing any transplant, and they comply with all applicable OPTN policies and procedures. All MHS beneficiaries may voluntarily elect to direct such a donation including participation in deceased donor-initiated transplant chains for incompatible living donor/recipient pairs. Contact Information is below:

DHA Transplant Service at Walter Reed National Military Medical Center (WRNMMC) WRNMMC
8901 Wisconsin Avenue
Bethesda, MD 20814
(301) 295-4331
email to:dha.bethesda.wrnmmc.mbx.organ-transplant@health.mil

- d. DHA-incurred retrieval costs for organs or tissues accepted for transplantation to non-DoD beneficiaries will be reimbursed by either the OPO or the transplanting institution. Reimbursement for these costs should be made payable to the MTF through the U.S. Treasury in which the organ and/or tissue donation occurred.
- e. Each inpatient MTF (or MTF with inpatient services) will have an appropriate MOA between the MTF and the local OPO. MTFs are required to use the template sample MOA that is included in Appendix 3 of this DHA-PI with modifications for state or country requirement.

3. MTF RESPONSIBILITIES

- a. MTFs will comply with guidelines of The Joint Commission (TJC) safety standards (see Reference (u)), documentation requirements, and education standards on recovering and donating organs, eyes, and other tissues. MTFs must also adhere to the following TJC standards to include, but not limited to: developing and implementing written policies and procedures for donating and procuring organs and tissues, complying with organ transplantation responsibilities, using standardized procedures for managing tissues, tracing all tissues bi-directionally, and investigating adverse events related to tissue use or donor infections.
- b. MTFs will develop a process that includes the Patient Administration Department to validate the most current organ donor status is reflected in the electronic medical record.
- c. MTFs will comply with References (i), (j), (k), (m), (n), (q) and procedures related to uses and disclosures of protected health information concerning transplantation.
- d. MTF staff will coordinate with the local OPO to provide informational materials explaining tissue donation and will establish reasonable methods for DoD beneficiaries to complete and carry a DD Form 2731, Organ and Tissue Donor Card.
- e. Inpatient MTFs will participate in the Congressionally-established OPTN and adhere to its policies that facilitate and coordinate organ and tissue donation, recovery of donated organs and tissues, and matching of donors and recipients through establishment of an MOA with the local OPO. Annual review of the MOA should be encouraged to reflect possible status and military instruction changes.
- f. All inpatient MTFs will maintain MOAs between the MTF and local OPO to provide organ and tissue procurement services, as well as assist with education of personnel and beneficiaries

regarding organ and tissue donation. All MOAs must receive legal review by the servicing DHA Office of General Counsel attorney before signature.

- g. Inpatient MTFs will enter into Institutional Review Board (IRB) review or like agreements with non-DoD institutions for which organ and/or tissue donation may be used in research.
- h. Inpatient MTFs 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 staff regarding which donors or potential donors should warrant a call to the OPO.
- i. If a patient dies while undergoing evaluation or treatment at an inpatient MTF, the Patient Administration Department will make an attempt to determine the organ donation status of the deceased individual within DEERS and coordinate further action with the appropriate donation service within geographical area. In the case of difference between sources regarding organ donation status, the most recent designated desire will take precedence, in accordance with Reference (d).
- j. Inpatient MHS facilities, which are not required to report a death to the local OPO, may do so, upon the request of the family or patient, as long as the request to be an organ or tissue donor is in writing prior to death.
 - k. All organ allocation and procurement must be coordinated through the OPO.
- 1. At or near the time of death, or recognition of potential for organ and/or tissue donation, the OPO will be immediately contacted by the attending physician for evaluation and determination of type(s) of donation possible for the patient, assuming the patient intended to be a donor. Contact is documented on the consent form for donation and/or in progress notes.
- (1) Scenarios which may prompt such contact include, but are not limited to: Glasgow Coma Scale of five or less, or equivalent measure of patient's grave neurological status; orders of discontinued resuscitation; or pronouncement of death.
- (2) Information that may be requested on initial call to OPO includes the following: patient's name, demographics, admitting diagnosis and cause of death, name of healthcare organization, full name of person making referral call and phone number, name of patient's registered nurse with phone number for return call, and attending physician's name.
- (3) Information that may be requested on follow-up call to OPO includes the following: past medical history, cultures, white blood cell count, temperature, height/weight, and fluid estimate.
- (4) In the event the OPO identifies the organ donor is unsuitable for transplantation, documentation will include: name of OPO staff determining incompatibility, reason for donation rejection, and closure of donation case in medical record.

