BUMED INSTRUCTION 6300.8B

From: Chief, Bureau of Medicine and Surgery

Subj: DONATIONS, TRANSPLANTS, AND DISPOSITION OF ORGANS AND TISSUE

Ref: (a) through (s) – see enclosure (1)

Encl: (1) References
(2) Organ and Tissue Donations from Department of Defense Sources
(3) Assistance for Organ Transplant Recipients and Family
(4) Transplants and Donations of Organs and Tissue from Living Donors
(5) Organ and Tissue Disposition after Autopsy
(6) Template - Request to Donate
(7) Template - Donor Endorsement
(8) Template - Memorandum of Understanding and DD Form 1144
(9) Template - Business Associate Agreement Privacy and Security of Protected Health Information
(10) Checklist for Screening Active Duty Living Donor Service Members
(11) Supplemental Health Care Program Waiver Instructions
(12) Template - Supplemental Health Care Program Waiver
(13) List of Acronyms

1. **Purpose.** To issue Bureau of Medicine and Surgery (BUMED) policy and procedures under reference (a), Uniform Anatomical Gift Act (UAGA) 2006, or current State guidelines in States where UAGA has not been enacted and reference (b) for donating, procuring, and transplanting functional human organs and tissues for use in the medical treatment of living patients after death of the donor. To establish coordination, counseling, and medical cognizance procedures in organ transplant and organ donation cases involving living active duty (AD) Navy and Marine Corps personnel. To issue policies and procedures for the disposition of human organs and tissue removed during an autopsy. Reference (a) is available at: [http://uniformlaws.org/Act.aspx?title=Anatomical%20Gift%20Act%20%282006%22](http://uniformlaws.org/Act.aspx?title=Anatomical%20Gift%20Act%20%282006%22). Enclosure (1) provides a list of references used in this instruction. This instruction is a complete revision and should be reviewed in its entirety.

2. **Cancellation.** BUMEDINST 6300.8A.

3. **Scope.** Applies to all Navy medical treatment facilities (MTF). References (c) through (s) amplify procedures for accomplishing the objectives regarding donating, transplanting, and other disposition of organs and tissues of living and deceased donors. Navy Medicine (NAVMED) supports organ donation and will follow the local laws, rules, and regulations.
4. **Definitions.** When used throughout this instruction, the following definitions are applicable:

   a. **Death.** A determination of death must be made following State law, if applicable, or reference (c), in the absence of State law. The determination will include one of the following:
      
      (1) Irreversible cessation of circulatory or respiratory functions in an individual.
      
      (2) Irreversible cessation of all functions of the entire brain including the brain stem.

   b. **Decedent.** A deceased individual including a stillborn infant or fetus.

   c. **Donor Card.** 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.

   d. **Donor (Deceased).** An individual who makes a gift of a part of his or her body for use after death for specific purposes.

   e. **Donor (Living).** An individual who makes a gift of a part of his or her body for the purpose of transplant while the donor is living.

   f. **Next of Kin (NOK).** The NOK will be determined by State law. In the absence of State law, the available interested party highest in the following order of priority will be designated the primary NOK: the spouse of the donor; an adult son or daughter of the donor; either parent of the donor; an adult brother or sister of the donor; a grandparent of the donor; a guardian of the donor at the time of death. The designated primary NOK may waive all referenced rights for organ disposition in favor of the next interested party in the priority list from reference (a).

   g. **Organ.** Includes heart, lung, liver, kidney, pancreas, or any other organs that are currently, or in the future, deemed suitable for transplantation including vascularized composite allografts. Vascularized composite allografts comprise a heterogeneous category of “organs” that include face, limb, long bones, and soft tissues.

   h. **Organ Procurement Organization (OPO).** A formally constituted civilian organization created to coordinate and recover organs and tissues for a specific type of transplantation or a special geographic area. OPO’s are members of the Organ Procurement and Transplantation Network (OPTN) which is overseen by the United Network for Organ Sharing (UNOS).

   i. **OPTN.** OPTN is operated under contract with the U.S. Department of Health and Human Services.

   j. **Tissue.** Includes cornea, skin, bone, bone marrow, dura-mater, blood vessel, fascia, or any other tissue that is currently or in the future deemed suitable for transplantation.
k. **UNOS.** UNOS is a non-profit, scientific, and educational organization that administers the only OPTN in the United States, established (section 274 of Title 42 U.S. Code) by the U.S. Congress in 1984.

5. **Action**

a. **All Addressees**

   (1) Ensure personnel are apprised of and adhere to the provisions in enclosures (1) through (12), and are familiar with the list of acronyms in enclosure (13). This will assist in establishing and maintaining a system of donations, transplants, and appropriate disposition of organs and tissues.

   (2) Beneficiaries of the TRICARE health care system will be encouraged to make organ and tissue donations. Coercion or the appearance of coercion of donors or their NOK will be avoided at all times. Donations from minors will be accepted only with appropriate informed consent of the NOK.


   (4) When deaths fall under the jurisdiction of the medical examiner per local or Federal law, the office of the Armed Forces Medical Examiner (AFME) and/or the local medical examiner (ME) or coroner must be consulted first before making any decisions on organ donation per reference (d). Twenty-four hour consultation is available through the duty office of the AFME. Telephone numbers are available on the AFMES Web site.

b. **NAVMED Regions.** Each NAVMED region will ensure compliance by their MTFs with this instruction, as applicable. Memoranda of understanding (MOU) between MTFs, civilian hospitals or institutions, and OPOs should be considered current and require review only at the desire of one of the parties, or when there are changes in the code, Navy, or Department of Defense (DoD) policy or standards of organ and tissue donation practice. Annual review of the MOU should be encouraged to reflect possible status and military instruction changes.

c. **Naval MTFs**

   (1) MTFs will establish reasonable methods for DoD beneficiaries to complete and carry DD Form 2731 Organ and Tissue Donor Card.
(2) 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 MOU with the local OPO. The MOUs may include participation in Non-Heart Beating Donor (NHBD) donation programs if practiced by the local OPO.

(3) All Navy inpatient MTFs will establish MOUs per enclosure (8) as guidance, as well as, the Army/Navy Organ Transplant Service, Walter Reed National Military Medical Center, 8901 Wisconsin Avenue, Bethesda, MD 20814 at (301) 295-4331, and local OPOs that grant DoD-eligible recipients access to organs and tissues from DoD donors.

(4) All Navy inpatient MTFs will maintain MOUs between the MTF and the local OPO to provide organ and tissue procurement services, as well as, assistance with education of personnel and beneficiaries regarding organ and tissue donation. All MOUs must receive legal review before enactment. Support agreements must comply with reference (e), DoD Instruction 4000.19, and SECNAV M-5216.5, chapter 10 as appropriate.

(5) All Navy inpatient MTFs will establish MOUs and appropriate parallel delegation of assurance authority with non-DoD institutions where a donation of tissue (such as from a living donor) will provide material by which the recipient’s institution will utilize such tissue in a transplant procedure which constitutes medical research, and which is covered under the authority of an appropriately constituted Institutional Review Board.

(6) All Navy inpatient MTFs must adhere to The Joint Commission safety standards, documentation requirements, and education standards presented in reference (f) which can be found via http://www.jointcommission.org/standards_information/hap_requirements.aspx.

6. Procedures

   a. An affirmative organ or tissue donation election shown on a DoD-issued card, DoD maintained database, driver’s license, or an advanced directive or “living will” should be considered by the DoD medical system to be guidance to the NOK; however, the decision of the NOK must be honored and is considered final, except in the situation described in paragraph 6b. A negative organ or tissue donation election on these documents must be honored.

   b. In cases in which State law provides that an organ or tissue donation election is irrevocable and may not be countermanded by the NOK, and the donor made such an election in a manner specified by State law (considering such matters as signature and witnesses), and such action is documented as provided by State law (such as on a driver’s license, if so provided by State law), DoD medical system personnel must follow the State law, donor election, and donation documentation. Most or nearly all States now have donor designation or “first person consent” that obviates OPO’s from obtaining consent from the families.
c. MTF personnel must immediately notify the appropriate OPO regarding any death, imminent death, or when they recognize the potential for organ and/or tissue donation. Patient affairs or the command duty officer/officer of the day will contact the AFME at (302) 346-8648 or DSN 366-8648 for all deaths in MTFs or on bases that fall under Federal jurisdiction. This will be done in addition to any contact between the OPO and the local ME. The attending physician must not participate in procedures for recovering or transplanting the donated organs and tissues.

d. Organ and tissue donation must be discussed with the NOK in every death in military MTFs 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.

e. An MOU with the local OPO will require that the OPO maintain a listing of patients who die in the MTF and record the results of action taken to secure the donation of organs or tissues from each patient who dies. Death chart review statistics should be made available to the MTF command to determine level of compliance with this instruction.

f. In cases where the transplant procedure will occur as part of medical research, there should be evidence of existence of an approved human research protocol which has been reviewed by an appropriately constituted human research protections body.

g. Organ donations and transplants conducted by organ and tissue procurement teams per this instruction, and treatment provided within Navy MTFs and dental treatment facilities (DTF) by personnel assigned to the AFMES to patients under their care, per reference (f) are authorized to be performed without formal credentials review and privileging. However, personnel assigned in support of these programs must present sufficient documentation e.g., official orders, assignment letter, and identification card to the commanding officer (CO) of the MTF/DTF to establish their authorization to perform the services.

h. After notification that a potential organ and/or tissue donor exists and subsequent confirmation of brain death or suitability for NHBD donation, the OPO will notify the MTF of potential organs and/or tissues available from DoD donors. (Note: See paragraph 6j for clarification of outside the continental United States (OCONUS) MTFs notification protocol).

i. Navy incurred retrieval costs for organs or tissues accepted for transplantation to non-DoD beneficiaries will be paid by either the OPO or the transplanting institution. Reimbursement for these costs must be made payable to the MTF through the U.S. Treasury in which the organ and/or tissue donation occurred.

j. The MTF will notify the NOK that death has been declared. The hospital must contact the casualty assistant calls officer (CACO) for deceased DoD donor beneficiaries if the primary
NOK is not already available at the hospital where the deceased is located. This ensures that the primary NOK who was not present at the hospital at the time of death is notified properly by a representative of the Casualty Area Command before organ or tissue donation is solicited by the OPO. The Casualty Area Command will not discuss organ donation, but may inform the NOK that they will be called by the OPO. The primary NOK should then be contacted by a member of the local OPO by telephone to request approval of organ or tissue donation from the deceased patient. A primary NOK's authorization of an organ or tissue gift from the deceased patient will be made on OF 523B Medical Record-Authorization for Tissue Donation. Telephonic consent is acceptable and should be appropriately documented.

k. Gifts of organs and tissues in the continental United States (CONUS) will be made following the laws of the State where the gift is made. If the gift is made in a foreign country, such gift will follow the UAGA, unless it is in violation of an international agreement or host nation law, in which case the latter will apply. MTFs in foreign countries will develop MOUs that address organ recovery services with the Army/Navy Organ Transplant Services of potential organ and tissue donors at (301) 295-4331. The civilian hospital or institution will be given the option of performing OCONUS organ recovery if practical.

l. MTFs will provide informational materials explaining organ and tissue donation and blank donor cards. Use DD Form 2731 as the organ donor card.

m. AD Service members as donors (deceased). There is no objection to AD Navy and Marine Corps Service members executing a declaration of intent to donate organs or tissues after death under the UAGA.

n. AD Service members as donors (living)

   (1) AD Navy and Marine Corps Service members may serve as living-related or living-unrelated organ donors.

