

DEPARTMENT OF THE NAVY BUREAU OF MEDICINE AND SURGERY 2300 E STREET NW WASHINGTON DC 20372-5300

IN REPLY REFER TO BUMEDINST 7050.3A BUMED-M7 15 Sep 2004

BUMED INSTRUCTION 7050.3A

From: Chief, Bureau of Medicine and Surgery

Subj: TRAINING AFFILIATION AGREEMENT (TAA) PROGRAM

- (a) BUMEDINST 7050.1
 - (b) BUMEDINST 1500.19A
 - (c) Title 28, USC, section 2679 (Westfall Act) (NOTAL)

Encl:

Ref:

- (1) Sample MOU for Navy Trainees at Civilian Institutions
 - (2) Sample MOU for Two-Way Exchange of Trainees Between Navy and Civilian Institutions
 - (3) Sample MOU for Civilian Trainees at Naval Medical Department Activities
 - (4) Sample Civilian Trainee Agreement Addendum

1. <u>Purpose</u>. To provide the procedural requirements for negotiating and establishing TAAs between Naval Medical Department activities and civilian institutions (Federal or non-federal). Memoranda of Understanding (MOUs) not involving TAAs are covered by reference (a).

2. Cancellation. BUMEDINST 7050.3.

3. <u>Background</u>. Health care education and training programs for Naval Medical Department officers and enlisted personnel are vital in administering competent health care support to the Operating Forces of the Navy and Marine Corps and providing quality health care to eligible beneficiaries. Certain professional educational training cannot be accomplished exclusively within the Department of the Navy. Full-time outservice (FTOS), other Federal institution (OFI), and integral parts of training (IPOT) for full-time inservice (FTIS) programs afford Naval Medical Department personnel the ability to train to mission requirements.

a. For the benefit of the Navy, Naval Medical Department activities may enter into agreements that allow civilian trainees to take part in clinical rotations at Medical Department activities.

b. The U.S. Department of Justice (DOJ) requires that Medical Department activities entering into TAAs make every effort to have military as well as civilian trainees covered under the civilian facilities' insurance programs. DOJ substitutes the United States as the party to the lawsuit in lieu of the military provider. However, DOJ requires proof that the military provider was acting in an official capacity. The evidence or proof required consists of the member's official temporary duty (TEMDU) orders or permanent change of station (PCS) orders for training and the TAA or MOU between the Service and the civilian institution. Enclosures (1) through (3) of this instruction provide template agreements for training military providers at civilian institutions and the exchange of trainees for training purposes, and the training of civilian providers at Naval institutions.

c. All training agreements must use this template agreement language and individual military treatment facility (MTF) commanders are not authorized to deviate from this language. Should a civilian institution or MTF desire a modification to these agreements, the changes *must* be approved by the Bureau of Medicine and Surgery (BUMED) Office of the Staff Judge Advocate (JAG) and may not be approved locally.

4. <u>Types of Agreements</u>. There are three general types of TAAs:

a. <u>Navy Trainees at Civilian Institutions, (See Enclosure (1))</u>. There are two categories of Navy trainee TAAs:

(1) <u>Full-Time Outservice Training</u>. Provides for Navy trainees to attend a civilian institution while under the auspice of an FTOS program managed by the Naval Medical Education and Training Command (NMETC), Bethesda, MD. These TAAs will be negotiated and approved by NMETC. In addition, establishment of a TAA or MOU at Federal/non-military institutions is necessary and this template agreement must be used as the framework for the MOU. Requested modifications to the template's language must be approved by BUMED JAG.

(2) <u>Integral Parts of Training</u>. Provides for a Navy trainee to engage in clinical learning experiences at qualified civilian institutions while participating in an FTIS program. These TAAs will be negotiated and approved by the Naval Medical Department activity where the training program is established, reference (b). It is necessary to establish a TAA for an IPOT when clinical care is provided by the Navy trainee at a civilian or a Federal/non-military institution. It is not necessary to establish a TAA when the IPOT is a short-term instructional conference where no clinical care is provided.

b. <u>Two-Way Exchange of Trainees Between Navy and Civilian Institutions, (See</u> <u>Enclosure (2)</u>). Provides for a reciprocal exchange of trainees for the mutual benefit of the two institutions. Typically, this formal agreement is established between a Naval Medical Department activity and a civilian (non-Federal) institution for an IPOT. These TAAs are negotiated and approved by the Naval Medical Department activity.

c. <u>Civilian Trainees at Naval Medical Department Activities, (See Enclosure (3))</u>. A formal agreement between a Naval Medical Department activity and a civilian or Federal/non-military institution that specifies that a civilian trainee associated with the civilian institution will participate in clinical learning experiences at the Naval Medical Department activity. These agreements are negotiated and approved by Naval Medical Department activities. The civilian trainee shall sign and date the "Civilian Trainee Agreement Addendum" if training at a Navy MTF. (See enclosure (4).)

5. General Criteria for Establishing TAAs. TAAs shall:

a. Be negotiated in the best interest of the Navy.

b. Be written as an MOU, using the samples in enclosures (1) through (3). TAAs may vary between Naval Medical Department activities and other institutions depending on the nature of the particular type of affiliation. The sample MOUs use the abbreviation "MTF" to indicate the Navy party to the Agreement. Other entities may be substituted, as appropriate.

c. Be negotiated for a training program approved by the Navy and applicable national accrediting or recognizing agencies.

d. Contain effective time periods and termination provisions. Generally, agreements should be subject to termination on 30-days written notice by either party and state that the Chief, BUMED may terminate the Agreement based on Navy-mission requirements at any time. The Naval Medical Department activity shall retain the authority to refuse to accept trainees, or to modify assignments or schedules of any trainee as necessary for the orderly operation of the Naval Medical Department activity as dictated by Navy-mission requirements.

e. Not require expenditure of Navy funds other than incidental expenses related to an agreement. Incidental expenses include, but are not limited to, a military trainee's pay, entitlements, tuition fees, approved travel and fees for required rotations, and use of Government-owned property. Any funds exchanged between Services or between Navy facilities must be documented on a DD 1144 (1 Apr 78), Support Agreement. However, if the Navy Medical Department is purchasing tuition from an institution, contract procedures must be followed rather than an MOU.

f. Require that each civilian trainee of the affiliating institution sign the training Agreement addendum, enclosure (4), when training on a Navy MTF.

g. Not result in displacing employees or impairing existing contracts for services.

6. Liability Requirements

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a. The Naval Medical Department activity must establish responsibility between parties for potential liability for any negligent act or omission by the trainee or faculty member. The affiliation Agreement should obtain the broadest possible protection for the Navy. The MOU must include the following basic liability requirements:

(1) <u>Navy Trainees at Civilian Institutions</u>. The civilian institution will establish and maintain professional liability or malpractice coverage through some form of insurance protection that covers the Navy trainees while at the civilian institution. This protection may be provided by the institution (contracted or self-insurance), State statutes, hospital bylaws, or other sources. The protection must apply to the Navy trainee and any liability producing act or omission by the trainee at the civilian institution. This liability coverage must be in amounts that are reasonable and customary in the community for the applicable specialty. If there is any question as to the extent of the coverage, obtain clarification from the appropriate authority within the institution or State government. Attach documentary proof of the coverage. If the civilian institution is "self-insured" and prohibited by State law in providing malpractice insurance to non-salaried employees (such as the Navy trainee) or the institution refuses to provide coverage, contact BUMED JAG office for guidance and recommendations.

(2) <u>Two-Way Exchange of Trainees Between Navy and Civilian Institutions</u>. Each party is usually held responsible for its own trainees. Navy trainees will be protected by reference (c), as long as they are acting within the scope of their Federal employment. Civilian trainees will be protected by the civilian institution through some form of liability protection, covering civilian faculty and trainees while at the Navy facility. This protection may be provided by the institution (contract or self-insurance), the faculty and trainees themselves, State statutes, hospital bylaws, or other sources. The protection must apply to the trainee and any liability producing act or omission by the trainee while at the Navy facility. The liability coverage must be in amounts that are reasonable and customary in the community for the applicable specialty. If there is a question as to the extent of the coverage, obtain clarification from the appropriate authority within the institution or State government. The approving authority will assess the adequacy of the coverage in light of tort liability experience for the type of training involved.