- m. The attending physician is responsible for making the determination of death and for notifying the NOK concerning the patient's death, except in cases of an AD death in which contact is made by the Casualty Assistance Calls Officer (CACO)/Casualty Assistance Office (CAO), or Military Department equivalent.
- n. MTF will notify AFMES of all deaths that occur at any DHA MTFs under federal jurisdiction, to include civilian and non-beneficiary deaths. For deaths that occur outside federal jurisdiction, notify the local medicolegal authority. Consult the local servicing DHA Office of General Counsel and law enforcement entities for information and guidance regarding jurisdictional issues, as needed.
- o. The OPO's procurement team coordinator or appropriate staff member must initially contact the CACO/CAO or Military Department equivalent for all deceased Service members, if the NOK is not already available at the MTF or private sector hospital where the deceased is located. This ensures the NOK, who was not present at the hospital at the time of death, is notified properly by a representative of the CACO/CAO before organ or tissue donation is solicited. A member of the local OPO must then contact the NOK to request approval of donation of organs or tissues from the deceased patient. NOK authorization of an organ or tissue gift from the deceased patient must be made either by a document signed by the NOK or by telegraphic, recorded telephonic, or other recorded message. Consent to record the NOK's telephonic or other recorded authorization must be obtained before recording. If the individual's donor designation is unknown, a member of the local OPO must then contact the NOK to request approval of donation of organs or tissues from the deceased patient.
- p. Organ and tissue donation must be discussed with NOK in every death in inpatient MTFs, unless the potential donor is determined to be medically unsuitable by the OPO, or if the patient previously elected "No" to participation as a donor. Discussion of donation must be initiated by the OPO and subsequent consent obtained by the OPO personnel.
- q. The OPO procurement team coordinator, attending physician, or appropriate staff member must ensure the DEERS database is queried and the medical record is reviewed to determine whether the deceased made his or her wishes known concerning organ or tissue donation. If the deceased was over the age of majority, which for purposes of this DHA-PI is 18 years of age, did wish to donate organs or tissues, and the wish was stated either orally or in writing, this desire must be honored, even if it is in conflict with the wishes of the NOK.
- r. If the OPO cannot use the organ(s) or tissue removed, the OPO must dispose of them in a humane and dignified manner.
 - s. The OPOs Organ and Tissue Procurement Team:
- (1) The procurement team coordinator must be responsible for training members of the organ and tissue procurement teams.
- (2) Members of the organ and tissue procurement team must be available on 24 hours a day, 7 days a week basis.

- (3) The organ and tissue procurement team must be responsible for all aspects of the surgical removal of donated organs and tissues at the inpatient MTF. This may include the need to sustain deceased donor patients.
- (4) To avoid conflict of interest between the healthcare team caring for the patient and the organ procurement team, the MTF's attending physician or any other healthcare personnel directly involved in patient care cannot be part of the organ procurement team and/or participate in procedures for removing or transplanting organs and tissues.
- t. A MOA with the local OPO must require the inpatient MTF, in association with the OPO, to maintain a listing of patients who die in the MTF and must record the results of action taken to secure the donation of organs or tissues from each patient who dies. All inpatient MTFs will maintain their own listing. Death chart review statistics will be made available to the MTF leadership to determine level of compliance with this instruction.
- u. Gifts of organs and tissues in the continental United States, Alaska, Hawaii, or a U.S. territory will be made following the laws of the state or territory where the gift is made, when not in conflict with federal law and DoD policy. If the gift is made in a foreign country outside the continental United States, such gift will follow the UAGA (Reference (v)), unless it is in violation of an international agreement or host nation law, in which case the latter will apply.

4. AFMES RESPONSIBILITIES. The AFMES will:

- a. Review and approve requests for organ and tissue donation for deaths that fall under the federal jurisdiction of AFMES. For deaths under AFMES jurisdiction, AFMES has the final authority to either grant or deny permission for organ or tissue recovery.
- b. Ensure that all medical and forensic requirements necessary to complete the necessary investigations are met for the AFMES cases approved for organ and tissue donation.
- c. Provide any information required to a procuring OPO, in accordance with References (m) and (n), when requested and when procurement documentation is 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. 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.

5. <u>ASSISTANCE FOR ORGAN TRANSPLANT RECIPIENTS AND FAMILY AT</u> WRNMMC REGARDING THE DHA TRANSPLANT SERVICE

a. <u>Administrative and Logistical Assistance</u>. Administrative and logistical assistance is available for organ transplant recipients and their families. While clinical considerations remain of primary importance, the DHA Transplant Service must make every effort to provide administrative and logistical assistance in such matters as: transportation, temporary housing,

reassignment when necessary, coordination for follow-up clinical evaluation, and possible interface with an appropriate Military Department Relief Society representative.

- b. <u>Dual/Multiple Listing for Organ Transplantation</u>. UNOS policy allows for multiple listing with registering at two or more transplant facilities including the DHA Transplant Service. Multiple listing may increase the probability of successful organ transplant match and reduce the length of wait time.
- 6. DHA DIRECT REPORTING MARKETS, HAWAII MARKET, SSO, AND DHAR DIRECTORS' ANNUAL REPORTING REQUIREMENTS. DHA Direct Reporting Markets, Hawaii Market, SSO, and DHAR Directors will report the following compliance metrics on an annual basis to DAD-MA by 15 February:
 - a. Approved and current MOA for all inpatient MTFs with local OPO (see Appendix 3)
- b. Completion of annual training to inpatient MTF staff about organ and tissue donation process.
- 7. <u>DHA TRANSPLANT SERVICE AT WRNMMC REPORTING REQUIREMENTS.</u> The DHA Transplant Service at WRNMMC will report on an annual basis to DAD-MA by 15 February an annual summary of the number of completed organ transplants.