   (2) AD Navy and Marine Corps Service members must obtain approval by their CO and be counseled in writing prior to becoming a living donor by his or her 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 that the AD Service member understands that his or her qualification for continued service will be contingent upon favorable medical evaluation results following organ donation.

   (3) Prior approval from Assistant Deputy Chief, Healthcare Operations (BUMED-M3) is required when AD Navy or Marine Corps Service members request to be living donors in a transplant facility other than the Army/Navy Organ Transplant Service. The Service member’s request package must meet the requirements outlined in enclosure (10) and be forwarded to the Navy Blood Program Office for review. These packages contain patient information and must
be encrypted if sent electronically. After initial review and screening, the package will be forwarded to the Army/Navy Organ Transplant Service for medical evaluation, and then returned to BUMED-M3 to receive written approval. Requests requiring immediate response, that have been approved by the unit commander or officer in charge (OIC), may be given telephonically by contacting the Navy Blood Program Office directly at (703) 681-9125/5541. All request packages to serve as an AD live organ donor other than in the Army/Navy Organ Transplant Service must contain the following information:

(a) Name, rank, grade, DoD identification number, work phone, home phone, military unit and location of prospective donor.

(b) Recipient's name and relationship to donor.

(c) Recipient's primary diagnosis and prognosis.

(d) Name of recipient's physician and place of transplant.

(e) A signed statement from the prospective donor that provides the acknowledgements listed below. Enclosure (6) is provided as a template statement.

1. Acknowledges understanding of required counseling by a medical officer.

2. Acknowledges the Navy or Marine Corps is not responsible for costs associated with a transplant performed in a civilian institution except when the recipient is a DoD beneficiary, in which case TRICARE pays the bills of both recipient and donor.

3. Acknowledges understanding a follow-up medical evaluation by a nephrologist, hepatologist, or internist will be completed at 6 and 12 months after donation. The evaluation should include a routine medical exam and labs. UNOS requires living donors to be followed for a specified period of time, usually 2 years. The center that performed the operation should report this data.

(f) DD Form 2808 Report of Medical Examination and DD Form 2807-1 Report of Medical History completed within 90 days preceding the request.

(g) Basic laboratory exams, including human immunodeficiency virus, Hepatitis B, and Hepatitis C virus by nucleic acid test or the most current Food and Drug Administration approved technology for these tests, urinalysis, complete blood count, blood urine nitrogen/creatinine, serum electrolytes, and fasting glucose obtained during initial physical evaluation by a military physician. For potential liver donors, a record of liver function tests is also required. If the potential liver donor is over 45 years old, a cardiac risk assessment is needed, preferably including a graded exercise test.
(h) A copy of the results of ABO blood types and compatibility testing performed at the transplanting institution.

(i) Signed statement from the unit commander or OIC approving the request to donate. Enclosure (6) is provided as a template statement.

(j) Signed statement from the attending physician associated with the transplant facility which provides the recipients diagnosis, prognosis, and verification that no other donor is available.

(k) Name and address of intended operating facility.

(4) AD Navy and Marine Corps Service members approved under this paragraph for organ donation will be placed on convalescent leave at the time of admission to a non-military MTF (civilian facility) through discharge. Convalescent leave must be approved by unit commander, CO, or OIC. Administrative responsibility will be assumed by the appropriate Navy MTF. Any absence from duty before hospital admission will be charged as regular leave.

(5) AD Navy and Marine Corps Service members in a non-military medical facility when donating an organ will be transferred to a Navy MTF at that point in his or her hospital course when he or she would normally be discharged. This transfer is not to be used as a means of transferring the responsibility for treatment or expenses associated with the transplant to the Navy, but to ensure Service member is medically evaluated after the organ donation to determine his or her future profile, assignments, and qualification for continued service.

(a) There is no requirement that a kidney donor be separated from the Service or denied the opportunity to reenlist. The donation of a kidney, without complications, resulting in normal functioning of the remaining kidney, would cause no disruption in the career of the Service member.

(b) There are restrictions placed on certain career fields associated with donating, past donation, or reception of an organ. Issues such as this are covered under reference (g). Under this directive, the absence of a kidney is listed as a disqualifying condition for both entry into the military, duty as a flight crew member, or Navy diver. However, waivers for accession into the military can be considered, and both the submarine and aviation communities have a process through which waivers can be granted. Specialized communities are able to evaluate members who have donated an organ, are considering donation, or who have received an organ, on a case-by-case basis.

(6) Requests for live organ donation may be sent directly to the Navy Blood Program Office, 7700 Arlington Blvd, Fall Church, VA 22042 or by calling (703) 681-9125/5541.
(7) Guidance for handling requests for Supplemental Health Care Program (SHCP) waivers is discussed in enclosure (11).

7. **Review and Effective Date.** Per OPNAVINST 5215.17A, review this instruction annually on the anniversary of its effective date to ensure applicability, currency, and consistency with Federal, DoD, Secretary of the Navy, and Navy policy and statutory authority using OPNAV 5215/40 Review of Instruction. This instruction will automatically expire 5 years after the effective date unless reissued or canceled prior to the 5-year anniversary date, or an extension has been granted.

8. **Information Management Control.** The reporting requirement is exempt from reports control per SECNAV M-5214.1 of December 2005, part IV, paragraph 7p.

9. **Forms**
   
a. The following General Service Administration forms are available electronically at: [http://www.gsa.gov/forms/gsanumer.htm](http://www.gsa.gov/forms/gsanumer.htm):

   (1) SF 523 Medical Record - Authorization for Autopsy.

   (2) OF 523B Medical Record - Authorization for Tissue Donation.

   b. The following DoD forms are available electronically at: [http://www.dtic.mil/whs/directives](http://www.dtic.mil/whs/directives):

   (1) DD Form 2731 Organ and Tissue Donor Card.

   (2) DD Form 2808 Report of Medical Examination.

   (3) DD Form 2807-1 Report of Medical History.

   (4) DD Form 1144 Support Agreement.

   (5) DD Form 2959 Breach of Personally Identifiable Information (PII) Report.

   

   Releasability and distribution:
This instruction is cleared for public release and is available electronically only via the Navy Medicine Web site at: [http://www.med.navy.mil/directives/Pages/BUMEDInstructions.aspx](http://www.med.navy.mil/directives/Pages/BUMEDInstructions.aspx)
REFERENCES

(a) Uniform Law Commission Anatomical Gift Act, 2006 (as amended 2009)
(b) 42 U.S.C. §273
(c) BUMEDINST 5360.24A
(d) Joint Publication 4-06
(e) BUMEDINST 7050.1B
(f) Joint Commission Comprehensive Manual for Hospitals
(g) MANMED Chapter 15, articles 15-84 and 15-102
(h) DoD Directive 6465.3 of 4 May 2004
(i) Organ Procurement and Transplantation Network (OPTN) Policies
(j) ASD(HA) Policy Memo 12-002 of 21 Feb 2012
(k) 32 CFR Part 199.17
(l) BUMEDINST 6320.72
(m) DoD Instruction 5154.30 of 29 December 2015
(n) 37 U.S.C. §555
(o) MILPERSMAN 1770-160
(p) MANMED Chapter 17, articles 17-2 and 17-3
(q) 10 U.S.C. §1471
(r) BUMEDINST 6010.30
(s) PHS Guideline for Reducing HIV, HBV, HCV through Organ Transplant Aug 2013

Enclosure (1)
ORGAN AND TISSUE DONATIONS FROM DEPARTMENT OF DEFENSE SOURCES

1. General
   a. Donation Pledges. Opportunities for a DoD beneficiary to make organ and/or tissue donation pledges should be made available with arrival at the first duty station, at regular physical examinations, during issuance, and re-issuance of military identification cards, in all MTFs, and at military unit meetings. Unless prohibited medically, legally, or for religious reasons, organ and tissue donation must be discussed with the NOK in every death in a military MTF.
   
   b. Laws. Gifts of organs and tissues must follow the law of the State or foreign country where the gift is made and must follow reference (a).

2. Policy
   a. Encourage organ and tissue donations from all DoD beneficiaries, while avoiding coercion or the appearance of coercion of donors or their NOK. Donations from minors will be accepted only under the guidelines of reference (h).
   
   b. Establish reasonable methods for DoD beneficiaries to complete and carry a DD Form 2731 Organ and Tissue Donor Card.
   
   c. Mandate participation in the congressionally established national OPTN that facilitates and coordinates organ and tissue donation, the recovery of donated organs and tissues, and the matching of donors and recipients. Navy MTFs should engage in donor identification activities on a daily basis. This includes:

      (1) Identifying potential donors (at MTFs and at civilian facilities).

      (2) Ensuring the proper notification of the NOK of every deceased beneficiary and providing them the opportunity to make a donation commitment.