(3) <u>Civilian Trainees at Naval Medical Department Activities</u>. The civilian institution will establish and maintain professional liability or malpractice coverage through some form of insurance protection which covers civilian faculty and trainees while at the Navy facility. This protection may be provided by the institution (contract or self-insurance), the faculty and trainees themselves, State statutes, hospital bylaws, or other sources. The protection must apply to the civilian trainee and any liability producing act or omission by the trainee while at the Navy facility. The liability coverage must be in amounts that are reasonable and customary in the community for the applicable specialty. If there is a question as to the extent of the coverage, obtain clarification from the appropriate authority within the institution or State government. Documentary proof of the coverage and the source of coverage shall be attached to the Agreement. The approving authority will assess the adequacy of the coverage in light of tort liability experience for the type of training involved.

b. Navy trainces are protected by reference (c), as long as they are acting within the scope of their Federal employment. To ensure trainees are acting within the scope of their employment with the Navy, they must be issued temporary additional duty (TAD), TEMDU, or PCS orders. TAD orders may be no-cost, but shall not be permissive TAD.

c. The Agreement must be signed by both parties before trainees may receive orders or participate in any form of clinical care.

7: Approval of TAAs

a. NMETC is responsible for graduate education training and shall negotiate and approve TAAs under their supervision using the sample Agreements. NMETC program managers shall forward requests for TAA/MOU modifications directly to BUMED JAG for review and approval. Any changes to long-term Agreements shall be forwarded to BUMED JAG for review every 3 years.

b. Local commands that provide training for FTIS programs shall negotiate and approve TAAs for Navy trainees that require clinical rotations at civilian institutions, generally defined as IPOT.

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c. Naval Medical Department activities shall negotiate and approve those TAAs involving civilian trainees participating in clinical learning experiences at the Naval Medical Department activity.

8. Processing of TAAs

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a. Ensure all MOUs include the statement: "This written Agreement embodies the entire terms and understanding of the parties regarding this affiliation, and no other agreements exist between parties except as herein expressly set forth."

b. Ensure all MOUs include the names of each facility entering into Agreement with complete addresses of each.

c. Ensure the named official of the civilian affiliating institution that has authority to bind the institution to its terms, signs the written Agreement. The authority to bind shall be stated or otherwise evidenced on the signature page.

d. Ensure the commanding officer of the Naval Medical Department activity signs the MOU and specifies a facility point of contact.

e. Ensure that if an existing MOU includes an addendum for additional training, arrangements for the liability coverage do not change.

f. Ensure the MOU clearly states that the Navy trainee is under the supervision of the civilian facility officials for training purposes. In the event that a Navy trainee is required to rotate to another civilian training institution to successfully complete a training program, the supervision of the Navy trainee established in the MOU remains intact.

g. Ensure each MOU, regardless of type, includes the Business Associate Agreement, Åppendix A, as required by Department of Defense (DOD) Instruction 6025.18 and DOD 6025.18-R. (See enclosures (1) through (3).)

9. Review of TAAs

a. Naval Medical Department activities shall review their respective Agreements for appropriateness and currency every 3 years. All Naval Medical Department activities shall maintain up-to-date copies of their MOU. During their periodic review, the Medical Department activity shall change existing Agreements to the format indicated in this instruction.

b. NMETC shall request an annual review and approval of the MOU samples by BUMED JAG to appropriately manage the high volume of new Agreements established each academic year by this command.

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c. Naval Medical Department activities shall ensure that their local command JAG reviews the proposed Agreement and specifically assesses the adequacy of insurance and indemnification provisions relevant for the particular training contemplated by the Government. BUMED JAG shall review the appropriateness and sufficiency of any waiver or modification requests.

10. Deviation From Standard MOU Language

All deviations from standard MOU language shall be reviewed and approved by BUMED JAG.

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b. If the training institution cannot or will not agree to liability/malpractice coverage for the Navy trainee, BUMED JAG will determine whether a waiver may be approved. There are some circumstances where the civilian training institution is prohibited from providing malpractice insurance to non-salaried employees by State law. In certain circumstances, it may be in the best interest of the Navy to allow the Navy trainee to train at the civilian institution, even without the civilian malpractice coverage, as the trainee is still covered under the Federal Tort Claims Act and is receiving training under military orders.

11. Waivers. A request for waiver must be submitted, in writing, if the liability language in the proposed MOU is altered, or if significant changes to the MOU are requested. Send request to Chief, Bureau of Medicine and Surgery (M00J), 2300 E Street, NW, Washington, DC 20372-5300, or fax (202) 762-3092.

a. The Naval Medical Department activity must clearly specify the proposed changes on the Agreement and state the reasons for the waiver request. The requested modifications should be highlighted and easy to recognize.

b. The Naval Medical Department activity should determine the impact on the training program, its accreditation status, or its mission if the proposed TAA is not approved.

c. The local Naval Medical Department JAG must review the request for waiver and forward the proposed Agreement, request for waiver, supporting documents and recommendation to Chief, Bureau of Medicine and Surgery (M00J), 2300 E Street, NW, Washington, DC 20372-5300 for decision on the request for waiver and approval of Agreement. ۹.

d. Chief, BUMED (M00J) is the TAA waiver authority.

12. Form. DD 1144 (1 Apr 78), Support Agreement, can be found in electronic format at http://www.dior.whs.mil/forms/DD1144.pdf.

D. C. ARTHUR

Distribution: (See next page.)

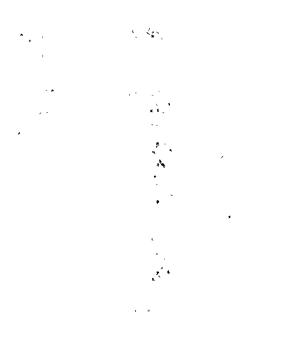
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SAMPLE MOU FOR NAVY TRAINEES AT CIVILIAN TRAINING INSTITUTIONS

MEMORANDUM OF UNDERSTANDING FOR NAVY TRAINEE BETWEEN (NAME OF NAVY MTF) AND (NAME OF CIVILIAN TRAINING INSTITUTION) (CITY AND STATE)

Subj: MEMORANDUM OF UNDERSTANDING

Ref: (a) BUMEDINST 7050.3A

1. This Agreement is entered into by and between (name of Navy MTF), hereafter (abbreviation of Navy MTF), and _____ (name of civilian training institution), hereafter referred to as "training institution."

2. The administrators of the training institution have established an approved professional program that has been recognized, accredited, or certified by the appropriate accrediting agencies, as applicable. The specific nature of this program is to train ______ (name of trainee), hereinafter "the trainee," in a ______ (timeframe) ______ (residency, fellowship, or clinical rotation) program from ______ (month/year) to ______ (month/year).

3. 'It is in the best interest of the U.S. Navy for its trainee to receive clinical experience from the training institution. This clinical experience is necessary to complete the training program and deemed invaluable to the educational preparation of Medical Department personnel of the U.S. Navy. It is to the benefit of the training institution to receive and use the trainee's clinical experience and performance.

4. The parties acknowledge and agree to the following:

a. While training at the training institution, the trainee will be under the supervision of facility officials for training purposes and will be subject to and required to abide by all facility rules and applicable regulations, except where compliance would be inconsistent with Federal statute, regulation, or any other law binding members of the U.S. Navy.

b. This program will not result in, nor is it meant to displace employees or impair existing contracts for services.

c. The number and assignment of trainees will be mutually agreed upon between (name of Navy MTF) and the training institution prior to the beginning of each training period. The training institution reserves the right to refuse acceptance of any trainee or bar any trainee when it is determined that further participation would not be in the best interest of the training institution.