APPENDIX 1

CONTACT INFORMATION

Armed Forces Medical Examiner System (AFMES)

https://www.health.mil/Military-Health-Topics/Research-and-Innovation/Armed-Forces-

Medical-Examiner-System/Armed-Forces-Medical-Examiner

115 Purple Heart Drive

Dover Air Force Base, DE 19902

(302) 346-8648 (During Duty Hours)

(202) 409-6811 (After Duty Hours)

usarmy.dover.medcom-afmes.mbx.operations@health.mil

DHA Transplant Service at Walter Reed National Military Medical Center (WRNMMC)

WRNMMC

8901 Wisconsin Avenue

Bethesda, MD 20814

(301) 295-4331

dha.bethesda.wrnmmc.mbx.organ-transplant@health.mil

United Network for Organ Sharing (UNOS)

https://unos.org

700 N. 4th Street

Richmond, VA 23219

(804) 782-4800

Organ Procurement and Transplantation Network (OPTN)

https://optn.transplant.hrsa.gov

Post Office Box 2484

Richmond, VA 23218

Department of the Navy

BUMED-M3, Healthcare Operations

Navy Blood Program Office

7700 Arlington Blvd, Falls Church, VA 22042

703-681-5541/5565

usn.ncr.bumedfchva.mbx.bumed-general-inquiries@health.mil

Chief Medical Consultant to the AF/SG

usaf.pentagon.afmra.mbx.afsg3xr@health.mil

Air Force Medical Readiness Agency

7700 Arlington Blvd

Falls Church, VA

The Surgeon General of the Army 7700 Arlington Blvd, Falls Church, VA 22042 JB San Antonio MEDCOM Mailbox Army SHCP: usarmy.jbsa.medcom.mbx.army.shcp@health.mil

Defense Health Agency, Medical Affairs Directorate Clinical Support Division, Specialty Care Support 7700 Arlington Blvd, Falls Church, VA 22042 dha.ncr.j-3.mbx.ccps-tasks@health.mil

APPENDIX 2

REQUIRED FORMS AND TEMPLATES REQUEST TO DONATE

Date

From: Rank and name of donor, name and address of donor's command

To: MILDEP SG or designee

Via: (1) (Rank and name of donor's immediate supervisor, name and address of donor's command)

(2) Commanding Officer, name and address of donor's

Subject: REQUEST TO BE A LIVING DONOR

Enclosure: (1) DD Form 2807-1, Report of Medical History or the equivalent in the electronic health record (EHR)

- (2) DD Form 2808, Report of Medical Examination or State equivalent in EHR
- (3) Attending Physician Statement
- (4) Test results
- (5) Transplant Clinic Points(s) of Contact
- 1. I request authorization to be a living organ donor. Specifically, I wish to donate (name of tissue, organ, stem cells or bone marrow). All donor options have been explored and my donation is the recipient's only option. Enclosures (1) through (5) provide supporting documentation.
- 2. The intended recipient for this donation is (recipient name) and relationship is (relationship to the donor).
- 3. I understand and accept that the Department of Defense is not responsible for any costs associated with the transplant performed by (name of transplant/ collection facility). Furthermore, I understand and have been counseled by my medical provider or treating medical staff on the risks of donating (name of organ, tissue, stem cells or bone marrow). This includes, but is not limited to, a follow-up appointment with my Primary Care physician or command medical staff and the medical staff from the facility that collects and performs the donor transplant. This responsibility may include several follow-up appointments with a military medical physician/internist between 6 and 12 months post-surgery/collection.
- 4. Required tests have been completed and are included in this package to ensure the health and safety of myself and the recipient of my donation.

REQUEST TO DONATE (CONTINUED)

- 5. I have met with my healthcare provider to ensure I am competent, emotionally stable, and in good health to donate my (name of organ, tissue, stem cells or bone marrow). I fully understand the risks involved and freely wish to donate my (name of organ, tissue, stem cells or bone marrow).
- 6. I understand that I must be seen by my Primary Care provider before and six weeks after the donation to assess my fitness for duty. Further, I understand that any surgery, including organ donation, may result in me being found unfit for duty and impact continued service.
- 7. Please contact me with questions at (donor's work/cell phone numbers) and (e-mail address).

Donor's Signature Donor's First, Last Name (Typed)

DONOR ENDORSEMENT

Date

FIRST ENDORSEMENT on (rank and name of prospective donor) letter of (date of donor's letter)

From: (Rank and name of donor's immediate supervisor, name and address of donor's command)

To: MILDEP SG or designee

Via: (1) Commanding Officer, (name and address of donor's command)

Subject: REQUEST TO BE A LIVING DONOR

- 1. Forwarded recommending approval.
- 2. (Rank and name of donor) living donor request has been considered by this command and found to be a reasonable request. Based on the medical information provided, the Service member appears to be best suited to be a donor for the intended recipient. I and (rank and name of donor) understand medical consequences resulting from this donation could adversely affect the ability to continue on AD (or Reserve Duty). After reviewing all the facts, my recommendation is to allow (rank and name of donor) to donate (name of tissue, organ).
- 3. (Rank and name of donor) has been counseled and found to be both competent and knowledgeable regarding the risks involved with the donation and requirements for post-surgery/collection care.
- 4. The office of the respective Surgeon General or Reserve Component commander must approve the surgery to proceed.
- 5. Recommend approval of (rank and name of donor) to be a living donor of (name of tissue or organ).