      (3) Checking the status of seriously ill or injured or very seriously ill or injured patients for potential solid organ donors (heart, kidney, liver, pancreas, etc.).

   d. Ensure appropriate agreements exist with local OPOs, civilian hospitals, tissue and eye banks for tissue and eye donation procedures, and the Army/Navy Organ Transplant Service, Walter Reed Army Military Medical Center, 8901 Wisconsin Ave, Bethesda, MD 20814.

   e. Require all inpatient MTFs maintain an MOU with the local OPO to provide organ and tissue procurement services. All MOUs should be subject to legal review before enactment.
3. Commanders and COs of MTFs

   a. Must secure and make available to all DoD beneficiaries the DD Form 2731. MTFs must also provide information materials to explain organ and tissue donation.

   b. COs of inpatient MTFs must establish MOUs or contracts among themselves and the local OPOs for organ recovery services. Existing MOUs with civilian OPOs should be reviewed, following this instruction, and modifications should be made as warranted. New MOUs and contracts should require OPOs to immediately notify the MTF when a potential donor, who is an active Service, is hospitalized in a civilian hospital. DoD beneficiary includes the U.S. Coast Guard and the U.S. Public Health Service. New MOUs and contracts must prohibit the sale for profit of any DoD beneficiary-donated organs and tissues by any receiving civilian procurement agency.

   c. An MOU with the local OPO must require the 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 MTFs should maintain their own listing.

   d. To the maximum extent possible, educate beneficiaries on the benefits of organ donation and encourage program participation.

   e. MOUs and contracts with OPOs should require equitable sharing of organs and tissues.

   f. COs of all MTFs must ensure their staff is familiar with the content of this instruction.

      (1) All organ allocation and procurement should be coordinated through the OPO.

      (2) The procurement team coordinator if established, or attending physician should immediately notify the local OPO when the potential for organ or tissue donation is recognized, i.e., the possibility of irreversible brain injury and brain death. If the procurement team coordinator, or attending physician, is unable to contact the OPO, any staff member familiar with the case may contact the OPO.

      (3) 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 CACO.

   g. The procurement team coordinator, attending physician, or appropriate staff member must ensure the Defense Enrollment Eligibility Reporting System (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 and did not 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.

h. If there is no record of the deceased's wishes, or if a valid donation document exists, and donation or transplant is not contraindicated for medical, legal, or religious reasons, the OPO, procurement team coordinator, or attending physician must contact the NOK to discuss and expeditiously request organ or tissue donation.

(1) Under no circumstances will either the attending physician or any other health care personnel involved in the care of the patient participate in procedures for removing or transplanting organs and tissues. It is a Joint Commission requirement that hospitals must contact the OPO for donors or potential donors. The OPO has personnel trained to approach the family about donating.

(2) The procurement team coordinator or appropriate staff member must initially contact the CACO for all deceased AD beneficiaries if the NOK is not already available at the MTF or civilian 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 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.

(3) When a conflict exists between the positive wishes of the donor to provide organs and tissues upon death and the wishes of the NOK, the wishes of the donor will be honored unless it conflicts with state law. To clarify any confusion on organ or tissue donation the following table is provided for guidance, and must follow applicable State law where it exists:

<table>
<thead>
<tr>
<th>Donation Scenarios</th>
<th>Donate (yes or no)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Deceased wished to donate and NOK wishes to donate.</td>
<td>YES</td>
</tr>
<tr>
<td>Deceased made no decision to donate and NOK wishes to donate.</td>
<td>YES</td>
</tr>
<tr>
<td>Deceased made no decision to donate and NOK wishes not to donate.</td>
<td>NO</td>
</tr>
<tr>
<td>Deceased wished to donate, but NOK wishes not to donate unless it conflicts with state law.</td>
<td>YES</td>
</tr>
<tr>
<td>Deceased did not wish to donate, but NOK does wish to donate.</td>
<td>NO</td>
</tr>
<tr>
<td>Deceased did not wish to donate and NOK does not wish to donate.</td>
<td>NO</td>
</tr>
</tbody>
</table>
i. To show permission was sought, complete and sign an OF 523B, Authorization for Tissue Donation (or a State required request form) on each death that occurs at a naval MTF. This form is required whether or not a donation is made.

j. The procurement team coordinator or appropriate staff member must assure all organs and tissues from DoD beneficiaries at the MTF, at time of death, are first made available to the Army/Navy Organ Transplant Service, unless the terms of the gift specify otherwise.

k. Organs and tissues removed from DoD beneficiaries that are not used by a civilian OPO must be disposed of in a humane and dignified manner. The preferable manner of disposition is by incineration, see enclosure (5).

l. Donation suitability will be determined by the OPO and the transplanting center per reference (i).

m. 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 a 24-hour-a-day basis.

   (3) The organ and tissue procurement team must be responsible for surgical removal of donated organs and tissues at the MTF. Inpatient MTFs may allow civilian OPO recovery teams to sustain deceased donor patients and to perform the actual surgical recovery of donated organs and tissues.
ASSISTANCE FOR ORGAN TRANSPLANT RECIPIENTS AND FAMILY

1. Administrative and Logistical Assistance

   a. Administrative and logistical assistance is available for organ transplant recipients and their family. While clinical considerations remain of primary importance, the Navy 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 the nearest Navy Relief Society representative. Some DoD beneficiaries requiring organ transplants have been evacuated to civilian facilities far removed from major naval facilities. This severely limits the Navy in its ability to be of real assistance to accompanying family members. Often, families arrive at a civilian transplant center, usually located in an unfamiliar metropolitan area, with no prearranged contact with naval personnel in the area who could be of assistance in obtaining or arranging for the above services. Also, when the patient is a family member of an AD member, BUMED is often asked to provide advice to the Navy Personnel Command or Headquarters, U.S. Marine Corps relative to the immediate reassignment or future assignment of the patient's sponsor.

   b. Requests should have a 45-day lead time. Emergent requests can be processed. Contact the Navy Blood Program Office directly at (703) 681-9125/5541.

2. Organ Transplants. Medical personnel contacting BUMED should be aware of the overall effects on the patient and family members and should be prepared to discuss possible sources of care consistent with these requirements. Several sources of care may be available. When each source is equally acceptable clinically, first preference should be given to care available in MTFs and then to other sources located near naval facilities, since these cases offer an opportunity to build and strengthen liaison between the medical department and the civilian community.

3. Vascularized Composite Allografts

   a. Vascularized composite allografts involve the transplantation of multiple structures that may include skin, bone, muscles, blood vessels, nerves and connective tissue. Members of the uniformed services are entitled to medical and dental care in MTFs and in private facilities (purchased care) using SHCP funds. Coverage of medical care in private facilities for Service members must be comparable to coverage for medical care under the TRICARE Prime Program.

   b. The Defense Health Agency (DHA) is authorized to exercise discretionary authority to waive any requirements of TRICARE regulations, including the TRICARE Basic Program Benefits, except those specifically set forth in statute, based on “a determination that such waiver is necessary to assure adequate availability of health care to AD Service members.” When vascularized composite allografts become the standard of care with respect to TRICARE, the waiver request process will not be needed. Until then, clinical history, and medical justification for the requested non-covered medical service, and information regarding the potential impact of

Enclosure (3)
the requested health care service on the Service member's fitness for duty and military readiness, are essential elements of the waiver request. At the request of an authorized official of the uniformed services, the Director, DHA may waive any restrictions or limitations.

c. AD Service members and retirees may request emerging technology care as a result of serious injury or illness while on AD or who have received care at a TRICARE approved facility. All non-standard of care medical services, which constitute medical research must have been approved by an appropriately constituted Institutional Review Board at the facility where such service, such as composite tissue allotransplantation, will be provided. Prior to provision of tissue for transplant, an authorized official of the uniformed services must be provided with evidence of such Institutional Review Board approval, in writing, prior to waiving any restrictions or limitations under the Basic Program Benefits. Likewise, any naval MTF must have in writing evidence of such Institutional Review Board approval of the non-standard transplant procedure prior to transfer of composite tissue for transplantation to the facility where the procedure is to be performed. Once a candidate is identified, the health care provider should submit a SHCP waiver package to Navy Blood Program Office, BUMED-M32, who will review the package with the transplant service team at the Walter Reed National Military Medical Center prior to obtaining BUMED-M3 approval for the waiver.

d. The requesting provider must follow the instructions for preparing the SHCP waiver approval, see enclosures (11) and (12), as established by the Assistant Secretary of Defense for Health Affairs, per reference (j). Reference (j) is available at: http://www.health.mil/Policies?query=12-002&daterange=2010-2016. Since waiver packages contain patient health information, they must be encrypted when sending via e-mail.
1. **General.** In some instances, BUMED-M32 must provide advice to the sponsor or other responsible family member concerning possible benefits for the individual donating organs or tissues, and the recipient under the provisions of reference (k).

2. **Approval.** Navy personnel, who wish to donate an organ or tissue, while living, need approval from BUMED-M3. Marine Corps personnel need approval from their respective CO and concurrence from BUMED-M3. After completion of compatibility studies following paragraph 4 of this enclosure, the member must inform their CO and as appropriate of intent to be a living donor.

3. **Counseling and Evaluation.** Upon receipt of notification of intent to be a living donor, the Service member's CO must provide or arrange for the following:

   a. Counseling by a Medical Corps officer (or civilian physician at member's expense) concerning nature of donation and the surgical procedures involved. A specialist of the organ being donated should do this counseling (e.g., nephrologist for kidney donation, gastroenterologist for liver donation, etc.).

   b. Counseling by a medical department officer that loss of a kidney or other organ will not become a basis for special duty assignment, and the member may not be eligible after surgery for disability benefits administered by the Department of the Navy or the Department of Veterans Affairs. The Service member must sign a service record entry attesting the provisions of this paragraph have been explained and are understood.

   c. Counseling that only care in a uniformed services or other Federal MTF, and care provided under reference (k), when the donation is for a TRICARE standard beneficiary, may be incurred at the Navy's expense.

   d. Examination by a Medical Corps officer (or civilian physician at member's expense) to determine present physical fitness and, if qualified, evaluation of the member's fitness for donation surgery.