Subj: MEMORANDUM OF UNDERSTANDING

d. The training institution will not use (name of Navy MTF) or the name of the trainee in any of their publicity or advertising media. However, the existence and scope of the program may be made known.

e. There will be no training expense incurred by the U.S. Navy as a result of this Agreement, with the exception of necessary tuition and fees, as applicable. Additionally, the trainee assigned under this MOU receives compensation from the U.S. Navy only, and is prohibited from receiving compensation, in any form, from the training institution or any other source.

f. In the event that training institution policy requires that trainees in the same or similar programs are individually responsible for financing the cost of meetings, courses, or travel to certain clinical or nonclinical rotations, trainees may request funding from appropriate military sources via their administrative chain of command. Only those meetings, courses, or certain clinical or nonclinical rotations required and necessary for the trainee to satisfactorily complete the program will be considered.

g. It is understood and agreed that the training institution may generate bills for services rendered by the trainee. Proceeds from these bills will become the exclusive property of the training institution, and the U.S. Navy shall have no right to claims to such proceeds. Notwith-standing the above, as required by 32 Code of Federal Regulations (CFR) §199.6(a)(3), the training institution cannot bill under the TRICARE Program for the services rendered by a U.S. Navy trainee.

h. The trainee affected by this Agreement, assigned to the training institution, under orders issued by the U.S: Navy, remains an employee of the United States and performs duties within the course and scope of the Federal employment. Consequently, the provisions of the Federal Tort Claims Act (title 28, USC, sections 1346(b), 2671-2680), including its defenses and immunities, will apply to allegations of negligence or wrongful acts or omissions of the trainee while acting within the scope of duties pursuant to this Agreement.

i. The parties understand and agree that consistent with the Federal statute and the Federal Acquisition Regulation (FAR), the U.S. Navy trainee performing under this Agreement is not required to satisfy the State of the training institution's temporary or permanent licensure requirements. Under the provision of 10 USC 1

(a) Notwithstanding any law regarding the licensure of a U.S. Navy trainee, a health care professional described in paragraph (2), may practice the health profession or professions of the health care professional in any State, District of Columbia, or a Commonwealth, territory, or

Subj: MEMORANDUM OF UNDERSTANDING

possession of the U.S., regardless of whether the practice occurs in a health care facility of the Department of Defense, a civilian facility affiliated with the Department of Defense, or any other location authorized by the Secretary of Defense.

(b) A health care professional referred to in paragraph (1) is a member of the Armed Forces who:

<u>1</u>. Has a current license to practice medicine, osteopathic medicine, dentistry, or another health profession.

2. Is performing authorized duties for the Department of Defense.

(2) (name of Navy MTF), in accordance with the requirements of 10 USC \$\$1094(4)(d)(1) and (2), authorizes the training location and duties of the U.S. Navy trainee at (name of civilian facility), as he or she will be performing his or her duties under military orders issued by the U.S. Navy.

j. <u>Health Information Privacy</u>. Pursuant to DOD Instruction 6025.18, Privacy of Individually Identifiable Health Information in DOD Health Care Programs, December 19, 2002, DOD 6025.18-R, and 45 CFR Parts 160 and 164, the parties agree to enter into a Business Associate Agreement, attached as Appendix A to this agreement.

5. <u>Affiliating Institution's Responsibilities</u>. In addition to other provisions in this Agreement, the training institution specifically agrees to:

a. Make available the clinical and related facilities needed for training.

b. Arrange schedules that will not conflict with other education programs.

c. Designate an official to coordinate trainee's clinical learning experiences. This will involve planning with faculty or staff members for the assignment of the trainee to specific clinical cases and experiences, including attendance at selected conferences, courses, and programs conducted under the direction of the training institution.

d. Provide reasonable classroom, conference, office, storage, dressing, and locker room space for participating trainee.

e. Grant U.S. Navy trainee the same administrative privileges typically enjoyed by the training institution's non-military trainees.

f. Permit, on reasonable request, the inspection of clinical and related facilities by government agencies or other agencies charged with the responsibility for accreditation of the U.S. Navy's educational programs.

Subj: MEMORANDUM OF UNDERSTANDING

g. Provide emergency medical and dental treatment to the trainee while at the training institution for training. The reasonable cost of such treatment will be paid for by the U.S. Navy.

h. Provide professional liability (malpractice) coverage in amounts that are reasonable and customary in the community for the appropriate specialty, covering liability for personal injury and property damage, including legal representation and expense of defense of any such liability claims, actions, or litigation resulting from participation by the trainee or faculty under this Agreement. This coverage may come from any source, but shall clearly cover the trainee while participating under this Agreement at the training institution. The training institution agrees that if it intends to change such liability coverage during the tenure of this Agreement in a way that will affect the protection provided to the trainee, then the training institution will notify (name of Navy MTF) in writing, at least 45 days prior to the effective

date of the change, specifying the change intended to be made. The training institution must provide documentary proof of the insurance coverage and such documentary proof will be attached to this Agreement.

i. The training institution further agrees not to seek indemnification from either the United States, the U.S. Navy, or the trainee for any settlement, verdict, or judgment resulting from any claim or lawsuit arising out of the performance of the trainee's professional duties while acting under the control of the training institution and its employees.

j. Furnish an annual written report evaluating trainee performance. Reports shall be directed to ______ (Name and address of Navy MTF).

a. Ensure compliance with all training institution's rules and applicable instructions that are not inconsistent with Federal statutes, regulations, or other law binding on the U.S. Navy.

b. The U.S. Navy shall be responsible for the health care and such other medical examinations and protective measures necessary for its trainee.

7. It is expressly agreed that this written statement embodies the entire agreement of the parties regarding this affiliation, and no other agreements exist between the parties except as herein expressly set forth. Any changes or modifications to this Agreement must be in writing and be signed by both parties.

Subj: MEMORANDUM OF UNDERSTANDING

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8. It is understood that the Chief, Bureau of Medicine and Surgery will have the right to terminate this affiliation agreement without notice at any time, if determined necessary to be in the interests of the Navy's mission requirements.

9. The terms of this Agreement will commence as of the date signed by both parties, and will continue until completion of training or until terminated by either party. Termination by either party will require written notification be sent by registered mail 30 days prior to termination date.

 Date
 Signature and Title of Official authorized to approve Agreement for USN MTF

 Date
 Signature and Title of Official authorized to approve Agreement for affiliating institution

 Facility Point of Contact
 Telephone Number

APPENDIX A BUSINESS ASSOCIATE AGREEMENT PRIVACY OF PROTECTED HEALTH INFORMATION

1. Definitions. As used in this Appendix:

a. <u>Business Associate</u> has the same meaning as the term "Business Associate" in 45 CFR 160.103.

b. <u>Covered Entity</u> has the same meaning as the term "Covered Entity" in 45 CFR 160.103.

c. <u>Individual</u> has the same meaning as the term "individual" in 45 CFR 164.501 and shall include a person who qualifies as a personal representative in accordance with 45 CFR 164.502(g).

d. <u>Privacy Rule</u> means the Standards for Privacy of Individually Identifiable Health Information at 45 CFR part 160 and part 164, subparts A and E.

e. <u>Protected Health Information</u> has the same meaning as the term "protected health information" in 45 CFR 164.501, limited to the information created or received by The Business Associate from or on behalf of The Covered Entity.

f. <u>Required by Law</u> has the same meaning as the term "required by law" in 45 CFR 164.501.

g. <u>Secretary</u> means the Secretary of the Department of Health and Human Services or his or her designee.

2. Terms used, but not otherwise defined, in this Training Affiliation Agreement (TAA) shall have the same meaning as those terms in 45 CFR 160.103 and 164.501.

3. We have determined that both parties serve as employer and supervising institutions in this MOU. Consequently, in this MOU, both the employer institution and the supervising institution are Covered Entities as defined above; likewise, both the employer institution and the supervising institution are Business Associates as defined above.