Donor's Chain of Command Signature Chain of Command First and Last Name (Typed)

APPENDIX 3

MEMORANDUM OF AGREEMENT BETWEEN

(NAME OF INPATIENT DONOR MILITARY MEDICAL TREATMENT FACILITY) AND

(NAME OF CIVILIAN ORGAN PROCUREMENT ORGANIZATION) FOR ORGAN/TISSUE DONATIONS

This is a [select: new or amended] memorandum of agreement (MOA) between **DONOR MILITARY MEDICAL TREATMENT FACILITY (MTF)** located in **CITY, STATE**, and **ORGAN PROCUREMENT ORGANIZATION (OPO)** located in **CITY, STATE**. When referred to collectively, the OPO and the donor MTF are referred to as the "Parties."

1. BACKGROUND: This agreement is intended to increase the number of organs available for patients awaiting transplantation in civilian institutions and to ensure the rights of military families to pursue the right to donate organs upon death of a loved one if they so choose.

2. AUTHORITIES:

- a. DoD Instruction 4000.19, "Support Agreements," December 16, 2020
- b. DoD Instruction 6465.03, "Anatomic Gifts and Tissue Donation," June 8, 2016
- c. DoD Manual 6025.18, "Implementation of the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule in DoD Health Care Programs," March 13, 2019
- d. Defense Health Agency-Procedural Instruction 6465.01, "Anatomic Gifts and Tissue Donation," [insert this publication date]
- 3. PURPOSE AND SCOPE: The purpose of this agreement is for the Parties to establish mutually agreeable term and a cooperative program for the recovery of cadaveric organs and tissues amenable for transplantation from DoD beneficiaries and civilian employees who die at a donor MTF.

4. RESPONSIBILITIES OF THE PARTIES:

4.1. The donor MTF will—

4.1.1. Increase medical facility and installation awareness of the donor program to encourage growth by providing information materials to patients and staff to explain organ and tissue donation.

- 4.1.2. Collaborate with the Organ Procurement Organization (OPO) in development of standard operating procedures to establish efficient mechanisms for the success of this organ transplant mission. These include, but are not restricted to: public and professional education; potential donor surveillance; identification and referral; donor management; organ and tissue procurement; distribution of organs and tissues; and chart reviews.
- 4.1.3. In compliance with CMS interpretive guidelines for 42 CFR Section 482.45, MTF is not required to perform formal credentialing reviews for, or grant privileges to, members of OPO recovery teams as long as OPO sends only qualified, trained individuals to perform the organ recovery.
- 4.1.4. Provide basic laboratory support and other ancillary support necessary for the evaluation of potential donors to the extent that such support does not jeopardize the operational requirements of the donor MTF as determined by that facilities' Director.
- 4.1.5. Provide information materials to patients and staff to explain organ and tissue donation.
- 4.1.6. Provide organ donor indicators. It is DoD policy that all DoD beneficiaries, 18 years of age or older, are also given the opportunity to elect to be organ and tissue donors. These beneficiaries may elect to be organ and tissue donors when obtaining a Uniformed Services Identification card and enrolling in the Defense Enrollment Eligibility Reporting System (DEERS).
- 4.1.7. Attempt to notify the legally authorized representative that death was declared. Contact Casualty Affairs or comparable office for all deceased DoD beneficiary donors if the legally authorized representative is not at the donor military medical treatment facility (MTF) where the deceased is located. This enables Casualty Affairs to properly notify the legally authorized representative of the death before organ or tissue donation is solicited by the OPO. Casualty Affairs will not discuss donation, but only that death has occurred. The donor MTF or Casualty Affairs will then notify the OPO to proceed with consent. Telephonic consent is acceptable and should be appropriately documented. [Add appropriate telephone number/contact information]
- 4.1.8. Provide OPO with timely notification of all cardiac deaths (controlled and uncontrolled) and brain deaths. The determination of brain death or cardiac death donor is the responsibility of the attending physician and will follow donor MTF policy. The members of the OPO will not be responsible for completion of the usual and customary death paperwork completed at the donor MTF.
- 4.1.8.1. Timely notification is defined as within one hour of the time of a patient's uncontrolled cardiac death; or within one half hour of determining death is imminent as defined in 4.1.8.2.
- 4.1.8.2. A patient meeting imminent death criteria is defined as: a patient who is severely brain injured; on a ventilator with a Glasgow Coma Scale less than or equal to five; all cases

involving a severely brain injured patient; prior to the withdrawal of ventilator support; initiation of brain death examination(s); or de-escalation of medical care.