4. **Compatibility Studies.** Required of all prospective living donors:

   a. Compatibility studies must be completed before the Service member informs their chain of command of their intent to be a living donor. See paragraphs 6n(3)(g) and 6n(3)(h) of the basic instruction for a list of studies that must be completed prior to submission.

   b. The Service member must be in a leave status during the complete time of these studies unless admission to a non-Federal facility is required.
5. **Medical Cognizance.** Upon admission to the medical facility where the removal is to be accomplished:
   
a. The member’s leave status will be canceled and medical cognizance assumed by the naval MTF serving the region.

   b. After the member's surgery and convalescence period are completed, the cognizant MTF must order the member to the nearest appropriate medical facility to undergo examination to determine the member's fitness for continued service.
ORGAN AND TISSUE DISPOSITION AFTER AUTOPSY

1. General. The interests of DoD and individual military departments require an appropriate protocol for dignified disposition of human organs and tissues required to be removed during autopsies. DoD and the Department of the Navy recognize the right of the deceased's NOK to direct, except as specified in this enclosure, the disposition of organs and tissues. NAVMED supports the continued advancement of medical science and recognizes the significant potential advances in research and education that may result from the study of organs and tissues of deceased individuals. We also recognize the direct benefit to recipients of both transplanted organs, tissues, and growth hormone extracted from the pituitary gland. Accordingly, measures must be implemented to assure appropriate action is taken each time an autopsy is performed.

2. Policy. For autopsies performed under the provisions of reference (a), commanders and COs with Mortuary Affairs Program oversight responsibility must either establish or change protocol at each activity to ensure:

   a. All organs and tissues, or portions thereof, removed during an autopsy are returned to the remains before release of remains to mortuary officials, unless use or other disposition of organs or tissues is authorized by the NOK, except for:

      (1) Organs or tissues required for determination of the cause or manner of death.

      (2) Those organs or tissues required for other studies authorized by law or regulation.

      (3) Organs or tissues removed following the specific desires of the decedent per a State law adopted in conformity with reference (a) or similar statutory authority.

   b. Any organs or tissue specimens removed for diagnostic, research, or any other reasons, per paragraph 2a(1) through 2a(3) of this enclosure or paragraph 3k of enclosure (2) as directed by this instruction, are safeguarded and when no longer needed are disposed of in a humane and dignified manner. The preferable manner of disposition is by incineration for both organs and tissue specimens, unless there are religious prohibitions against cremation stipulated by the last will and testament of the deceased or by NOK.

   c. The NOK's written permission is obtained for organ or tissue removal unless disposition was specified as in paragraphs 2a(1) through 2a(3) of this enclosure. For sites OCONUS, obtain written permission following the provisions of reference (l), Non-Naval Health Care Program, on a SF 523 Medical Record Authorization for Autopsy.
 TEMPLATE
REQUEST TO DONATE
(use command letterhead)

Date

From: Rank and name of donor, name and address of donor’s command
To: Director, Navy Blood Program (M3B22), Bureau of Medicine and Surgery,
7700 Arlington Blvd, Falls Church, Virginia 22048
Via: Commanding Officer, name and address of donor’s command

Subj: REQUEST TO BE A LIVING DONOR

Encl: (1) DD 2807-1 Report of Medical History
      (2) DD 2808 Report of Medical Examination
      (3) Attending Physician Statement
      (4) Test results
      (5) Transplant Clinic Points(s) of Contact

1. Request authorization to be a living organ donor. I wish to donate (name of tissue, organ, 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. I understand and accept that neither the Department of Defense, nor its branches are 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 command medical staff on the risks of donating (name of organ, tissue, 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.

3. Required tests have been completed are included in this package to ensure the health and safety of myself and the recipient of my donation.

4. I have met with my health care provider to ensure I am competent, emotionally stable, and in good health to donate my (name of organ, tissue, or bone marrow). I fully understand the risks involved and freely wish to donate my (name of organ, tissue, or bone marrow).

Enclosure (6)
Subj: REQUEST TO BE A LIVING DONOR

5. 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)
TEMPLE
DONOR ENDORSEMENT
( submit on command letterhead)

6300
Code
Date

FIRST ENDORSEMENT on (rank & name of prospective donor) ltr of (date of donor’s letter)

From: (Rank & name of donor’s immediate supervisor, name and address of donor’s command)
To: Director, Navy Blood Program (M32), Bureau of Medicine and Surgery, 7700 Arlington Blvd, Falls Church, Virginia 22048
Via: Commanding Officer, (name and address of donor’s command)

Subj: 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, he/she appears to be best suited to be a donor for the intended recipient. I and (rank and name of donor) understand that medical consequences resulting from this donation could adversely affect his/her ability to continue on AD. After reviewing all the facts, my recommendation is to allow (rank and name of donor) to donate (name of tissue, organ, or bone marrow).

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.

Donor’s Chain of Command Signature
Chain of Command First & Last Name (Typed)

Enclosure (7)
MEMORANDUM OF UNDERSTANDING
BETWEEN
NAVAL MEDICAL FACILITY
AND
CIVILIAN ORGANIZATION
FOR
TISSUE DONATIONS

1. General. This Memorandum of Understanding (MOU) is entered into by (name of civilian hospital) located at (address of civilian hospital) and (name of naval medical facility) located at (address of naval medical facility).

2. Purpose. This agreement, hereinafter referred to as the MOU, is to assist in identifying Department of Defense (DoD) personnel who wish to donate their organs or tissues; procuring such members' tissues through an Organ Procurement Organization (OPO), following their documented wishes, or the wishes of their next of kin (NOK) upon their demise in a civilian hospital; and making recovered tissues available for transplantation to qualified recipients.


4. Background. The need for cadaver tissues is far greater than the available supply. Previously, the Army, Navy, and Air Force provided procurement teams to remove deceased donor patient’s tissues and organs, however, military and civilian hospitals should defer to an OPO for collection of those tissues and organs.

5. Articles of Agreement
   a. Definition of Terms
      (1) Donor patient is any patient who is a likely candidate to have his or her tissues surgically removed and used for transplantation.

      (2) DoD patient is any person who is entitled to use inpatient DoD medical facilities, including but not limited to AD military members, retirees, and family members of AD members and retirees.

      (3) Recipient is any person who receives transplanted tissues.

      (4) DoD recipient is a person who receives transplanted tissues while entitled to use inpatient DoD medical facilities, regardless of site of actual transplantation.
(5) Procurement is the surgical removal of tissues from cadavers.

(6) OPO is a group of trained health care professionals authorized to surgically procure cadaver tissues.

(7) OPO is a civilian organization that provides and coordinates a procurement team to procure organs or tissues at a civilian or military hospital.

(8) Participating hospital is any civilian or military facility that signs an agreement as depicted in this MOU.

b. Participating Civilian Facility Responsibilities

(1) When a potential donor patient is admitted to a participating civilian organization and is determined by the treating physician to be a donor patient, the organization will make a reasonable and good faith effort to identify the patient's status as a DoD patient.

(2) When it is determined the potential donor is a DoD patient, the civilian organization will then place a telephone call immediately to their OPO to determine the tissue donor status of the DoD patient.

(3) Under this MOU, the civilian organization agrees to allow the organ procurement team reasonable access to all medical equipment and facilities at the facility that are necessary to carry out organ procurement from DoD donor patients.

(4) Participating civilian organizations must document deaths of potential DoD donors and allow DoD representatives reasonable access to DoD patient medical records and facilities to ensure compliance with this MOU.

(5) Participating civilian organizations agree to maintain a record of all DoD patients who are determined by the attending physician to be potential donor patients. The record will describe what action the civilian organization used in attempting to procure the patient's organs. Records of such action must be sent to the naval medical facility negotiating this MOU.

(6) Attending physicians, at civilian organizations, are solely responsible for determining the death of a donor patient following local law and established medical protocol. Such determination must, however, receive the concurrence of at least two other members of the medical staff practicing in different medical specialties. Concurrence must be documented in the progress notes of the patient's medical chart.
c. Naval Medical Facility’s Procurement Team Coordinator Responsibilities

(1) When notified by a civilian organization that a DoD patient is a potential donor, the procurement team coordinator must evaluate the potential donor for satisfactory medical criteria for organ or tissue donation by:

(a) Checking Defense Enrollment Eligibility Reporting System.

(b) Checking the medical records.

(c) Checking other documents.

(2) Upon death of the patient, the facility must contact their OPO coordinator who will then approach the family to discuss the details of donation.

(3) When the OPO is notified that a patient is a donor patient, they may participate in the “military share” and direct a kidney to the Army/Navy Organ Transplant Service by notifying the Army/Navy Organ Transplant Service at the Walter Reed National Military Medical Center at DSN 295-4331 or commercial (301) 295-4331

(4) If possible, the procurement team coordinator or attending physician will arrange with the treating facility to allow access to the procurement team to examine the patient and the patient's medical records before death.

(5) Immediately after death of a potential donor patient, the procurement team coordinator or attending physician must contact the procurement team (if one exists) for orders concerning cadaver maintenance before procurement. The procurement team coordinator or attending physician must arrange for procurement and relay information to the participating civilian organization. Proper cadaver maintenance takes precedence over obtaining concurrence for procurement from the NOK or through the Casualty Assistance Calls Program coordinator.

d. Costs and Reimbursement for Services at Civilian Organizations

(1) If procured tissues of DoD donor patients are transplanted into a DoD recipient, DoD must reimburse the civilian organization for all reasonable expenses directly related to the cost of cadaver maintenance and tissue procurement. Such expenses as laboratory analysis, drugs, equipment, operating room costs, and similar overhead expenses are considered. Reimbursable agreements require a DD Form 1144 Support Agreement, see pages 5 through 7 of this enclosure for a sample form.

(2) If the procured tissue is not transplanted into a DoD recipient, DoD is not responsible for costs incurred because of cadaver maintenance or tissue procurement. If DoD provides the procurement team for a DoD donor patient at a civilian organization and procured tissues are not transplanted into a DoD recipient, the civilian organization is responsible for the procurement

e. Other Considerations

(1) Effective Period. This agreement is effective upon the day after the date of last signature, for a period of ____ (not to exceed 5 years). It may be continued without change during that period, but must be reviewed annually by all parties.

(2) The approval of agreements must be in compliance with BUMEDINST 7050.1C

(3) Provisions for Amendment, Change, or Modification. Once the support agreement is approved by BUMED, no further amendments, changes, or modifications are authorized. Additional amendments, changes, or modifications shall be processed as if a new agreement.

(4) Termination. The agreement may be cancelled at any time by mutual consent of the parties concerned. The agreement may also be terminated by either party upon giving ____ days written notice to the other party. In the case of mobilization or other emergency, the agreement may be terminated immediately upon written notice by (insert BUMED activity name), and it will remain in force during mobilization or other emergency only within (insert BUMED activity name's) capabilities.