4. The Business Associate agrees not to use or further disclose Protected Health Information other than as permitted or required by this TAA or as required by law.

5. 'The Business Associate agrees to use appropriate safeguards to prevent use or disclosure of the Protected Health Information other than as provided for by this TAA.

6. The Business Associate agrees to mitigate, to the extent practicable, any harmful effect that is known to the Business Associate of a use or disclosure of Protected Health Information by the Business Associate in violation of the requirements of this TAA.

7. The Business Associate agrees to report to the Covered Entity any use or disclosure of the Protected Health Information not provided for by this TAA.

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8. The Business Associate agrees to ensure that any agent, including a subcontractor, to whom it provides Protected Health Information received from, or created or received by the Business Associate on behalf of the Covered Entity agrees to the same restrictions and conditions that apply through this TAA to the Business Associate with respect to such information.

9. The Business Associate agrees to provide access, at the request of the Covered Entity, and in the time and manner designated by the Covered Entity to Protected Health Information in a Designated Record Set, to the Covered Entity or, as directed by the Covered Entity, to an Individual in order to meet the requirements under 45 CFR 164.524.

10. The Business Associate agrees to make any amendment(s) to Protected Health Information in a Designated Record Set that the Covered Entity directs or agrees to pursuant to 45 CFR 164.526 at the request of the Covered Entity or an Individual, and in the time and manner designated by the Covered Entity.

11. The Business Associate agrees to make internal practices, books, and records relating to the use and disclosure of Protected Health Information received from, or created or received by the Business Associate on behalf of, the Covered Entity, available to the Covered Entity, or at the request of the Covered Entity to the Secretary, in a time and manner designated by the Covered Entity or the Secretary, for purposes of the Secretary determining the Covered Entity's compliance with the Privacy Rule.

12. The Business Associate agrees to document such disclosures of Protected Health Information and information related to such disclosures as would be required for the Covered Entity to respond to a request by an Individual for an accounting of disclosures of Protected Health Information in accordance with 45 CFR 164.528.

13. The Business Associate agrees to provide to the Covered Entity or an Individual, in time and manner designated by the Covered Entity, information collected in accordance with this Appendix of the TAA, to permit the Covered Entity to respond to a request by an Individual for an accounting of disclosures of Protected Health Information in accordance with 45 CFR 164.528.

14. <u>General Use and Disclosure Provisions</u>. Except as otherwise limited in this TAA, the Business Associate may use or disclose Protected Health Information on behalf of, or to provide services to, the Covered Entity for the following purposes, if such use or disclosure of Protected Health Information would not violate the Privacy Rule or the Department of Defense Health Information Privacy Regulation if done by the Covered Entity (If "None" so state. Purposes that may be included are):

a. When required by law or government regulation.

- b. About victims of abuse or neglect.
- c. For health oversight activities authorized by law.
- d. For judicial or administrative proceedings.
- e. For law enforcement purposes.
- f. Concerning decedents in limited circumstances.

g. For cadaveric organ, eye, or tissue donation purposes.

- h. For research involving minimal risk.
- i. To avert a serious threat to health or safety.

j. For specialized government functions, including certain activities relating to Armed Forces personnel.

k. For workers' compensation programs.

15. Specific Use and Disclosure Provisions

a. Except as otherwise limited in this TAA, the Business Associate may use Protected Health Information for the proper management and administration of the Business Associate or to carry out the legal responsibilities of the Business Associate.

b. Except as otherwise limited in this TAA, the Business Associate may disclose Protected Health Information for the proper management and administration of the Business Associate, provided that disclosures are required by law, or the Business Associate obtains reasonable assurances from the person to whom the information is disclosed that it will remain confidential and used or further disclosed only as required by law or for the purpose 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.

c. Except as otherwise limited in this TAA, the Business Associate may use Protected Health Information to provide Data Aggregation services to the Covered Entity as permitted by 45 CFR 164.504(e)(2)(i)(B).

d. Business Associate may use Protected Health Information to report violations of law to appropriate Federal and State authorities, consistent with 45 CFR 164.502(j)(1).

16. <u>Obligations of the Covered Entity</u>. Provisions for the Covered Entity to Inform the Business Associate of Privacy Practices and Restrictions.

a. Upon request the Covered Entity shall provide the Business Associate with the notice of privacy practices that the Covered Entity produces in accordance with 45 CFR 164.520, as well as any changes to such notice.

b. The Covered Entity shall provide the Business Associate with any changes in, or revocation of, permission by Individual to use or disclose Protected Health Information, if such changes affect the Business Associate's permitted or required uses and disclosures.

c. The Covered Entity shall notify the Business Associate of any restriction to the use or disclosure of Protected Health Information that the Covered Entity has agreed to in accordance with 45 CFR 164.522.

17. <u>Permissible Requests by the Covered Entity</u>. The Covered Entity shall not request the Business Associate to use or disclose Protected Health Information in any manner that would not be permissible under the Privacy Rule if done by the Covered Entity, except for providing Data Aggregation services to the Covered Entity and for management and administrative activities of the Business Associate as otherwise permitted by this Appendix.

18. Termination

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a. <u>Termination</u>. A breach by the Business Associate of this Appendix, may subject the Business Associate to termination under any applicable default or termination provision of this TAA.

b. Effect of Termination

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(1) If this TAA has records management requirements, the records subject to the Appendix should be handled in accordance with the records management requirements. If this TAA does not have records management requirements, the records should be handled in accordance with paragraphs 18b(2) and 18b(3) below.

(2) If this TAA does not have records management requirements, except as provided in paragraph (3) of this section, upon termination of this TAA, for any reason, the Business Associate shall return or destroy all Protected Health Information received from the Covered Entity, or created or received by the Business Associate on behalf of the Covered Entity. This provision shall apply to Protected Health Information that is in the possession of subcontractors or agents of the Business Associate. The Business Associate shall retain no copies of the Protected Health Information.

(3) If this TAA does not have records management provisions and the Business Associate determines that returning or destroying the Protected Health Information is infeasible, the Business Associate shall provide to the Covered Entity notification of the conditions that make return or destruction infeasible. Upon mutual TAA of the Covered Entity and the Business Associate that

return or destruction of Protected Health Information is infeasible, the Business Associate shall extend the protections of this TAA to such Protected Health Information and limit further uses and disclosures of such Protected Health Information to those purposes that make the return or destruction infeasible, for so long as the Business Associate maintains such Protected Health Information.

19. Miscellaneous

a. <u>Regulatory References</u>. A reference in this Appendix to a section in the Privacy Rule means the section as in effect or as amended, and for which compliance is required.

b. <u>Survival</u>. The respective rights and obligations of Business Associate under the "Effect of Termination" provision of this Appendix shall survive the termination of this TAA.

c. <u>Interpretation</u>. Any ambiguity in this Appendix shall be resolved in favor of a meaning that permits the Covered Entity to comply with the Privacy Rule.

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SAMPLE MOU FOR TWO-WAY EXCHANGE OF TRAINEES BETWEEN NAVY AND CIVILIAN INSTITUTIONS

MEMORANDUM OF UNDERSTANDING BETWEEN (NAME AND ADDRESS OF NAVY MTF) AND (NAME AND ADDRESS OF AFFILIATING INSTITUTION)

Subj: MEMORANDUM OF UNDERSTANDING

• Ref: (a) BUMEDINST 7050.3A

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3. The MTF and the U.S. Navy will benefit by participating in a well diversified professional program which will enable its trainees to use the clinical facilities of the affiliating institution to receive their clinical experience.

4. The affiliating institution will benefit by participating in a well diversified professional program which will enable its trainees to use the clinical facilities at the MTF to receive their clinical experience.

