U.S. ARMY PUBLIC HEALTH CENTER

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Release of Anatomical Specimens

BACKGROUND. Medical Treatment Facilities (MTFs) periodically receive requests for the return of human tissues, organs, and fluids (herein referred to as anatomical specimens) to individuals following medical and surgical procedures such as biopsies, organ and tissue removal, joint repair, or labor and delivery. These requests are most often based on the personal, cultural, and religious beliefs of individuals.

Requests of this nature should be considered by the MTF as they arise and are addressed according to MTF, U.S. Army Medical Command (MEDCOM), and Defense Health Agency (DHA) policies. In the absence of local policy (or if the MTF has further questions or concerns), the MTF should conduct a legal review of statutory requirements and develop policy and procedures that govern the return of anatomical specimens to patients. As specified in MEDCOM Regulation 40-35, *Management of Regulated Medical Waste (RMW)* and DHA Procedural Manual DHA-PM-6050.01, *Medical Logistics (MEDLOG) Regulated Medical Waste (RMW) Management*, the MTF should contact the supporting staff judge advocate and the DHA Public Health Service for guidance tailored to the particular circumstance and geographic location. Guidance contained in this fact sheet is presented for consideration for those requests in which the MTF has approved the return of anatomical specimens to the patient. The return of amputated limbs for ceremonial purposes and the release of placentas for consumption have been addressed in separate fact sheets.

Return of anatomical specimens will only be accommodated when a risk evaluation (i.e., patient screening, pathological testing) determines that no public health hazards exist through their release from the MTF and as the requests can be reasonably accommodated. Reasonable accommodation is construed as those requests not considered extreme or excessive and those requests that pose no financial burden to the MTF. Anatomical specimens that are infected with communicable disease (i.e., hepatitis, HIV/AIDS, etc.) pose a public health hazard and will not be released.

RELEASE PROCEDURES. Evaluation and coordination for the release of anatomical specimens must be conducted in advance of the medical or surgical procedure and incorporated into patient counseling. Physicians should ensure that a disposition plan has been developed by the patient and agreed to by both parties during patient counseling. As part of the disposition plan, the patient may undergo prior screening and/or testing to verify the absence of infectious disease. The disposition plan will include:

(1) A statement from the patient specifying a request to have the specimen returned;
(2) Notification as to the condition of the specimen being released, chemicals used for preservation, known risks or potential hazards associated with handling the material;
(3) Instructions on safe handling of the specimen once received; and
(4) A signed “Release of Anatomical Specimen and Waiver of Liability” form for release of the specimen.

Figure 1 provides an example of the release form to be signed by the patient and/or authorized recipient and physician and/or MTF authority.

Positive findings of a potential public health risk from the MTF’s Pathology Department will void the release approval and the anatomical specimen will be managed by the MTF as regulated medical waste.

Anatomical specimens approved for release by the MTF will be classified as an Exempt Human Specimen and should only be released to individuals via proper shipment and transportation to the individual’s private residence. Individuals requesting the return of anatomical specimens will assume financial responsibility for all costs and services associated with packaging and shipment of the specimens to their private residences. Some specimens may qualify for exemption from the shipping and transportation requirement and may be released directly to the individual for transportation home because they are easily disinfected, require no preservative, and pose no threat once placed in a container. Examples of exempted specimens include but are not limited to the following: extracted teeth; disinfected orthopedic hardware; and disinfected foreign objects such as pacemakers, and prostheses.

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The MTF will follow existing procedures utilized by the Pathology Department to arrange for the release of identified specimens. The MTF's Pathology Department should already have policy established that governs the release of pathology specimens to healthcare providers, patients and/or their authorized representatives, research programs, attorneys, and other parties. These procedures should include protocols for possession, packaging, labeling, transportation, distribution, and final receipt of identified specimens.

MANAGEMENT IN THE MTF. When a release of anatomical specimens to the patient has been approved, the MTF will ensure the safe management of specimens until such time that the specimens are shipped or released to the patient and/or authorized recipient for transportation home. Specimens will not be shipped until the patient or authorized recipient is available to receive the shipment. Refrigerated storage in the Pathology Department may be required to preserve the specimens until shipment. A copy of the signed release form will accompany the specimens to the storage location.