(5) Health Insurance Portability and Accountability Act (HIPAA). Pursuant to 45 C.F.R. parts 160 and 164, DoD Instruction 6025.18 and DoD 6025.18-R, the parties agree to enter into a Business Associate Agreement (BAA), attached to this agreement.

(6) Compliance. Both parties have read and agree to comply with all terms and provisions of this MOU.

______________________________________________________________
Name Typed Date
Civilian Organization
Title

______________________________________________________________
Name Typed Date
Commanding Officer, Naval Hospital, _____

Attachments: Business Associate Agreement
            DD Form 1144
**SUPPORT AGREEMENT**

<table>
<thead>
<tr>
<th>1. AGREEMENT NUMBER</th>
<th>2. SUPERSEDED AGREE NO.</th>
<th>3. EFFECTIVE DATE:</th>
<th>4. EXPIRATION DATE:</th>
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<tbody>
<tr>
<td>(Provided by Supplier)</td>
<td>(If this replaces another agreement)</td>
<td>Date of last signature</td>
<td>NTE 5 Years</td>
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<td>16RA032</td>
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5. **SUPPLYING ACTIVITY**

<table>
<thead>
<tr>
<th>6. RECEIVING ACTIVITY</th>
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<tbody>
<tr>
<td>a. NAME AND ADDRESS</td>
</tr>
<tr>
<td>Civilian Hospital</td>
</tr>
<tr>
<td>Street</td>
</tr>
<tr>
<td>City, State, Zip</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>7. SUPPORT PROVIDED BY SUPPLIER</th>
</tr>
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<tbody>
<tr>
<td>a. SUPPORT</td>
</tr>
<tr>
<td>Navy Medicine will reimburse the civilian organization for all reasonable expenses directly related to the cost of cadaver maintenance and tissue procurement. Associated expenses are listed below:</td>
</tr>
<tr>
<td>Laboratory analysis</td>
</tr>
<tr>
<td>Drugs</td>
</tr>
<tr>
<td>Equipment</td>
</tr>
<tr>
<td>Operating room costs</td>
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<td></td>
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</table>

<table>
<thead>
<tr>
<th>Total Estimated Reimbursement</th>
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<td>$13,200.00</td>
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</table>

Total Estimated Reimbursement

This Cost Proposal is from FY 16 to FY 18

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<tr>
<th>8. SUPPLYING COMPONENT</th>
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<tbody>
<tr>
<td>a. COMPROLLER SIGNATURE:</td>
</tr>
<tr>
<td>John Doe</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>9. RECEIVING COMPONENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. COMPROLLER SIGNATURE:</td>
</tr>
<tr>
<td>Jane Doe, LT, MSC USN</td>
</tr>
</tbody>
</table>

c. APPROVING AUTHORITY

<table>
<thead>
<tr>
<th>10. TERMINATION</th>
<th>(Complete only when agreement is terminated prior to scheduled expiration date.)</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. APPROVING AUTHORITY SIGNATURE</td>
<td>b. DATE SIGNED</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>
11. GENERAL PROVISIONS (Complete blank spaces and add additional general provisions as appropriate: e.g., exceptions to printed provisions, additional parties to this agreement, billing and reimbursement instructions.)

a. The receiving components will provide the supplying component projections of requested support. (Significant changes in the receiving component’s support requirements should be submitted to the supplying component in a manner that will permit timely modification of resource requirements.)

b. It is the responsibility of the supplying component to bring any required or requested change in support to the attention of See block 6a prior to changing or cancelling support.

c. The component providing reimbursable support in this agreement will submit statements of costs to: See block 6a.

d. All rates expressing the unit cost of services provided in this agreement are based on current rates which may be subject to change for uncontrollable reasons, such as legislation, DoD directives, and commercial utility rate increases. The receiver will be notified immediately of such rate changes that must be passed through to the support receivers.

e. This agreement may be cancelled at any time by mutual consent of the parties concerned. This agreement may also be cancelled by either party upon giving at least 180 days written notice to the other party.

f. In case of mobilization or other emergency, this agreement will remain in force only within supplier’s capabilities.

g. Authority. 42 USC 1320b-8

h. Annual Review. This agreement may be continued without change during the effective period, but must be reviewed annually by all parties. Annual receipt of good(s) and/or service(s) will be conducted as part of the annual review for internal control purposes and to validate that the support agreement is necessary and being executed in accordance with the identified terms and as intended. The annual review will be conducted no later than the annual day and month the agreement was put into effect. Verification of good(s) and/or service(s) will be documented as part of the annual review.

i. Modification, change, or amendment. Any modifications, changes, or amendments to this agreement must be in writing, and are contingent upon the approval authority’s approval. Subsequent to approval, the modification, change, or amendment must be signed by all parties.

j. Termination. The agreement may be cancelled at any time by mutual consent of the parties concerned. The agreement may also be terminated by either party upon giving 180 days written notice to the other party. In the case of mobilization or other emergency, the agreement may be terminated immediately upon written notice by (Navy Medicine Command), and it will remain in force during mobilization or other emergencies only within (Navy Medicine Command) capabilities.

ADDITIONAL GENERAL PROVISIONS ATTACHED: ☒ YES ☐ NO

12. SPECIFIC PROVISIONS (As appropriate: e.g., location and size of occupied facilities, unique supplier and receiver responsibilities, conditions, requirements, quality standards, and criteria for measurement/reimbursement of unique requirements.)

Attachment: MOA

ADDITIONAL SPECIFIC PROVISIONS ATTACHED: ☒ YES ☐ NO
ADDITIONAL PROVISIONS (Use this space to continue general and/or specific provisions, as needed.)

1. **Resources.** Execution of this support agreement is contingent upon local funding availability. Therefore, approval of this support agreement does not constitute approval of additional resources. Any resource requirements (funding, personnel, supplies, equipment, etc) associated with this MOU will be executed within the available funding allocations and programmed funding of the parties. Any funding or billet requirements that cannot be accommodated within a party's existing budget must be separately addressed through normal budget processes or other special programs. Commitment for exchange of resources by the parties will require formal amendment of this MOA beforehand or a separately prepared support agreement to document reimbursable requirements and resources involved to be approved by the approval authority.

2. **Health Insurance Portability and Accountability Act (HIPAA).** Pursuant to 45 CFR parts 160 and 164, DoD Directive 6025.18, Privacy of Individually Identifiable Health Information in DoD Health Care Programs of 19 December 2002, and DoD 6025.18-R, the parties agree to enter into a Business Associate Agreement (BAA), attached as Appendix A to this agreement.

3. **Disputes.** Any disputes relating to this MOA will, subject to any applicable law, Executive Order, Directive, or Instruction, be resolved by consultation between the Parties or in accordance with DoDI 4000.19.

4. **Transferability.** This Agreement is not transferable except with the written consent of the Parties.

5. **Billing and Payment.**
   a. Navy medicine is receiving support. Funding will be provided to the supplier from DHP, O&M. The impacted Budget Activity Group is 1.
   b. In accordance with Treasury Financial Manual Volume I, Part 2, Chapter 4700, Appendix 10, and in support of Department of the Navy audit readiness requirements, by accepting this reimbursable funding action, the performing agency agrees to deliver, upon request, detailed documentation supporting amounts billed and actual performance of work. For the duration of this agreement, “upon request” means monthly.

6. **Points of Contact.** The following points of contact (POC) will be used by the Parties to communicate in the implementation of this MOA. Each party may change its point of contact upon reasonable notice to the other Party.
   a. For the [first party]
      1. Position, phone number, email address, and address of Primary POC: XO, 111-23-3334, firstname.lastname.mil@mail.mil, Naval Medical Center, Street, City, State, Zip
      2. Position, phone number, email address, and address of Alternate POC: Deputy Comptroller, 111-23-3335, firstname.lastname.mil@mail.mil, Naval Medical Center, Street, City, State, Zip
   b. For the [second party]
      1. Position, phone number, email address, and address of Primary POC: Deputy Director, 132-34-1123, email address, Civilian Hospital, Street, City, State, Zip
      2. Position, phone number, email address, and address of Alternate POC: Billing specialist, 132-34-1111, email address, Civilian Hospital, Street, City, State, Zip
BUSINESS ASSOCIATE AGREEMENT
PRIVACY AND SECURITY OF PROTECTED HEALTH INFORMATION
APPENDIX

1. INTRODUCTION

a. In accordance with 45 C.F.R. Parts 164.502(e)(2) and 164.504(e) and paragraph C.3.4.1.3 of DoD 6025.18-R, “DoD Health Information Privacy Regulation,” January 24, 2003, this document serves as a Business Associate Agreement (BAA) between the signatory parties for purposes of the Health Insurance Portability and Accountability Act (HIPAA) and the “HITECH Act” amendments thereof, as implemented by the HIPAA Rules and DoD HIPAA issuances (both defined below). The parties are:

(1) A Department of Defense (DoD) Military Health System (MHS) component command such as a Navy Medicine medical treatment facility (naval medical center or naval hospital), or special mission command (research, public health, other), acting as a HIPAA covered entity.

(2) Another Federal or government organization, civilian academic institution, or other civilian entity, acting as a HIPAA business associate.

b. The HIPAA rules require BAAs between covered entities and business associates. Implementing this BAA requirement, the applicable DoD HIPAA issuance (DoD 6025.18-R, paragraph C3.4.1.3) provides that requirements applicable to business associates must be incorporated (or incorporated by reference) into the contract or agreement between the parties.