5. The parties acknowledge and agree to the following:

a. As used in this agreement, "employer institution" refers to the institution that pays the trainee's salary. "Supervising institution" shall refer to that institution to which the trainee is assigned for training.

b. When trainees of either party are participating under this agreement at the clinical facilities of the supervising institution, the trainees will be under the supervision of facility officials of the supervising institution and will be subject to and be required to abide by, all of the supervising institution's rules and applicable regulations. It is understood that Navy trainees will be subject to and required to abide by all civilian facility rules and applicable regulations, except where compliance would be inconsistent with Federal statutes, regulations, or any other law binding member of the U.S. Navy.

Enclosure (2)

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Subj: MEMORANDUM OF UNDERSTANDING

c. There will be no compensation paid to trainees of either party to this Agreement for participating in this program, other than what the compensation trainees receive from their employer institution. The use of either party's facilities is for the training described in this agreement and no compensation will be paid for any incidental work benefits that accrue to either party. It is agreed and understood that the supervising institution may generate bills for services rendered by the trainees. Proceeds from these bills will become the exclusive property of the supervising institution and the employer institution shall have no right or claim to such proceeds. Notwithstanding the above, as required by 32 CFR §199.6(a)(3), the affiliating institution cannot bill under the TRICARE Program for the services rendered by U.S. Navy trainees.

d. The programs described in this Agreement are not intended to displace employees or impair existing contracts for services.

e. The number and assignment of trainees will be mutually agreed upon between the MTF and the affiliating institution before the beginning of each training period. Each of the parties specifically reserves the right to refuse any trainee's acceptance into a program conducted at their respective facility or to bar any participant involved in a training program under this Agreement when it is determined that further participation would not be in the best interest of either party.

f. Neither party will use the name of the other party's institution or trainees' or faculty members' names in publicity or advertising media without the express written consent of the institution. However, the existence and scope of the program may be made known.

g. Neither the party of this Agreement nor their trainees will publish any materials developed as a result of their clinical experience until such publication has been approved for release, in writing, by the MTF and the affiliating institution.

h. <u>Health Information Privacy</u>. Pursuant to DOD Instruction 6025.18, Privacy of Individually Identifiable Health Information in DOD Health Care Programs, December 19, 2002, DOD 6025.18-R, and 45 CFR Parts 160 and 164, the parties agree to enter into a Business Associate Agreement, attached as appendix A to this agreement.

6. For all training programs under this Agreement, the supervising institution specifically agrees to:

a. Make available the clinical and related facilities needed for training under this agreement.

b. Arrange schedules that will not conflict with other educational programs and the orderly operation of the institution.

Subj: MEMORANDUM OF UNDERSTANDING

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c. Designate an official to coordinate trainees' clinical learning experience. This will involve planning with faculty or staff members for the assignment of trainees to specific clinical cases and experiences, including their attendance at selected conferences, clinics, courses, and programs conducted under the direction of the supervising institution.

d. Provide reasonable classroom, conference, office, storage, dressing, and locker room space for participating trainees and their faculty or staff supervisors.

e. Permit on reasonable request, the inspection of clinical and related facilities by agencies charged with the responsibility for accreditation of the employer institution's educational programs.

f. Provide emergency medical and dental treatment to trainees while in the medical facility for training. The cost of such treatment will be assessed according to the rendering institution's applicable rules and regulations and will be paid for by the trainee or the respective employer institution.

g. Arrange the necessary access to the clinical facilities, including necessary parking or base permits and access to the administrative privileges typically enjoyed by the supervising institution's trainees.

h. The civilian employer institution agrees to provide professional liability (malpractice) coverage, in amounts that are reasonable and customary in the community for the appropriate specialty, covering liability for personal injury and property damage, including expense of defense of any such liability claims or actions, resulting from participation by their civilian trainees or faculty under this Agreement. The civilian employer institution's liability coverage may come from any source, but shall clearly cover their faculty and trainees while participating under this agreement.

i. Each party agrees that if the supervising institution intends to change such liability coverage during the tenure of this Agreement in a way that will affect the protection provided the employer institution, then the supervising institution will notify the employer institution in writing, at least 45 days before the effective date of the change, specifying the change intended to be made. Each party agrees not to seek indemnification from the other party or its trainees for any settlement, verdict, or judgment resulting from any claim or lawsuit arising out of the performance of the trainee's professional duties while acting under the control of the supervising institution and its employees.

j. U.S. Navy trainees affected by this Agreement, assigned to the training institution(s), under orders issued by the U.S. Navy, remains an employee of the United States and performs duties within the course and scope of the Federal employment. Consequently, the provision of

Subj: MEMORANDUM OF UNDERSTANDING

the Federal Tort Claims Act (title 28, USC, sections 1346(b), 2671-2680), including its defenses and immunities, will apply to allegations of negligence or wrongful acts or omissions of the Navy trainees while acting within the scope of duties pursuant to this Agreement.

k. In the event the employer institution is sued by a plaintiff seeking to hold it vicariously liable for negligent acts of its trainee while performing duties at the supervising institution, the employer institution shall make all legal defenses including the terms of this Agreement to defend the claim. However, neither the employer institution nor the supervising institution shall seek indemnification from any trainee. When the supervising institution settles or pays any claims against it involving trainees of the other institution, the supervising institution shall obtain as broad a release as possible from the plaintiff or claimant to provide the employer institution protection from further claims. Each institution agrees to notify the other when a claim is received and to cooperate to the fullest extent possible with the other institution in preparing for and conducting the defense of any malpractice claim involving the trainees.

7. The parties understand and agree that consistent with the Federal statute and the Federal Acquisition Regulation (FAR), the U.S. Navy trainee performing under this Agreement is not required to satisfy the State of training institutions temporary or permanent licensure requirements. Under the provision of 10 USC §§1094(d)(1) and (2), the U.S. Navy trainee has portability of his or her health care professional licenses.

a . Specifically, 10 USC §§1094(d)(1) and (2) provide:

(1) Notwithstanding any law regarding the licensure of a U.S. Navy trainee, a health care professional described in paragraph (2), may practice the health profession or professions of the health care professional in any State, District of Columbia, or a Commonwealth, territory, or possession of the U.S., regardless of whether the practice occurs in a health care facility of the Department of Defense, a civilian facility affiliated with the Department of Defense, or any other location authorized by the Secretary of Defense.

(2) A health care professional referred to in paragraph (2) is a member of the Armed Forces who:

(a) Has a current license to practice medicine, osteopathic medicine, dentistry, or another health profession.

(b) Is performing authorized duties for the Department of Defense.

b. ______ (Name of Navy MTF), in accordance with the requirements of 10 USC §§1094(4)(d)(1) and (2), authorizes the training location and duties of the U.S. Navy trainee at ______ (name of civilian facility), as they will be performing their duties under military orders issued by the U.S. Navy.

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Subj: MEMORANDUM OF UNDERSTANDING

8. According to Navy instructions, each trainee from the affiliating institution is required to sign a trainee agreement addendum containing the provisions of the sample attached to this Agreement.

9. It is expressly agreed that this written statement embodies the entire agreement of the parties regarding this affiliation, and no other agreements exist between the parties, except as herein expressly set forth. Any changes or modifications to this Agreement must be in writing and be signed by both parties.

10. It is understood that the Chief, Bureau of Medicine and Surgery will have the right to terminate this affiliation agreement without notice at any time, if determined necessary to be in the interests of the Navy's mission requirements.

11. The terms of this Agreement will commence as of the date signed by both parties and will continue until terminated by either party. Termination by either party will require that written notification be sent by registered mail 30 days before the termination date.

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APPENDIX A BUSINESS ASSOCIATE AGREEMENT PRIVACY OF PROTECTED HEALTH INFORMATION

1. Definitions. As used in this Appendix:

a. *Business Associate* has the same meaning as the term "Business Associate" in 45 CFR 160.103.

b. <u>Covered Entity</u> has the same meaning as the term "Covered Entity" in 45 CFR 160.103.

c. <u>Individual</u> has the same meaning as the term "individual" in 45 CFR 164.501 and shall include a person who qualifies as a personal representative in accordance with 45 CFR 164.502(g).

d. <u>Privacy Rule</u> means the Standards for Privacy of Individually Identifiable Health Information at 45 CFR part 160 and part 164, subparts A and E.

e. <u>Protected Health Information</u> has the same meaning as the term "protected health information" in 45 CFR 164.501, limited to the information created or received by The Business Associate from or on behalf of The Covered Entity.

f. <u>Required by Law</u> has the same meaning as the term "required by law" in 45 CFR 164.501.

g. <u>Secretary</u> means the Secretary of the Department of Health and Human Services or his or her designee.