Anatomical specimens designated for the return to patients are classified as Exempt Human Specimens. The MTF will ensure that standard operating procedures are implemented for the possession, packaging, labeling, and shipping of specimen to the intended recipient. Following the medical or surgical procedure, the specimens should be placed in a leak proof, rigid, puncture-resistant, durable plastic container at the point of generation (e.g., operating room). The container will be tightly closed and labeled with the following information:

- Exempt Human Specimen
- Date of origination
- "For Patient Use Only"
- Identity of the intended recipient
- Hazard Warnings for liquids - this side up markings
- Biohazard label

SHIPPING/TRANSPORTATION REQUIREMENTS. Prior to release, the patient and/or authorized recipient will be required to establish a shipping account with an approved shipper authorized to transport items classified as Exempt Human Specimen. This information will be provided to the MTF during patient counseling. Most commercial shipping companies are capable of transporting this type of material with proper notification and coordination.

Anatomical specimens should be packaged sufficiently to completely contain the specimens. The packaging must consist of the following components:

- A leak-proof primary receptacle.
- A leak-proof secondary receptacle.
- An outer packaging of adequate strength for its capacity, mass, and intended use, and with at least one surface having minimum dimensions of 100 mm x 100 mm.
- For liquids, absorbent material in sufficient quantity to absorb the entire contents must be placed between the primary receptacle and the secondary packaging, so that during transport, any release or leak of a liquid substance will not reach the outer packaging and will not compromise the integrity of the cushioning material.
- A signed copy of the "Release of Anatomical Specimens and Waiver of Liability Form."
- Safety Data Sheets (SDS) for all chemicals used to preserve the specimens.

The outer container will be labeled as Exempt Human Specimen, and the universal biohazard symbol will be placed on the outside of the secondary receptacle. If chemicals are utilized for preservation, their applicable hazard warning labels will be affixed to the outer package.

The MTF will establish chain-of-custody and complete a transfer form to release custody to the authorized shipper.

Release of Anatomical Specimens and Waiver of Liability

Between

_____

and

_____
(Medical Treatment Facility)

I, _____ (patient), do hereby request and authorize _____ (Medical Treatment Facility) to release the identified specimens/material listed below following proper pathological screening. Patient understands that certain medical conditions, known or unknown at the present time and which may be discovered during pathology testing, may preclude the release of the identified specimens.

Identified Specimens/Material

1. _____
2. _____
3. _____

Pathology Department Approval

Specimens acceptable for release	
Specimens not acceptable for release	
Specimens exempted from shipping/transportation requirement (e.g., extracted teeth, orthopedic hardware, etc.)	

Acceptance of Material/Waiver of Liability

I, _____ (patient/recipient), do hereby acknowledge receipt of the specimens/material listed above. I understand that the specimens/material may be fixed in a neutral buffered solution, which is a poison and a hazard if ingested, and that I should not handle the specimens/material directly. The risk from the subject specimens/material to myself and/or others has been explained to me and I have been provided special instructions regarding the safe handling of specimens/material by the undersigned. Upon release of specimens/material, the Medical Treatment Facility is absolved of all responsibility for the specimens/material.

By his/her signature below, the recipient hereby agrees to hold the U.S. Federal Government, it's entities, and its personnel, harmless for any and all liability/responsibility for damage, injury, and/or loss that may result from the recipient's receipt of the subject specimens/material. The recipient also agrees to assume any and all risks of damage, injury, and/or loss associated with the recipient's receipt of the subject specimens/material. The recipient hereby further waives any and all legal rights recipient may have to pursue civil/criminal claims or litigation against the United States Government, its entities, and/or its personnel related to the recipient's receipt of the subject specimens/material.

Signed _____ _____
(Patient/Recipient) (Date)

Signed _____ _____
(Medical Treatment Facility/Attending Physician) (Date)

Witness _____ _____
(Date)

Figure 1. Release of Anatomical Specimens and Waiver of Liability Form Example