2. DEFINITIONS

a. Terms. Except as provided otherwise in this BAA, the following terms used in this BAA shall have the same meaning as those terms in the DoD HIPAA rules (DoD 6025.18-R): Data Aggregation, Designated Record Set, Disclosure, Health Care Operations, Individual, Minimum Necessary, Notice of Privacy Practices (NoPP), Protected Health Information (PHI), Required By Law, Secretary, Security Incident, Subcontractor, Unsecured Protected Health Information, and Use, 45 C.F.R. Parts 160.103, 164.501, 164.502.

b. Breach means actual or possible loss of control, unauthorized disclosure of or unauthorized access to PHI or other personally identifiable information (which may include, but is not limited to PHI), where persons other than authorized users gain access or potential access to such information for any purpose other than authorized purposes, where one or more individuals will be adversely affected. The foregoing definition is based on the definition of breach in DoD Privacy Act issuances as defined herein.
c. **Business Associate** shall generally have the same meaning as the term “business associate” in the DoD HIPAA issuances, and in reference to this BAA, shall mean the entity (another Government organization, civilian academic institution, or other civilian organization), entering into agreement with a Navy Medicine medical treatment facility or special mission command.

d. **Agreement** means this BAA together with the documents and/or other arrangements under which the Business Associate signatory performs services involving access to PHI on behalf of the MHS component signatory to this BAA.

e. **Covered Entity** shall generally have the same meaning as the term “covered entity” in the DoD HIPAA issuances, and in reference to this BAA, shall mean a *Navy Medicine medical treatment facility or special mission command under the Bureau of Medicine and Surgery.*

f. **DHA Privacy Office** means the Defense Health Agency (DHA) Privacy and Civil Liberties Office. The DHA Privacy Office Director is the HIPAA Privacy and Security Officer for DHA, including the National Capital Region Medical Directorate (NCRMD).

g. **DoD HIPAA Issuances** means the DoD issuances implementing the HIPAA Rules in the DoD Military Health System. These issuances are DoD 6025.18-R (2003), DoDI 6025.18 (2009), and DoD 8580.02-R (2007).

h. **DoD Privacy Act Issuances** means the DoD issuances implementing the Privacy Act, which are DoDD 5400.11, DoD Privacy Program (2014) and DoD 5400.11-R, DoD Privacy Program (2007).

i. **HIPAA Rules** means, collectively, the HIPAA Privacy, Security, Breach and Enforcement Rules, issued by the U.S. Department of Health and Human Services (HHS) and codified at 45 C.F.R. Parts 160 and 164, Subpart E (Privacy), Subpart C (Security), Subpart D (Breach) and 45 C.F.R. Part 160, Subparts C-D (Enforcement), as amended by the 2013 modifications to those Rules, implementing the “HITECH Act” provisions of Pub. L. 111-5. See 78 Fed. Reg. 5566-5702 (Jan. 25, 2013) (with corrections at 78 Fed. Reg. 32464 (June 7, 2013)). Additional HIPAA rules regarding electronic transactions and code sets (45 C.F.R. Part 162) are not addressed in this BAA and are not included in the term HIPAA Rules.

j. **HHS Breach** means a breach that satisfies the HIPAA Breach Rule definition of breach in 45 C.F.R. Part 164.402.

k. **Service-Level Privacy Office** means one or more offices within the military services (Army, Navy, or Air Force) with oversight authority over Privacy Act and HIPAA privacy compliance.
3. OBLIGATIONS AND ACTIVITIES OF BUSINESS ASSOCIATE

   a. The Business Associate shall not access, use or disclose PHI other than as permitted or required by this Agreement, the controlling memorandum of understanding (MOU) or training affiliation agreement (TAA), or as required by law.

   b. The Business Associate shall use appropriate safeguards and comply with the DoD HIPAA Rules with respect to electronic PHI to prevent use or disclosure of PHI other than as provided for by this Agreement, the controlling MOU, or law.

   c. The Business Associate shall report to the Covered Entity any Breach of which it becomes aware and shall proceed with breach response steps required by paragraph 7 (breach response) of this BAA. With respect to electronic PHI, the Business Associate shall also respond to any security incident of which it becomes aware in accordance with any Information Assurance provisions of the Agreement. If at any point the Business Associate becomes aware that a security incident involves a Breach, the Business Associate shall immediately initiate breach response as required by paragraph 7 (breach response) of this BAA.

   d. In accordance with 45 C.F.R. Parts 164.502(e)(1)(ii) and 164.308(b)(2), respectively, as applicable, the Business Associate shall ensure that any entities that create, receive, maintain, or transmit PHI on behalf of the Business Associate agree to the same restrictions, conditions, and requirements that apply to the Business Associate with respect to such PHI.

   e. The Business Associate shall make available PHI in a Designated Record Set, to the Covered Entity or, as directed by the Covered Entity, to an Individual, as necessary to satisfy the Covered Entity obligations under 45 C.F.R. Part 164.524.

   f. The Business Associate shall make any amendment(s) to PHI in a Designated Record Set as directed or agreed to by the Covered Entity pursuant to 45 C.F.R. Part 64.526, or take other measures as necessary to satisfy Covered Entity’s obligations under 45 C.F.R. Part 164.526.

   g. The Business Associate shall maintain and make available the information required to provide an accounting of disclosures to the Covered Entity or an individual as necessary to satisfy the Covered Entity’s obligations under 45 C.F.R. Part 164.528.

   h. To the extent the Business Associate is to carry out one or more of Covered Entity's obligation(s) under the HIPAA Privacy Rule, the Business Associate shall comply with the requirements of HIPAA Privacy Rule that apply to the Covered Entity in the performance of such obligation(s); and

   i. The Business Associate shall make its internal practices, books, and records available to the Secretary and the Covered Entity for purposes of audit and in determining compliance with the HIPAA Rules.
4. PERMITTED USES AND DISCLOSURES BY BUSINESS ASSOCIATE

   a. The Business Associate may only use or disclose PHI as necessary to perform the services set forth in the Agreement or as required by law. The Business Associate is not permitted to de-identify PHI under DoD HIPAA issuances or the corresponding 45 C.F.R. Part 164.514(a)-(c), nor is it permitted to use or disclose de-identified PHI, except as provided by the Agreement or directed by the Covered Entity.

   b. The Business Associate agrees to use, disclose, and request PHI only in accordance with the HIPAA Privacy Rule “minimum necessary” standard and corresponding DHA policies and procedures as stated in the DoD HIPAA issuances.

   c. The Business Associate shall not use or disclose PHI in a manner that would violate the DoD HIPAA issuances or HIPAA Privacy Rules if done by the Covered Entity, except uses and disclosures for the Business Associate’s own management and administration and legal responsibilities or for data aggregation services as set forth in the following three paragraphs:

      (1) Except as otherwise limited in the Agreement, the Business Associate may use PHI for the proper management and administration of the Business Associate or to carry out the legal responsibilities of the Business Associate. The foregoing authority to use PHI does not apply to disclosure of PHI, which is covered in the next paragraph.

      (2) Except as otherwise limited in the Agreement, the Business Associate may disclose PHI for the proper management and administration of the Business Associate or to carry out the legal responsibilities of the Business Associate, provided that disclosures are required by law, or the Business Associate obtains reasonable assurances from the person to whom the PHI is disclosed that it will remain confidential and used or further disclosed only as required by law or for the purposes for which it was disclosed to the person, and the person notifies the Business Associate of any instances of which it is aware in which the confidentiality of the information has been breached.

      (3) Except as otherwise limited in the Agreement, the Business Associate may use PHI to provide Data Aggregation services relating to the Covered Entity’s health care operations, 45 C.F.R. Part 164.504(e)(2)(i)(B).

5. PROVISIONS FOR COVERED ENTITY TO INFORM BUSINESS ASSOCIATE OF PRIVACY PRACTICES AND RESTRICTIONS

   a. The Covered Entity shall provide the Business Associate with the notice of privacy practices that the Covered Entity produces in accordance with 45 C.F.R. Part 164.520 and the corresponding provision of the DoD HIPAA issuances (DoD 6025.18-R).
b. The Covered Entity shall notify the Business Associate of any changes in, or revocation of, the permission by an individual to use or disclose his or her PHI, to the extent that such changes affect the Business Associate’s use or disclosure of PHI.

c. The Covered Entity shall notify the Business Associate of any restriction on the use or disclosure of PHI that the Covered Entity has agreed to or is required to abide by under 45 C.F.R. Part 164.522, to the extent that such changes may affect the Business Associate’s use or disclosure of PHI.

6. PERMISSIBLE REQUESTS BY COVERED ENTITY

a. The Covered Entity shall not request the Business Associate to use or disclose PHI in any manner that would not be permissible under the HIPAA Privacy Rule or any applicable Government regulations (including without limitation, DoD HIPAA issuances) if done by the Covered Entity.

b. Exceptions include providing Data Aggregation services to the Covered Entity and for management and administrative activities of the Business Associate as otherwise permitted by this BAA.

7. BREACH RESPONSE

a. General. Breach Response is designed to satisfy the DoD Privacy Act issuances and the HIPAA Breach Rule as implemented by the DoD HIPAA Issuances. In general, the Business Associate shall report the breach to the Covered Entity, assess the breach incident, notify affected individuals, and take mitigating actions, as applicable. Because DoD defines “breach” to include possible (suspected) as well as actual (confirmed) breaches, the Business Associate shall implement these breach response requirements immediately upon the Business Associate’s discovery of a possible breach. The following provisions set forth the Business Associate’s Privacy Act and HIPAA breach response requirements for all breaches, including but not limited to HHS breaches (defined below). In the event of a breach of PII/PHI held by the Business Associate, the Business Associate shall follow the breach response requirements set forth under paragraphs 7 through 9 of this BAA, which are designed to satisfy both the Privacy Act and HIPAA, as applicable.

   (1) If a breach involves PII without PHI, then the Business Associate shall comply with DoD Privacy Act issuance breach response requirements only.

   (2) If a breach involves PHI (a subset of PII), then the Business Associate shall comply with both Privacy Act and HIPAA breach response requirements.
(3) If a breach involves PHI, it may or may not constitute an HHS Breach. If a breach is not an HHS Breach, then the Business Associate has no HIPAA breach response obligations. In such cases, the Business Associate must still comply with breach response requirements under the DoD Privacy Act issuances.

b. HHS Breach. If the DHA Privacy Office determines that a breach is an HHS Breach, then the Business Associate shall comply with both the HIPAA Breach Rule and DoD Privacy Act issuances, as directed by the DHA Privacy Office, regardless of where the breach occurs.

c. Non-HHS Breach. If the DHA Privacy Office determines that the breach does not constitute an HHS Breach, then the Business Associate shall comply with DoD Privacy Act Issuances, as directed by the applicable Service-Level Privacy Office.