2. Terms used, but not otherwise defined, in this Training Affiliation Agreement (TAA) shall have the same meaning as those terms in 45 CFR 160.103 and 164.501.

3. We have determined that both parties serve as employer and supervising institutions in this MOU. Consequently, in this MOU, both the employer institution and the supervising institution are Covered Entities as defined above; likewise, both the employer institution and the supervising institution are Business Associates as defined above.

4. The Business Associate agrees not to use or further disclose Protected Health Information other than as permitted or required by this TAA or as required by law.

5. The Business Associate agrees to use appropriate safeguards to prevent use or disclosure of the Protected Health Information other than as provided for by this TAA.

6. The Business Associate agrees to mitigate, to the extent practicable, any harmful effect that is known to the Business Associate of a use or disclosure of Protected Health Information by the Business Associate in violation of the requirements of this TAA.

7. The Business Associate agrees to report to the Covered Entity any use or disclosure of the Protected Health Information not provided for by this TAA.

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8. The Business Associate agrees to ensure that any agent, including a subcontractor, to whom it provides Protected Health Information received from, or created or received by the Business Associate on behalf of the Covered Entity agrees to the same restrictions and conditions that apply through this TAA to the Business Associate with respect to such information.

9. The Business Associate agrees to provide access, at the request of the Covered Entity, and in the time and manner designated by the Covered Entity to Protected Health Information in a Designated Record Set, to the Covered Entity or, as directed by the Covered Entity, to an Individual in order to meet the requirements under 45 CFR 164.524.

10. The Business Associate agrees to make any amendment(s) to Protected Health Information in a Designated Record Set that the Covered Entity directs or agrees to pursuant to 45 CFR 164.526 at the request of the Covered Entity or an Individual, and in the time and manner designated by the Covered Entity.

11. The Business Associate agrees to make internal practices, books, and records relating to the use and disclosure of Protected Health Information received from, or created or received by the Business Associate on behalf of, the Covered Entity, available to the Covered Entity, or at the request of the Covered Entity to the Secretary, in a time and manner designated by the Covered Entity or the Secretary, for purposes of the Secretary determining the Covered Entity's compliance with the Privacy Rule.

12. The Business Associate agrees to document such disclosures of Protected Health Information and information related to such disclosures as would be required for the Covered Entity to respond to a request by an Individual for an accounting of disclosures of Protected Health Information in accordance with 45 CFR 164.528.

13. The Business Associate agrees to provide to the Covered Entity or an Individual, in time and manner designated by the Covered Entity, information collected in accordance with this Appendix of the TAA, to permit the Covered Entity to respond to a request by an Individual for an accounting of disclosures of Protected Health Information in accordance with 45 CFR 164.528.

14. <u>General Use and Disclosure Provisions</u>. Except as otherwise limited in this TAA, the Business Associate may use or disclose Protected Health Information on behalf of, or to provide services to, the Covered Entity for the following purposes, if such use or disclosure of Protected Health Information would not violate the Privacy Rule or the Department of Defense Health Information Privacy Regulation if done by the Covered Entity (If "None" so state. Purposes that may be included are):

a. When required by law or government regulation.

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- b. About victims of abuse or neglect.
- c. For health oversight activities authorized by law.
- d. For judicial or administrative proceedings.
 - e. For law enforcement purposes.
 - f. Concerning decedents in limited circumstances.
- g. For cadaveric organ, eye, or tissue donation purposes.
 - h. For research involving minimal risk.
 - i. To avert a serious threat to health or safety.

• j. For specialized government functions, including certain activities relating to Armed Forces personnel.

k. For workers' compensation programs.

15. Specific Use and Disclosure Provisions

a. Except as otherwise limited in this TAA, the Business Associate may use Protected Health Information for the proper management and administration of the Business Associate or to carry out the legal responsibilities of the Business Associate.

b. Except as otherwise limited in this TAA, the Business Associate may disclose Protected Health Information for the proper management and administration of the Business Associate, provided that disclosures are required by law, or the Business Associate obtains reasonable assurances from the person to whom the information is disclosed that it will remain confidential and used or further disclosed only as required by law or for the purpose 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.

c. Except as otherwise limited in this TAA, the Business Associate may use Protected Health Information to provide Data Aggregation services to the Covered Entity as permitted by 45 CFR 164.504(e)(2)(i)(B).

d. Business Associate may use Protected Health Information to report violations of law to appropriate Federal and State authorities, consistent with 45 CFR 164.502(j)(1).

16. <u>Obligations of the Covered Entity</u>. Provisions for the Covered Entity to Inform the Business Associate of Privacy Practices and Restrictions.

a. Upon request the Covered Entity shall provide the Business Associate with the notice of privacy practices that the Covered Entity produces in accordance with 45 CFR 164.520, as well as any changes to such notice.

b. The Covered Entity shall provide the Business Associate with any changes in, or revocation of, permission by Individual to use or disclose Protected Health Information, if such changes affect the Business Associate's permitted or required uses and disclosures.

c. The Covered Entity shall notify the Business Associate of any restriction to the use or . disclosure of Protected Health Information that the Covered Entity has agreed to in accordance with 45 CFR 164.522.

17. <u>Permissible Requests by the Covered Entity</u>. The Covered Entity shall not request the Business Associate to use or disclose Protected Health Information in any manner that would not be permissible under the Privacy Rule if done by the Covered Entity, except for providing Data Aggregation services to the Covered Entity and for management and administrative activities of the Business Associate as otherwise permitted by this Appendix.

18. Termination

a. <u>Termination</u>. A breach by the Business Associate of this Appendix, may subject the Business Associate to termination under any applicable default or termination provision of this TAA.

b. <u>Effect of Termination</u>

(1) If this TAA has records management requirements, the records subject to the Appendix should be handled in accordance with the records management requirements. If this TAA does not have records management requirements, the records should be handled in accordance with paragraphs 18b(2) and 18b(3) below.

(2) If this TAA does not have records management requirements, except as provided in paragraph (3) of this section, upon termination of this TAA, for any reason, the Business Associate shall return or destroy all Protected Health Information received from the Covered Entity, or created or received by the Business Associate on behalf of the Covered Entity. This provision shall apply to Protected Health Information that is in the possession of subcontractors or agents of the Business Associate. The Business Associate shall retain no copies of the Protected Health Information.

(3) If this TAA does not have records management provisions and the Business Associate determines that returning or destroying the Protected Health Information is infeasible, the Business Associate shall provide to the Covered Entity notification of the conditions that make return or destruction infeasible. Upon mutual TAA of the Covered Entity and the Business Associate that

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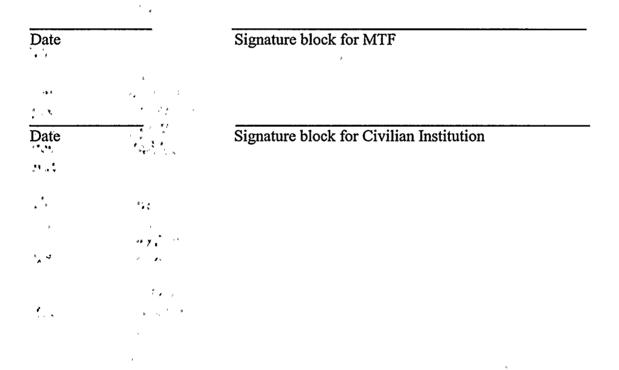
return or destruction of Protected Health Information is infeasible, the Business Associate shall extend the protections of this TAA to such Protected Health Information and limit further uses and disclosures of such Protected Health Information to those purposes that make the return or destruction infeasible, for so long as the Business Associate maintains such Protected Health Information.

