



THE ASSISTANT SECRETARY OF DEFENSE

1200 DEFENSE PENTAGON
WASHINGTON, DC 20301-1200

JUL 26 2012

HEALTH AFFAIRS

MEMORANDUM FOR ASSISTANT SECRETARY OF THE ARMY (MANPOWER AND
RESERVE AFFAIRS)
ASSISTANT SECRETARY OF THE NAVY (MANPOWER AND
RESERVE AFFAIRS)
ASSISTANT SECRETARY OF THE AIR FORCE (MANPOWER
AND RESERVE AFFAIRS)
JOINT STAFF SURGEON
COMMANDER, JOINT TASK FORCE, NATIONAL CAPITAL
REGION (MEDICAL)

SUBJECT: Guidance on the Establishment of a Human Cell, Tissue, and Cellular and Tissue-
Based Products Program

The U.S. Food and Drug Administration (FDA) regulates Human Cell, Tissue, and Cellular and Tissue-based Products (HCT/Ps) under Title 21, Code of Federal Regulations, Parts 16, 1271, and under Current Good Tissue Practices (cGTP) for Human Cell, Tissue, and Cellular and Tissue-Based Product Establishments Inspection and Enforcement (69 FR 68612). A representative list of HCT/Ps is attached. This memorandum requests the Services resource a HCT/Ps Program that complies with regulatory standards for management and oversight of HCT/Ps, according to the best fit for their Service.

The field of HCT/Ps has rapidly grown with advances in medical care over the past several years, and the FDA has reorganized and established a new directorate, the Office of Cellular, Tissue, and Gene Therapies. The Services should establish directives to create a Tissue Program within their respective Services that identifies and oversees policies, procedures, and responsibilities. This program should include the management structure, responsibilities, and funding to address personnel, space, equipment, information technology support, training, etc., to comply with regulatory and accreditation requirements. The Services should each provide resources to support the implementation and management of this program. It is requested that each Service provide the Office of the Assistant Secretary of Defense (Health Affairs) (OASD(HA))/TRICARE Management Activity (TMA), Center for Clinical Laboratory Medicine with a copy of their policy on this matter within 120 days of receipt of this memorandum.

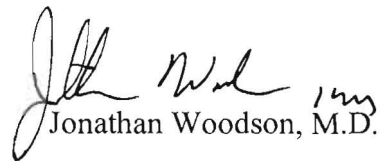
Since 2005, The Joint Commission (TJC) has required hospitals to designate oversight responsibility for the organization-wide tissue program and to identify, by position, the people with responsibility for regulatory compliance. In 2009, TJC went one step further and separated the standards on tissue management into a distinct chapter, thereby increasing the emphasis on these standards. TJC standards also require standardized procedures for managing tissues, the ability to trace all tissues bi-directionally, and the investigation of adverse events related to tissue use or donor infections.

Department of Defense (DoD) facilities presently receive, store, and use HCT/Ps within their establishments. In addition, there are DoD facilities that collect and transplant tissue products (e.g., stem cells). In both cases, facilities are required to follow all regulatory requirements.

When the Services establish the Tissue Program, due diligence is required in selecting the department and personnel to manage the program in order to ensure regulatory compliance. Key responsibilities include, but are not limited to:

- Compliance with federal regulations and accreditation standards;
- Qualifying suppliers and holding them accountable;
- Controlled ordering process;
- Appropriate storage, temperature monitoring, inventory management, and control;
- Recordkeeping that ensures tissue traceability from the supplier to the patient and back to the manufacturer.
- Ensure clear traceability for supplier recalls to identify affected patients;
- Investigations of patient adverse outcomes;
- Adverse event notification to suppliers and the FDA;
- Management of recalls, and look back investigations;
- Assigning responsibilities to qualified physicians and other personnel to ensure patient safety and program regulatory compliance;
- Organizing or reporting to medical staff oversight committees;
- Peer review of appropriate HCT/Ps use;
- Appropriate staffing for administrative, medical, quality, and operation functions.

Feedback, comments, or questions should be addressed to the OASD(HA)/TMA, Center for Clinical Laboratory Medicine, 7700 Arlington Blvd, Suite 5101, Falls Church, Virginia 22042-5101, (703) 681-6042 or DSN 761-6042.



Jonathan Woodson, M.D.

cc:
Surgeon General of the Army
Surgeon General of the Navy
Surgeon General of the Air Force

Attachments:
As stated