Contact Information for the applicable Service-Level Privacy Office is as follows:

Bureau of Medicine and Surgery
Detachment Jacksonville FL
(BUMED DET JAX)
BUMED-M3B1 Privacy Office
H2005 Knight Lane, P.O. Box 140
NAS Jacksonville, FL 32212
COMM: (904) 542-7200 ext. 8139
DSN: (312) 942-7200 ext. 8139
E-mail: usn.ncr.bumedfchva.list.bumed-pii-rpt@mail.mil

8. BREACH REPORTING FORMS

a. The Department of the Navy (DON) CIO memo of 19 April 2016 designates two forms for breach reporting within DON:

(1) SECNAV 5211/1 DON Loss or Compromise of Personally Identifiable Information (PII) Breach Reporting Form.

(2) SECNAV 5211/2 DON Loss or Compromise of Personally Identifiable Information (PII) After Action Reporting Form.


9. BREACH REPORTING PROVISIONS

   a. Business Associate. The Business Associate shall report the breach within 1 hour of discovery to the Service-Level Privacy Office above and within 24 hours of discovery to the DHA Privacy Office. The Business Associate is deemed to have discovered a breach as of the time a breach (suspected or confirmed) is known, or by exercising reasonable diligence would have been known, to any person (other than the person committing it) who is an employee, officer, or other agent of the Business Associate.

   b. Service-Level Privacy Office. The Service-Level Privacy Office or DHA Privacy Office, after review of a breach report, must notify the DON CIO, who shall determine which breaches to report to US-CERT and submit the US-CERT report using the online form at https://forms.us-cert.gov/report. Before submission to US-CERT, the DON CIO will be responsible for saving a copy of the on-line report. After submission, the DON CIO will be responsible for recording the US-CERT Reporting Number. Although only limited information about the breach may be available as of the 1 hour deadline for submission, the DON CIO will be responsible for submitting the US-CERT report by the deadline.

   c. U.S. Computer Emergency Readiness Team (US CERT). DON CIO memo of 19 April 2016 removed US CERT from automatic distribution for every DON breach reported. The DON CIO Privacy Team will now review breach reports submitted by the Service-Level Privacy Office and DHA Privacy Office and determine which to report to US CERT, under the Department of Homeland Security.

   d. Business Associate Report, due within 24 hours to DHA Privacy office, shall be submitted by completing the following DON PII breach reporting forms:

      (1) SECNAV 5211/1 (May 2016) (initial breach report only). E-mail buttons are provided with built-in distribution lists. For example, selecting the submit button on the electronic form will automatically forward the breach report to: DON Chief Information Officer Privacy Office, Director, Navy Staff (OPNAV DNS-36), Chief of Naval Information (CHINFO), Bureau of Medicine and Surgery (BUMED), and Defense Health Agency (DHA) Privacy office.

      (2) SECNAV 5211/2 (May 2016) (after action breach report, corrections, incomplete initial reports, and all other updates).

   e. Business Associate Notifications. The Business Associate shall e-mail initial and updated information as it is obtained to:
(1) Service-Level Privacy Office.


(3) Contracting Officer (CO) and Contracting Officer’s Representative (COR) as applicable. [If the Agreement is not a contract, delete these references to the CO and COR].

(4) Business Associate’s DoD point of contact (POC) unless the POC specifies another addressee for breach reporting.

f. Encryption of Reports. Encryption is not required because breach report forms should not contain PII/PHI. If e-mail is not available, telephone notification is also acceptable, but all notifications and reports delivered telephonically must be confirmed by e-mail as soon as technically feasible. The Business Associate shall not submit reports direct to US-CERT per CIO memo of 19 April 2016.

g. Multiple Beneficiaries. If multiple beneficiaries are affected by a single event or related set of events, then a single reportable breach may be deemed to have occurred, depending on the circumstances. The Business Associate shall inform the DHA Privacy Office as soon as possible if it believes that “single event” breach response is appropriate. The DHA Privacy Office will determine how the Business Associate shall proceed and, if appropriate, consolidate separately reported breaches for purposes of Business Associate report updates, beneficiary notification, and mitigation.

h. After Action Report. When the initial Breach Reporting Form, SECNAV 5211/1, is submitted incomplete or incorrect due to unavailable information, or when significant developments require an update, the Business Associate shall submit a SECNAV 5211/2, After Action Report, stating the updated status and previous report date(s). Examples of updated information the Business Associate shall report include, but are not limited to:

(1) Confirmation on the exact data elements involved.

(2) Root cause of the incident.

(3) Mitigation actions, including sanctions, training, incident containment, follow-up, etc.

i. Updates. The Business Associate shall submit these report updates promptly after the new information becomes available. Prompt reporting of updates is required to allow the DHA Privacy Office to make timely final determinations on any subsequent notifications or reports. The Business Associate shall provide updates to the same parties as required for the initial
Breach Reporting Form, SECNAV 5211/1. The Business Associate is responsible for reporting all information needed by the DHA Privacy Office to make timely and accurate determinations on reports to HHS as required by the HHS Breach Rule and reports to the Defense Privacy and Civil Liberties Office as required by DoD Privacy Act issuances.

j. Consultation. In the event the Business Associate is uncertain on how to apply the above requirements, the Business Associate shall consult with the DHA Privacy Office or the Service-Level Privacy Office when determinations on applying the above requirements are needed.

10. BREACH – INDIVIDUAL NOTIFICATION PROVISIONS

a. Determine if Notification is Required. If the DHA Privacy Office or DON CIO determines that individual notification is required, the Business Associate shall provide written notification to individuals affected by the breach as soon as possible, but no later than 10 working days after the breach is discovered and the identities of the individuals are ascertained. The 10-day period begins when the Business Associate is able to determine the identities (including addresses) of the individuals whose records were impacted.

b. Draft Proposed Notification. The Business Associate’s proposed notification to be issued to the affected individuals shall be submitted to the parties to which reports are submitted under paragraph 7 (breach response) for their review and for approval by the DHA Privacy Office. Upon request, the Business Associate shall provide the DHA Privacy Office with the final text of the notification letter sent to the affected individuals. If different groups of affected individuals receive different notification letters, then the Business Associate shall provide the text of the letter for each group. PII shall not be included with the text of the letter(s) provided. Copies of further correspondence with affected individuals need not be provided unless requested by the Privacy Office. The Business Associate’s notification to the individuals, at a minimum, must include the following:

1. Identify PII Lost. The individual(s) must be advised of what specific data was involved. It is insufficient to simply state that PII has been lost. Where names, social security numbers (SSNs) or truncated SSNs, and dates of birth (DOB) are involved, it is critical to advise the individual that these data elements potentially have been breached.

2. Inform. The affected individual(s) must be informed of the facts and circumstances surrounding the breach. The description should be sufficiently detailed so that the individual clearly understands how the breach occurred.

3. Protective Actions. The affected individual(s) must be informed of what protective actions the Business Associate is taking or the individual can take to mitigate against potential future harm. The notice must refer the individual to the current Federal Trade Commission (FTC) Web site pages on identity theft and the FTC’s Identity Theft Hotline:

(4) Credit Monitoring. The individual(s) must also be informed of any mitigating support services (e.g., 1 year of free credit monitoring, identification of fraud expense coverage for affected individuals, provision of credit freezes, etc.) that the Business Associate may offer affected individuals, the process to follow to obtain those services, the period of time the services will be made available, and contact information (including a phone number, either direct or toll-free, e-mail address and postal address) for obtaining more information. Paragraph 9d below refers.

(5) Labeling. Business Associates must ensure any envelope containing written notifications to affected individuals are clearly labeled to alert the recipient to the importance of its contents, e.g., “Data Breach Information Enclosed,” and that the envelope is marked with the identity of the Business Associate and/or subcontractor organization that suffered the breach. The letter must also include contact information for a designated POC to include, phone number, e-mail address, and postal address.

c. Notification Within 10 Days. If the Business Associate determines that it cannot readily identify, or will be unable to reach, some affected individuals within the 10-day period after discovering the breach, the Business Associate shall so indicate in the Initial Breach Report on SECNAV 5211/1 or After Breach Report on SECNAV 5211/2. Within the 10-day period, the Business Associate shall provide the approved notification to those individuals who can be reached. Other individuals must be notified within 10 days after their identities and addresses are ascertained. The Business Associate shall consult with the DHA Privacy Office, who will determine which media notice is most likely to reach the population not otherwise identified or reached. The Business Associate shall issue a generalized media notice(s) to that population in accordance with Privacy Office approval.

d. Costs. The Business Associate shall, at no cost to the government, bear any costs associated with a breach of PII/PHI that the Business Associate has caused or is otherwise responsible for addressing.

e. Security Incident versus Breach. Breaches are not to be confused with security incidents (often referred to as cyber security incidents when electronic information is involved), which may or may not involve a breach of PII/PHI. In the event of a security incident not involving a PII/PHI breach, the Business Associate shall follow applicable DoD Cybersecurity requirements under its Agreement. If at any point the Business Associate finds that a cyber security incident involves a PII/PHI breach (suspected or confirmed), the Business Associate shall immediately initiate the breach response procedures set forth herein. The Business Associate shall also continue to follow any required cyber security incident response procedures to the extent needed to address security issues, as determined by DoD/DHA.
11. TERMINATION

a. **Termination.** Noncompliance by the Business Associate (or any of its staff, agents, or subcontractors) with any requirements in this BAA may subject the Business Associate to termination under any applicable default or other termination provision of the Agreement.

b. **Effect of Termination**

   (1) If the Agreement has records management requirements, the Business Associate shall handle such records in accordance with the records management requirements. If the Agreement does not have records management requirements, the records should be handled in accordance with subparagraphs (2) and (3) below. If the Agreement has provisions for transfer of records and PII/PHI to a successor Business Associate or if DHA gives directions for such transfer, the Business Associate shall handle such records and information in accordance with such Agreement provisions or DHA direction.

   (2) If the Agreement does not have records management requirements, except as provided in the following paragraph (3), upon termination of the Agreement, for any reason, the Business Associate shall return or destroy all PHI received from the Covered Entity, or created or received by the Business Associate on behalf of the Covered Entity that the Business Associate still maintains in any form. This provision shall apply to PHI that is in the possession of subcontractors or agents of the Business Associate. The Business Associate must not retain copies of the PHI.