19. Miscellaneous

means the section as in effect or as amended, and for which compliance is required.

b. <u>Survival</u>. The respective rights and obligations of Business Associate under the "Effect of Termination" provision of this Appendix shall survive the termination of this TAA.

c. <u>Interpretation</u>. Any ambiguity in this Appendix shall be resolved in favor of a meaning that permits the Covered Entity to comply with the Privacy Rule.



SAMPLE MOU FOR CIVILIAN TRAINEES AT NAVAL MEDICAL DEPARTMENT ACTIVITIES

MEMORANDUM OF UNDERSTANDING BETWEEN (NAME AND ADDRESS OF MEDICAL DEPARTMENT ACTIVITY) AND (NAME AND ADDRESS OF AFFILIATING INSTITUTION)

Subj: MEMORANDUM OF UNDERSTANDING

Ref: (a) BUMEDINST 7050.3A

2. The administrators of the affiliating institution have established an approved professional program that has been recognized, accredited, or certified by the appropriate accrediting agencies, as applicable. The specific nature of this program is to train ______ (names of trainees) in ______ (residency, fellowship or clinical rotation) over a period of ______ (timeframe or training), from ______ (month/year) to ______ (month/year).

3. It is in the best interest of the affiliating institution and its trainees to use the clinical facilities at the MTF to receive their clinical experience. The Department of the Navy and the MTF will benefit by completely utilizing program resources, by maintaining diplomatic relations with community medical institutions, and by affording its medical staff an opportunity to obtain teaching experience.

4. The parties acknowledge and agree to the following:

a. While training at the MTF, the affiliating institution civilian trainees will be under the supervision of MTF officials for training purposes and will be subject to and required to abide by all MTF rules and applicable regulations.

. b. There will be no training expense to the Navy for the civilian trainees of the affiliating institution who participate in this program other than expenses incidental to their supervision. The use of Government-owned property by the trainees is primarily to further their training. Any work benefits that the MTF and the Navy receive are incidental to this training and trainees of affiliating institution will not be compensated.

c. This program will not result in, nor is it meant to displace employees or impair existing contracts for services.

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BUMEDINST 7050.3A 15 Sep 2004

Subj: MEMORANDUM OF UNDERSTANDING

d. The number and assignment of trainees will be mutually agreed upon between the MTF and the affiliating institution before the beginning of each training period. The MTF reserves the right to refuse acceptance of any participant in this training program or to bar any civilian trainee when it is determined that further participation would not be in the best interest of the MTF.

e. The affiliating institution will not use the MTF's name in any of their publicity or advertising media. However, the existence and the scope of the program may be made known.

f. Each trainee of the affiliating institution will be required to sign the civilian trainee agreement addendum attached to this Agreement.

g. <u>Health Information Privacy</u>. Pursuant to DOD Instruction 6025.18, Privacy of Individually Identifiable Health Information in DOD Health Care Programs, December 19, 2002, DOD 6025.18-R, and 45 CFR Parts 160 and 164, the parties agree to enter into a Business Associate Agreement, attached as appendix A to this Agreement.

5. In addition to other provisions in this Agreement, the MTF specifically agrees to:

a. Make available the clinical and related facilities needed for training.

b. Arrange schedules that will not conflict with other educational programs.

c. Designate an MTF official to coordinate the civilian trainees' clinical learning experiences. This will involve planning with faculty or staff members for the assignment of civilian trainees to specific clinical cases and experiences, including their attendance at selected conferences, clinics, courses, and programs conducted under the direction of the MTF.

d. Provide reasonable classroom, conference, office, storage, dressing, and locker room space for participating trainees and their faculty or staff supervisors.

e. Permit, on reasonable request, the inspection of clinical and related facilities by agencies charged with the responsibility for accreditation of the affiliating institution's educational programs.

f. Provide emergency medical and dental treatment to the trainees while at the MTF for training. The cost of such treatment will be paid for by the trainees or the affiliating institution.

g. Allow faculty and trainees access to the hospital dining facilities at their own expense.

h. Provide guidance and instruction as long as the instruction and presence of civilian trainees do not interfere with official duties and training of military personnel.

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Subj: MEMORANDUM OF UNDERSTANDING

i. Arrange with the installation MTF commander to allow civilian faculty and trainees access to the military base or facility.

6. In addition to other provisions of this Agreement, the civilian affiliating institution specifically agrees to:

a. Provide faculty or staff members who will be responsible for instruction and overall supervision of the civilian trainees' program.

b. Have the civilian faculty or staff member coordinate with the designated MTF official the assignment that will be assumed by the civilian trainees and their attendance at selected conferences, clinics, courses, and programs conducted under the direction of the MTF.

c. Provide and maintain accurate personnel records and reports developed during the course of the trainees' clinical experience.

d. Ensure compliance with all MTF rules and applicable instructions.

e. Require all civilian faculty and trainees who operate an automobile on the military base to maintain the minimum requirements of local and State law and U.S. Navy regulations on automobile liability insurance.

f. Be responsible for health examinations and such other medical examinations and protective measures necessary for its trainees.

g. Prohibit trainees, faculty, or staff members from publishing any materials developed as a result of their clinical experiences that have not been approved for release, in writing, by the MTF and the affiliating institution.

h. Provide professional liability (malpractice) coverage, in amounts that are reasonable and customary in the community for the appropriate specialty, covering liability for personal injury and property damage, including legal representation and expense of defense for any such liability claims, actions, or litigation resulting from participation by their civilian trainees and faculty under this agreement. This coverage may come from any source, but shall clearly cover the civilian faculty and trainees while participating under this Agreement at the MTF. The affiliating institution agrees that if it intends to change such liability coverage during the tenure of this Agreement in a way that will affect the protection provided their trainees, then the affiliating institution will notify the Navy in writing, at least 45 days before the effective date of the change, specifying the change intended to be made. The affiliating institution must provide documentary proof of the insurance coverage to the MTF and such documentary proof will be attached to this Agreement. The affiliating institution further states not to seek indemnification from either the United States or the U.S. Navy for any settlement, verdict, or judgment resulting from any claim or lawsuit arising out of the performance of the civilian trainees' professional duties while training at the MTF.

BUMEDINST 7050.3A 15,Sep 2004 в **ж**.

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7.⁴ It is expressly agreed that this written statement embodies the entire agreement of the parties regarding this affiliation and no other agreements exist between the parties except as herein expressly set forth. Any changes or modifications to this Agreement must be in writing and be signed by both parties.

8. The terms of this Agreement will commence as of the date signed by both parties and will continue until terminated by either party. Termination by either party will require that written notification be sent by registered mail 30 days before the termination date. It is understood that the Chief, Bureau of Medicine and Surgery, will have the right to terminate this affiliation agreement without notice at any time if determined necessary to be in the interests of the Navy's mission requirements.

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APPENDIX A BUSINESS ASSOCIATE AGREEMENT PRIVACY OF PROTECTED HEALTH INFORMATION

1. Definitions. As used in this Appendix:

a. <u>Business Associate</u> has the same meaning as the term "Business Associate" in 45 CFR 160.103.

b. <u>Covered Entity</u> has the same meaning as the term "Covered Entity" in 45 CFR 160.103.

c. <u>Individual</u> has the same meaning as the term "individual" in 45 CFR 164.501 and shall include a person who qualifies as a personal representative in accordance with 45 CFR 164.502(g).

d. <u>Privacy Rule</u> means the Standards for Privacy of Individually Identifiable Health Information at 45 CFR part 160 and part 164, subparts A and E.

e. <u>Protected Health Information</u> has the same meaning as the term "protected health information" in 45 CFR 164.501, limited to the information created or received by The Business Associate from or on behalf of The Covered Entity.

f. <u>Required by Law</u> has the same meaning as the term "required by law" in 45 CFR 164.501.

g. <u>Secretary</u> means the Secretary of the Department of Health and Human Services or his or her designee.