- 4.1.9. Determine the policy for brain death and keep the file for review by the OPO as is customary at private sector institutions. The determination of death will be confirmed by the OPO prior to proceeding with organ/tissue procurement.
 - 4.1.10. Not participate in the organ and tissue donation consent process.
- 4.1.11. Record the tissue donation election information in electronic systems for DoD beneficiaries.
- 4.1.12. Encourage, without coercion, all Service members, other DoD beneficiaries, and civilian employees of the DoD/Uniformed Services to donate organs and tissue.
- 4.1.13. Maintain a listing of patients who die and record the results of the action taken to secure donation of the organs and tissue.
 - 4.1.14. Notify the legally authorized representative that death was declared.
 - 4.1.15. Comply with The Joint Commission (TJC) guidelines.
- 4.1.16. Coordinate and work with the OPO to arrange for transportation of the organ or tissue and recovery teams.
- 4.1.17. Make medical records and reports available to the OPO in accordance with DoD Manual 6025.18, for the purpose of allowing the OPO to carry out its duties. In particular, records should be available so the OPO may evaluate and manage potential donors and validate the circumstances surrounding the donor's illness and terminal course.
- 4.1.18. For patients who have died or who meet the criteria of imminent death, search for information identifying whether the individual is a donor, as soon as practical after admission to the donor MTF, in accordance with the responsibilities as outlined in State law, when State law is consistent with federal law and DoD policy.
- 4.1.19. Facilitate communication between the OPO Coordinator and the donor candidate's legally authorized representative to ensure the donation option can be provided, following verification by the OPO that a donation option exists.
- 4.1.20. Develop a donor billing mechanism, which will identify any cost incurred during donor evaluation and management to include organ procurement, which can be billed to the OPO.
- 4.1.21. Ensure organ and tissue donation is discussed with Next of Kin (NOK) in every death unless the potential donor is determined to be medically unsuitable by the OPO or if the

patient previously elected not to participate as a donor. The discussion of donation must be initiated by the OPO and subsequent consent obtained by the OPO personnel.

4.1.22. Notify the OPO immediately of adverse events that would indicate the donor may have had a transmissible disease that could impact the morbidity or mortality of recipients of other organs or tissues from the same donor.

4.2. The OPO will:

- 4.2.1. Provide consultative services, instructional programs, and educational materials for the donor MTF personnel and others to aid the donor MTF in its responsibilities. Assure this includes necessary training in accordance with federal law, DoD policy, and State laws that are consistent with federal law and DoD policy, regulations, and rules for the donor MTF representatives and staff on dealing with donor NOK and obtaining consent for organ and tissue donation. The training should include respect for sensitivities of potential donors, NOK, and circumstances where the discussion of donation is warranted.
- 4.2.2. Provide credentialing and privileging information about physicians and other practitioners of OPO team(s) that perform organ recovery from a donor upon request within a reasonable timeframe. Will be responsible for ensuring required credentialing records for OPO team(s) are completed and current.
- 4.2.3. Notify the donor MTF of any OPO policy changes that affect recovery, perfusion, or transport.
- 4.2.4. Maintain a 24-hour telephone referral number/point of contact for all potential organ or tissue donors by the donor MTF.
- 4.2.5. Determine the medical suitability for donation and transplantation of donors who are referred to the OPO by the donor MTF for evaluation.
- 4.2.6. Ensure OPO coordination staff manages the donor using the consultative advice from the attending physician. Beforehand, and at no cost to the donor MTF, identify any need to procure and provide a neurologist for the determination of brain death and/or an individual trained in determining brain death, in the event that they are not available at the donor MTF.
- 4.2.7. Screen potential donors for infectious or malignant transmission risk. The screening process will include a medical and social history, physical, necessary laboratory testing, and imaging in accordance with current donor management standards of care. This is to limit the possibility of disease transmission. Diseases include, but are not limited to, human immunodeficiency virus, hepatitis, syphilis, Epstein-Barr virus, cytomegalovirus, and rabies. Report the result of the testing to the appropriate authorities. The OPO has the responsibility of determining the quality of the organs/tissue.
- 4.2.8. Coordinate and/or assist in the recovery of donated organs and/or tissues, and their preservation and transportation as required.

- 4.2.9. To comply with federal law, request clearance from the Armed Forces Medical Examiner via telephone (302-346-8648) for donors who have been deployed to combat zones prior to organ recovery.
- 4.2.10. Provide appropriate follow-up information in a timely fashion regarding the eventual disposition of donated organs and tissues to nursing staff, physicians, and other appropriate health care providers involved in the donor process, and to the family of the deceased unless specifically notified by the NOK that they do not wish follow-up.
- 4.2.11. Provide confidential Performance Improvement Record Reviews (PIRR) of medical records monthly to ensure compliance with state and federal law as well as the standards of TJC. The OPO will submit results to the donor MTF by the last day of the following month. The donor MTF will grant OPO personnel access to the medical records of the deceased patients for the purpose of determining imminent and eligible donors in a form consistent with PIRR.
- 4.2.12. Maintain confidentiality of all information obtained from the medical records and reports.
 - 4.2.13. Provide the donor MTF a monthly report of organ referral activity.
- 4.2.14. Agree to reimburse the donor MTF for the charges it incurs from the time that consent is obtained, and donor suitability is determined. This includes a period of postmortem observation, intensive care unit charges, as well as charges related to the excision of tissues, procurement and initial preservation of excised organs, provided the OPO has given prior approval.
- 4.2.15. Maintain a listing of patients who die in the donor MTF and record the results of actions taken to secure the donation of tissue from these patients.
- 4.2.16. Be aware the OPO is prohibited from providing DoD beneficiary-donated organs and tissues to any receiving civilian procurement agency that would sell the DoD beneficiary donated organs and tissue for profit.
- 4.2.17. Ensure procurement surgeons, whose credentials are verified, perform organ recovery. The OPO will handle certification and credentialing of recovery teams. Recovery teams may sustain organ function of a deceased donor in order to perform an actual surgical recovery of donation.