   (3) If the Agreement does not have records management provisions and the Business Associate determines that returning or destroying the PHI is infeasible, the Business Associate shall provide to the Covered Entity notification of the conditions that make return or destruction infeasible. Upon mutual agreement of the Covered Entity and the Business Associate that return or destruction of PHI is infeasible, the Business Associate shall extend the protections of the Agreement to such PHI and limit further uses and disclosures of such PHI to those purposes that make the return or destruction infeasible, for so long as the Business Associate maintains such PHI.

c. **Survival.** The obligations of Business Associate under the “Effect of Termination” provision of this BAA shall survive the termination of the Agreement.

12. MISCELLANEOUS INTERPRETATION. Any ambiguity in the Agreement shall be resolved in favor of a meaning that permits the Covered Entity and the Business Associate to comply with HIPAA and the DoD HIPAA Rules.
For Federal or Non-Federal Entity:

NAME (caps)
Title
Civilian Agency

For Navy Medicine:

NAME (caps)
Rank, Corps, USN
Title,
Military Facility
CHECKLIST FOR SCREENING ACTIVE DUTY LIVING DONOR SERVICE MEMBERS

☐ 1. Written request from Service member to be a living organ donor in a military or
civilian hospital, stating that he/she has been counseled and accepts the risk(s) of
donation.
☐ 2. Prospective donor’s name, rank, military identification number, home and work
phone, unit address/phone/fax.
☐ 3. Statement signed by Service member acknowledging that the military is not
responsible for any costs associated with a transplant performed in a civilian institution
except when the recipient is a Tricare beneficiary, in which case TRICARE assumes
fiscal responsibility of both donor and recipient.
☐ 4. Statement by Service member that follow-up medical evaluation by a military
medical physician will be completed between 6 and 12 months after donation.
☐ 5. Letter from Service member’s commander/commanding officer approving the request
to donate.
☐ 6. Intended recipient’s name and relationship to the donor.
☐ 7. A signed statement from attending physician associated with the transplant facility,
which provides the recipient’s diagnosis, prognosis, and verifies that no other donor is
available.
☐ 8. Name, office address, and telephone number of the attending physician(s) for both the
donor and recipient.
☐ 9. Name, address, and phone number of the intended operative facility.
☐ 10. 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.
☐ 11. Copy of the DD 2807-1 and DD 2808 completed within 90 days preceding the
request to donate.
☐ 12. 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 urinalysis result, donor’s 5-day
blood pressure readings, height/weight, and imaging studies for kidney or liver donors.
☐ 13. If the donor is over 45 years of age, a copy of the cardiac risk assessment is required.
SUPPLEMENTAL HEALTH CARE PROGRAM WAIVER INSTRUCTIONS

1. Supplemental Health Care Program (SHCP) Waiver Instructions
   a. The SCHP provides coverage by civilian health care providers to AD Service members and designated non-TRICARE eligible patients. Although authorizations and claims processing are administered by the TRICARE contractors, it is funded separately by the DoD and follows different rules than TRICARE. See http://www.health.mil/Military-Health-Topics/Access-Cost-Quality-and-Safety/Access-to-Healthcare/Supplemental-Health-Care-Program.
   b. Waivers must be submitted per enclosure (12).
   c. Hand written waivers are not accepted.
   d. Waivers contain protected patient health information and must be encrypted when sent electronically.
   e. Regions are responsible for ensuring the waiver submission is accurate and complete.
   f. Incomplete waivers will be returned.
   g. The DHA will not accept waivers that have not been endorsed by the appointment representatives at BUMED.
   h. Special waiver cases:
      (1) For in-vitro fertilization requests, benefit verification is authorized at the clinical support division level. See TRICARE Operations Manual, chapter 17, section 3, 2.6 for information on the waiver process and criteria.
      (2) For waivers authorizing seriously ill or injured AD Service members to participate in non-cancer clinical trials, see Assistant Secretary of Defense (Health Affairs) memorandum of 9 May 2012 for guidance. It is titled, “Procedures for Allowing Seriously Ill or Injured Active Duty Service Members and Medically Retired Former Members Enrolled in the Federal Recovery Coordination Program to Participate in Non-Cancer Clinical Trials Involving Emerging Medical Technologies and Treatments.” (Note: Effective 31 December 2012, this policy does not apply to non-AD Service Members).

2. Waiver Format Instructions. AD Service member waivers may be submitted for non-Tricare covered medical care, medical equipment or non-authorized TRICARE facilities/providers.
a. Describe what medical care, medical equipment item, or non-authorized TRICARE provider is being requested. Be certain to include applicable Healthcare Common Procedure Coding System code(s).

b. Clinical history must include the following (as appropriate to support requested service, medical equipment, or non-authorized TRICARE provider):

   (1) History of present illness/condition (include age, sex, and current military duty).
   
   (2) What treatment(s) have been tried and were unsuccessful.
   
   (3) Current medications.
   
   (4) Relevant past medical history.
   
   (5) Results of consultations (Include copy of consultation).
   
   (6) Results of relevant laboratory, radiological, and other ancillary studies.
   
   (7) Any duty limitations due to condition.
   
   (8) If appropriate photographs can be submitted, include where and when photograph was taken.

c. Medical equipment requests must include the following (use N/A if not applicable):

   (1) Include cost of item.
   
   (2) For some medical equipment items medical evidence may not be available or necessary but will need discussion of medical justification.

d. If the request is to utilize a non-authorized TRICARE provider, the following must be included:

   (1) Was the health care service not available at another MTF, authorized TRICARE provider, or Department of Veterans Affairs (if applicable)?
   
   (2) Memorandum of Agreement between the Department of Veterans Affairs and DoD for Medical Treatment Provided to AD Service members with spinal cord injury, traumatic brain injury, blindness, or polytraumatic injuries (TRICARE Operations Manual, Chapter 17, Addendum D)

e. Medical evidence to support the waiver request is strongly encouraged. The DHA reviews each waiver individually and will not “attach” evidence to support your request.
(1) Acceptable examples include:

   (a) Well-controlled studies of clinically meaningful endpoints, published in referenced medical literature.

   (b) Published formal technology assessments.

   (c) Published reports of national professional medical associations.

   (d) Published national medical policy organization positions.

   (e) Published reports of national expert opinion organizations.

(2) Case studies and review articles (provide as attachment).

(3) Supporting articles/reports (provide as attachment).

f. Medical justification and impact of the requested medical service to the member’s ability to return to full fitness for duty and readiness must be included in addition to:

   (1) Description of the anticipated benefit on the Service member’s condition.

   (2) Reason the requested care is preferred over current standard treatment and how it compares to safety and efficacy over current standard treatment.

   (3) Case studies and review articles (provide as attachment).

   (4) Supporting articles/reports (provide as attachment).

   (5) For medical equipment items, describe the medical necessity for the requested item(s) for Service member’s condition and recovery.

   (6) For care with a non-authorized TRICARE provider, describe medical necessity to utilize this provider.

   (7) Describe the potential impact of the requested health care service or provider on Service member’s fitness for duty and military readiness.

  g. Point of Contact Information:

       (1) Please include name, phone number, and e-mail address. Final determination of the request will be forwarded to this point of contact.
(2) Recommendations and Service endorsement:

(3) Navy Medicine clinical specialty leader input and recommendation is required. The Specialty Leader is the first level of review, and must support the request in order for the waiver to be submitted to the Navy Medicine Region.

(4) Navy Medicine regions must support the waiver request, otherwise the waiver is not submitted to BUMED Head, Healthcare Business and Administration Office (M31).

(5) BUMED M31 will review the waiver and send it to the BUMED Chief Medical officer for endorsement. BUMED (M31) must either endorse the waiver request and submit it to the DHA or not support the waiver request; do not forward to the DHA.

3. Waiver requests supported by the appropriate clinical specialty leader must be forwarded to the responsible Navy Medicine region:

   a. Navy Medicine East, Navy Medicine East, 620 John Paul Jones Circle, Building 3, Suite 1400, Portsmouth, VA 23708

   b. Navy Medicine West, Navy Medicine West, 4170 Norman Scott Road, Suite 5, San Diego, CA 92136-5521

4. Forward waiver requests that are supported by the responsible NAVMED region to:

   BUMED-(M31), e-mail: usn.ncr.bumedfchva.list.healthcare-delivery@mail.mil
REQUEST TO USE SUPPLEMENTAL HEALTH CARE PROGRAM FUNDS ICO

From: [Name of Requesting Official]
To:  Director, Defense Health Agency
Via: (1) [Navy Medicine Clinical Specialty Leader]
     (2) [Navy Medicine Region]
     (3) [Chief, Bureau of Medicine and Surgery (BUMED-M3)]

Subj:  REQUEST TO USE SUPPLEMENTAL HEALTH CARE PROGRAM FUNDS ICO
       [Rank/name of active duty Service member, duty location]

1. This is a request for the Director, Defense Health Agency to approve the use of Supplemental Health Care Program funds for [name of drug, device, medical equipment, medical treatment, medical procedure, or a non-authorized Tricare provider].

2. Describe what healthcare service, medical equipment item, or non-authorized TRICARE provider is being requested. Include applicable current procedural terminology/health care common procedure coding system code(s):

3. Clinical history (as appropriate to support requested service, medical equipment, or non-authorized TRICARE provider):

4. Medical equipment (N/A if Not applicable):

5. Unauthorized facility/provider (if applicable):

SIGNATURE BLOCK
(Print Name of Requesting Official)
ACRONYMS

AD     Active Duty
AFME   Armed Forces Medical Examiner
AFMES  Armed Forces Medical Examiner System
BUMED  Bureau of Medicine and Surgery
CACO   Casualty Assistance Calls Officer
CDO    Command Duty Officer
CMC    Commandant of the Marine Corps
CO     Commanding Officer
CONUS  Continental United States
DOB    Date of Birth
DEERS  Defense Eligibility Enrollment Reporting System
DHA    Defense Health Agency
DoD    Department of Defense
DTF    Dental Treatment Facility
HHS    Health and Human Services
MOU    Memorandum of Understanding
MTF    Medical Treatment Facility
NAVMED Navy Medicine
NHBD   Non-Heart Beating Donor
NOK    Next of Kin
OIC    Officer in Charge
OCONUS Outside Continental United States
OPO    Organ Procurement Organization
OPTN   Organ Procurement and Transplantation Network
SHCP   Supplemental Health Care Program
SSN    Social Security Number
UAGA   Uniform Anatomical Gift Act
UNOS   United Network for Organ Sharing