2. Terms used, but not otherwise defined, in this Training Affiliation Agreement (TAA) shall have the same meaning as those terms in 45 CFR 160.103 and 164.501.

3. We have determined that both parties serve as employer and supervising institutions in this MOU. Consequently, in this MOU, both the employer institution and the supervising institution are Covered Entities as defined above; likewise, both the employer institution and the supervising institution are Business Associates as defined above.

4. The Business Associate agrees not to use or further disclose Protected Health Information other than as permitted or required by this TAA or as required by law.

5. The Business Associate agrees to use appropriate safeguards to prevent use or disclosure of the Protected Health Information other than as provided for by this TAA.

6. The Business Associate agrees to mitigate, to the extent practicable, any harmful effect that is known to the Business Associate of a use or disclosure of Protected Health Information by the Business Associate in violation of the requirements of this TAA.

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7. The Business Associate agrees to report to the Covered Entity any use or disclosure of the Protected Health Information not provided for by this TAA.

8. The Business Associate agrees to ensure that any agent, including a subcontractor, to whom it provides Protected Health Information received from, or created or received by the Business Associate on behalf of the Covered Entity agrees to the same restrictions and conditions that apply through this TAA to the Business Associate with respect to such information.

9. The Business Associate agrees to provide access, at the request of the Covered Entity, and in the time and manner designated by the Covered Entity to Protected Health Information in a Designated Record Set, to the Covered Entity or, as directed by the Covered Entity, to an Individual in order to meet the requirements under 45 CFR 164.524.

10. The Business Associate agrees to make any amendment(s) to Protected Health Information in a Designated Record Set that the Covered Entity directs or agrees to pursuant to 45 CFR 164.526 at the request of the Covered Entity or an Individual, and in the time and manner designated by the Covered Entity.

11. The Business Associate agrees to make internal practices, books, and records relating to the use and disclosure of Protected Health Information received from, or created or received by the Business Associate on behalf of, the Covered Entity, available to the Covered Entity, or at the request of the Covered Entity to the Secretary, in a time and manner designated by the Covered Entity or the Secretary, for purposes of the Secretary determining the Covered Entity's compliance with the Privacy Rule.

12. The Business Associate agrees to document such disclosures of Protected Health Information and information related to such disclosures as would be required for the Covered Entity to respond to a request by an Individual for an accounting of disclosures of Protected Health Information in accordance with 45 CFR 164.528.

13. The Business Associate agrees to provide to the Covered Entity or an Individual, in time and manner designated by the Covered Entity, information collected in accordance with this Appendix of the TAA, to permit the Covered Entity to respond to a request by an Individual for an accounting of disclosures of Protected Health Information in accordance with 45 CFR 164.528.

14. <u>General Use and Disclosure Provisions</u>. Except as otherwise limited in this TAA, the Business Associate may use or disclose Protected Health Information on behalf of, or to provide services to, the Covered Entity for the following purposes, if such use or disclosure of Protected Health Information would not violate the Privacy Rule or the Department of Defense Health Information Privacy Regulation if done by the Covered Entity (If "None" so state. Purposes that may be included are):

a. When required by law or government regulation.

.... b. About victims of abuse or neglect.

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- c. For health oversight activities authorized by law.
- d. For judicial or administrative proceedings.
 - e. For law enforcement purposes.
- f. Concerning decedents in limited circumstances.
- g. For cadaveric organ, eye, or tissue donation purposes.
 - h. For research involving minimal risk.
- i. To avert a serious threat to health or safety.

j. For specialized government functions, including certain activities relating to Armed Forces personnel.

k. For workers' compensation programs.

15. Specific Use and Disclosure Provisions

a. Except as otherwise limited in this TAA, the Business Associate may use Protected Health Information for the proper management and administration of the Business Associate or to carry out the legal responsibilities of the Business Associate.

b. Except as otherwise limited in this TAA, the Business Associate may disclose Protected Health Information for the proper management and administration of the Business Associate, provided that disclosures are required by law, or the Business Associate obtains reasonable assurances from the person to whom the information is disclosed that it will remain confidential and used or further disclosed only as required by law or for the purpose 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.

c. Except as otherwise limited in this TAA, the Business Associate may use Protected Health Information to provide Data Aggregation services to the Covered Entity as permitted by 45 CFR 164.504(e)(2)(i)(B).

d. Business Associate may use Protected Health Information to report violations of law to appropriate Federal and State authorities, consistent with 45 CFR 164.502(j)(1).

16. <u>Obligations of the Covered Entity</u>. Provisions for the Covered Entity to Inform the Business Associate of Privacy Practices and Restrictions.

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a. Upon request the Covered Entity shall provide the Business Associate with the notice of privacy practices that the Covered Entity produces in accordance with 45 CFR 164.520, as well as any changes to such notice.

b. The Covered Entity shall provide the Business Associate with any changes in, or revocation of, permission by Individual to use or disclose Protected Health Information, if such changes affect the Business Associate's permitted or required uses and disclosures.

c. The Covered Entity shall notify the Business Associate of any restriction to the use or disclosure of Protected Health Information that the Covered Entity has agreed to in accordance with 45 CFR 164.522.

17. <u>Permissible Requests by the Covered Entity</u>. The Covered Entity shall not request the Business Associate to use or disclose Protected Health Information in any manner that would not be permissible under the Privacy Rule if done by the Covered Entity, except for providing Data Aggregation services to the Covered Entity and for management and administrative activities of the Business Associate as otherwise permitted by this Appendix.

18. Termination

a. <u>Termination</u>. A breach by the Business Associate of this Appendix, may subject the Business Associate to termination under any applicable default or termination provision of this TAA.

: b. Effect of Termination

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(1) If this TAA has records management requirements, the records subject to the Appendix should be handled in accordance with the records management requirements. If this TAA does not have records management requirements, the records should be handled in accordance with paragraphs 18b(2) and 18b(3) below.

(2) If this TAA does not have records management requirements, except as provided in paragraph (3) of this section, upon termination of this TAA, for any reason, the Business Associate shall return or destroy all Protected Health Information received from the Covered Entity, or created or received by the Business Associate on behalf of the Covered Entity. This provision shall apply to Protected Health Information that is in the possession of subcontractors or agents of the Business Associate. The Business Associate shall retain no copies of the Protected Health Information.

(3) If this TAA does not have records management provisions and the Business Associate determines that returning or destroying the Protected Health Information is infeasible, the Business Associate shall provide to the Covered Entity notification of the conditions that make return or destruction infeasible. Upon mutual TAA of the Covered Entity and the Business Associate that

return or destruction of Protected Health Information is infeasible, the Business Associate shall extend the protections of this TAÅ to such Protected Health Information and limit further uses and disclosures of such Protected Health Information to those purposes that make the return or destruction infeasible, for so long as the Business Associate maintains such Protected Health Information.

19. Miscellaneous

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a. <u>Regulatory References</u>. A reference in this Appendix to a section in the Privacy Rule means the section as in effect or as amended, and for which compliance is required.

b. <u>Survival</u>. The respective rights and obligations of Business Associate under the "Effect of Termination" provision of this Appendix shall survive the termination of this TAA.

c. <u>Interpretation</u>. Any ambiguity in this Appendix shall be resolved in favor of a meaning that permits the Covered Entity to comply with the Privacy Rule.

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SAMPLE CIVILIAN TRAINEE AGREEMENT ADDENDUM

In consideration of being allowed to use the facilities of ______ (name of MTF) per the Memorandum of Understanding Agreement between ______ (name of affiliating institution) and ______ (name of MTF), I agree to abide by the rules and instructions listed in the Agreement. I am aware of the rules concerning automobile liability insurance, and, if I drive my private automobile on base, I will register it with base authorities and maintain the required liability insurance. I specifically agree and understand that I will receive no monetary compensation whatsoever from the United States for this training.

(Signature and Typed Name of Trainee)

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Date

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Enclosure (4)