4.3. The Parties will—

4.3.1. Ensure consent for organ and tissue donation in accordance with applicable federal law, DoD policy (DoD Instruction 6465.03), and State law that is consistent with federal law and DoD policy. When a patient whose elections regarding organ or tissue donation are unknown dies, permission of the legally authorized representative (e.g., NOK) will be sought and honored. Authorization by the legally authorized representative may be made by a signed document, or by telegraphic, recorded telephonic, or other recorded message.

- 4.3.2. Ensure approval for organ retrieval by the county medical examiner or appropriate coroner with jurisdiction will be obtained by a representative from the OPO or from the donor MTF in those cases which come under the jurisdiction of the medical examiner/coroner and that such permission must be documented in the medical record of the potential donor. If an autopsy is done, the parties will work to get the results to the OPO.
- 4.3.3. Ensure surgical removal of the cadaveric organs and tissues be performed by an individual trained, credentialed, and with experience in organ and/or tissue retrieval for transplantation. The attending physician or other health care providers directly involved in the care of the patient will not participate in procedures for recovering or transplanting the donated organs or tissue.
- 4.3.4. Ensure each Party is insured for professional liability for services and activities performed under this MOA, which covers its directors, officers, and employees providing services hereunder. Such coverage must survive the life of the MOA for so long as there exists professional liability exposure for incidents which occur during the term of this Agreement.
- 4.3.5. Ensure gifts of organs and tissues are handled in in accordance with the law of the state where the gift is made.
- 5. PERSONNEL: Each Party is responsible for all costs of its personnel, including pay, benefits, support, and travel, if applicable to the MOA. Each Party is responsible for supervision and management of its personnel.
- 5.1. Ensure DHA Organ Transplant Service be comprised of personnel assigned or attached to, and under the direction, supervision, and responsibility of Chief, DHA Organ Transplant Service at Walter Reed National Military Medical Center.
- 5.2. Ensure the OPO is comprised of personnel attached to, and under the direction, supervision, and responsibility of the Director of Organ Procurement Agency, OPO.
- 5.3. Ensure the donor MTF is comprised of personnel attached to, and under the direction, supervision, and responsibility of the MTF Director or MTF Director's designee.
- 6. HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT (HIPAA): The DoD covered entity may use or disclose protected health information (PHI) to OPO or other entities engaged in the procurement, banking, or transplantation of cadaveric organs, eyes, or tissues for the purpose of facilitating organ, eye, or tissue donation and transplantation in compliance with reference (n). This allows for the release of information by and to, donor hospitals, transplant hospitals, United Network for Organ Sharing, tissue and eye banks, and laboratories.

7. GENERAL PROVISIONS:

7.1. POINTS OF CONTACT (POCs). The following POCs will be used by the Parties to communicate matters concerning this MOA. Each Party may change its POC upon reasonable notice to the other Party.

7.1.1. For the **DONOR MTF**—

- 7.1.1.1. Position, office identification, phone number, and email of primary POC:
- 7.1.1.2. Position, office identification, phone number, and email of alternate POC:

7.1.2. For the **OPO**—

- 7.1.2.1. Position, office identification, phone number, and email of primary POC:
- 7.1.2.2. Position, office identification, phone number, and email of alternate POC:
- 7.2. CORRESPONDENCE. All correspondences and notices pursuant to this MOA must be addressed, if to the **DONOR MTF**, to—
- 7.2.1. [insert mailing address] and, if to the **OPO**, to—
- 7.2.2. [insert mailing address] or as may from time to time otherwise be directed by the Parties.
- 7.3. REVIEW OF AGREEMENT. The Parties will review the agreement annually on or around the anniversary date for financial impacts, and triennially in its entirety.
- 7.4. MODIFICATION OF AGREEMENT. This MOA may only be modified by the written agreement of the Parties, duly signed by their authorized representatives. Re-evaluation and renegotiation of the provisions of this MOA may be initiated by any participant at any time and will be effective upon the signed approval of the addendum by all participants.
- 7.5. DISPUTES. Any dispute relating to this MOA will, subject to any applicable law, Executive Order, or regulatory guidance, be resolved by consultation between the Parties.
- 7.6. TERMINATION OF AGREEMENT. This MOA may be immediately terminated when required by law or in the event of mobilization of forces. The donor MTF and the OPO reserve the right to terminate this MOA without cause upon written notice of not less than **90 days** to the other parties.
- 7.7. TRANSFERABILITY. This MOA is not transferable except with the written consent of the Parties.

- 7.8. ENTIRE AGREEMENT. It is expressly understood and agreed that this MOA embodies the entire agreement between the Parties regarding the MOA's subject matter, thereby merging and superseding all prior agreements and representations by the Parties with respect to such subject matter.
- 7.9. EFFECTIVE DATE. The term of this MOA will commence on the date of the last signature. It is for 10 years unless amended or rescinded in writing.
- 7.10. EXPIRATION DATE. This MOA expires on [INSERT DATE NOT LONGER THAN 10 YEARS PER DOD Regulation].
- 7.11. CANCELLATION OR MODIFICATION OF PREVIOUS AGREEMENT. This MOA cancels and supersedes the one previously entered into between the Parties, effective [INSERT DATE].
- 7.12. NO THIRD PARTY BENEFICIARIES. Nothing in this MOA, express or implied, is intended to give to, or will be construed to confer upon, any person or entity not a party any remedy or claim under or by reason of this MOA and this MOA will be for the sole and exclusive benefit of the Parties.
- 7.13. SEVERABILITY. If any term, provision, or condition of this MOA is held to be invalid, void, or unenforceable by a governmental authority and such holding is not or cannot be appealed further, then such invalid, void, or unenforceable term, provision, or condition will be deemed severed from this MOA and all remaining terms, provisions, and conditions of this MOA will continue in full force and effect. The Parties will endeavor in good faith to replace such invalid, void, or unenforceable term, provision, or condition with valid and enforceable terms, provisions, or conditions which achieve the purpose intended by the Parties to the greatest extent permitted by law.
- 7.14. OTHER FEDERAL AGENCIES. This MOA does not bind any federal agency, other than the Parties, nor waive required compliance with any law or regulation.

8. FINANCIAL DETAILS:

- 8.1. Costs associated for organs or tissues accepted for transplantation to non-DoD beneficiaries that are incurred by donor MTF will be (reimbursed) by either the OPO or the transplanting institutions. Other than those instances described, any resource requirements (funding, personnel, supplies, equipment, etc.) associated with this MOA will be executed within available funding allocations and programmed funding of the parties. If these conditions should change, the MOA will be formally amended prior to.
- 8.2. The obligation of funds by the Parties, resulting from this MOA, is subject to the availability of funds pursuant to the DoD Financial Management Regulation. No provision in this MOA will be interpreted to require obligation or payment of funds by any DoD entity in violation of the Anti-Deficiency Act, Section 1341 of Title 31, United States Code.

9. ADDITIONAL RESOURCES:

9.1. Organ Procurement and Transplantation Network (OPTN) policies as identified at the following web location: https://optn.transplant.hrsa.gov/media/eavh5bf3/optn_policies.pdf OPTN Policy 1.5, DoD Directive. Note: Until such time as the OPTN and the DoD reach a mutual understanding on organ allocation policies, Members may cooperate with U.S. military facilities that are bound by the U.S. DoD organ allocation directives that conflict with OPTN policies; however, the OPTN neither agrees with nor endorses present DoD Directives.

For the OPO —
Signature
Name and Title of Signatory
(Date)
[Enter date mid-point review due]
Signature and Name of Reviewer

APPENDIX 4

CHECKLIST FOR SCREENING LIVING DONOR SERVICE MEMBERS

	Written request from Service member to be a living organ donor in a military or civilian
	hospital, stating the donor has been counseled and accepts the risk(s) of donation.
	Prospective donor's name, rank, military identification number, home and work phone, and
	unit address/phone/fax.
	Statement signed by Service member acknowledging that the military is not responsible for
	any costs associated with a transplant performed in a private sector institution, except when
	the recipient is a TRICARE beneficiary, in which case TRICARE assumes fiscal
	responsibility of both donor and recipient.
	Statement by Service member that follow-up medical evaluation by a military medical
	physician will be completed between 6 and 12 months after donation.
	Letter from Service member's commander/commanding officer approving the request to
	donate.
	Intended recipient's name and relationship to the donor.
	A signed statement from attending physician associated with the transplant facility, which
	provides the recipient's diagnosis, prognosis, and verification that no other donor is
_	available.
	Name, office address, and telephone number of the attending physician(s) for both the donor
_	and recipient.
	Name, address, and phone number of the intended operative facility.
	Statement from a military medical officer or authorized medical physician that establishes the
	Service member's competency, emotional stability, bona fide volunteer status, and
	satisfactory health for donation. Evaluation should be based on personal interview, record
_	review, and objective clinical data.
	Copy of the DD Form 2807-1, Report of Medical History and DD Form 2808, Report of
_	Medical Examination completed within 90 days preceding the request to donate.
	Official reports of the following medical tests: ABO blood typing and cross match result of
	the donor and recipient; the donor's serum basic metabolic panel, fasting blood glucose, liver function studies (for liver transplants), and uninglysic results denor's 5, day blood prossures
	function studies (for liver transplants), and urinalysis result; donor's 5-day blood pressure
П	readings, height/weight, and imaging studies for kidney or liver donors. If the donor is over 45 years of age, a copy of the cardiac risk assessment is required.
ш	if the donor is over 43 years of age, a copy of the cardiac risk assessment is required.

GLOSSARY

PART I. ABBREVIATIONS AND ACRONYMS

AD Active Duty

AD-HCA Assistant Director, Health Care Administration AFMES Armed Forces Medical Examiner System

ASD(HA) Assistant Secretary of Defense for Health Affairs

CACO Casualty Assistance Calls Officer

CAO Casualty Assistance Office

DAD Deputy Assistant Director

DEERS Defense Enrollment Eligibility Reporting System

DHA Defense Health Agency

DHA-PI Department Health Agency-Procedural Instruction

DHAR Defense Health Agency Region

DoD Department of Defense

EHR electronic health record

HCO Health Care Operations

HIPAA Health Information Portability and Accountability Act

ID identification

IRB Institutional Review Board

J-9 Research and Engineering

MA Medical Affairs

MHS Military Health System MILDEP Military Department

MOA memorandum of agreement

MTF military medical treatment facility

NOK next of kin

OPO Organ Procurement Organization

OPTN Organ Procurement and Transplantation Network

POC point of contact

PIRR performance improvement record review

SG Surgeon General

SHCP Supplemental Health Care Program

SSO Small Market and Stand-Alone Military Medical Treatment Facility

Organization

TJC The Joint Commission

UAGA Uniform Anatomical Gift Act UNOS United Network for Organ Sharing

USD(P&R) Under Secretary of Defense for Personnel and Readiness

WRNMMC Walter Reed National Military Medical Center

PART II. DEFINITIONS

Unless otherwise noted, these terms and their definitions are for the purposes of this DHA-PI.

<u>anatomical gifts</u>. A donation of all or part (an organ, an eye, or tissue) of a human body to take effect after the donor's death for the purpose of transplantation, therapy, research, or education.

attending physician. A credentialed and privileged physician who has final responsibility for the care of a patient, whether or not the care was given by a subordinate provider.

<u>death</u>. A determination of death must be made following State law that is consistent with federal law and DoD policy, if applicable, or in the absence of State law, the determination will include at least one of the following:

Irreversible cessation of circulatory or respiratory functions in an individual.

Irreversible cessation of all functions of the entire brain including the brain stem.

<u>decedent</u>. A deceased individual, including a stillborn infant or fetus.

<u>DHA Component</u>. Activities under the authority, direction, and control of DHA.

<u>DoD</u> 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.

<u>DoD civilians</u>. Individuals who are civilian employees of DoD who possess a DoD ID card in accordance with Volume 1 of Reference (e).

<u>DoD ID card</u>. Identification issued to uniformed Service members, their dependents, and other eligible individuals in accordance with Volume 1 of Reference (e) will be used as proof of identity, DoD affiliation, and to facilitate access to Military Department benefits or privileges in accordance with Volume 2 of Reference (g).

<u>DoD recipients</u>. DoD beneficiaries who are eligible to receive organ, eye, and tissue donations.

<u>donor</u>. An individual who makes a gift of all or part of the body for specific purposes. <u>donor (deceased)</u>. An individual who makes a gift of a part of the body for use after death for specific purposes.

<u>donor (living)</u>. An individual who makes a gift of a part of the body for the purpose of transplant, while the donor is living.

<u>donor card</u>. A legal document signed by an individual, properly witnessed under the rules of informed consent, and indicating a desire to have one or more organs and/or tissues removed at death for donation to another individual.

<u>federal jurisdiction</u>. The term is applied when the Federal Government possesses, by whichever method acquired, all of the authority of the State, and in which the State concerned has not reserved to itself the right to exercise any of the authority to itself the right to exercise any of the authority concurrently with the United States except the right to serve civil or criminal process in the area for activities which occurred outside the area.

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

<u>NOK</u>. The person most closely related to the donor, or legally-authorized representative, designated according to the established order of priority in Section 274 of Reference (r).

<u>operating conditions</u>. The dynamic operational environment of a healthcare facility supporting and maintaining a specific military mission.

<u>OPO</u>. A formal civilian organization, 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: https://www.organdonor.gov/awareness/organizations/local-opo.html.

<u>OPTN</u>. Organ Procurement and Transplantation Network; operated under contract with the U.S. Department of Health and Human Services.

<u>organ</u>. 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 requires active biological patient support to ensure viability prior to removal.

<u>personally identifiable information</u>. Information that can be used to distinguish or trace an individual's identity, either alone or when combined with other information that is linked or linkable to a specific individual.

<u>Reserve Component</u>. The Armed Forces of the United States Reserve Component consists of the Army National Guard of the United States, the Army Reserve, the Navy Reserve, the Marine

Corps Reserve, the Air National Guard of the United States, the Air Force Reserve, and the Coast Guard Reserve.

<u>tissue</u>. The cornea, eye, skin, bone, stem cells, 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 and does not require ongoing biological patient support (active perfusion) at the time of harvest.

<u>UNOS</u>. United Network for Organ Sharing; A non-profit, scientific, and educational organization that administers the only OPTN in the United States, established (Section 274 of Reference (o)), by the U.S. Congress in 1984.