MANAGEMENT OF INVESTIGATIONAL HUMAN TISSUE PRODUCTS

OBJECTIVES:

To outline procedures for management of Investigational Human Tissues used in approved research protocols at the Atlanta VA Medical Center (AVAMC). This includes the receipt, storage, tracking, and issuance of Investigational Human Tissues.

IRB and R&D review, approval, and investigator conduct of all Investigational Human Tissue studies must be in accordance with all applicable VA and other requirements.

Tissue will be obtained from a source that meets national professional tissue banking standards and federal requirements and will be tracked from receipt to disposition.

DEFINITIONS:

a) Tissue – An immunological inert aggregation of similarly specialized cells united in the performance of a particular function. Solid tissue includes, but is not limited to, bone, skin, cornea, fascia lata, pericardium, heart valves/conduits, saphenous veins, arteries, and sclera.

b) Electronic Tissue Log – Is a secured electronic log for all human and non-human cellular based transplantable and implantable products received and either implanted or discarded by the organization. The log contains the date and time tissue was received, person accepting deliver/picking-up tissue, tissue type, name of the source facility, tissue ID number and/or lot identification number, verification of package integrity, temperature if indicated, storage location, expiration date, name of material used to prepare and/or reconstitute tissue including its lot number and expiration date, disposition of the tissue, date and time issued, person issuing tissue, tissue recipient, full social security number, reason for disposal or return, and comments. The location of the electronic tissue log is in SharePoint. The tissue record will be retained by Quality Management for a minimum of 10 years beyond the date of distribution, transplantation, disposition, or expiration of tissue.

PROCEDURES:

a) Investigational Human Tissues will be administered only to subjects who have agreed to participate in the study and have signed an Informed Consent Form (ICF) and HIPAA form.

b) Research staff will review the AVAMC Memorandum (MCM) 112-2 “Dispensing and Use of Solid Tissue”.

c) Principal Investigator (PI) will identify a member(s) of the research staff who will be designated as the Investigational Human Tissues (IHT) Manager. The IHT Manager will undergo Human Tissues management training. Responsibilities will include receipt, tracking, inventory, storage and documentation of Investigational Human Tissues.

d) AVAMC Quality Management shall provide Human Tissue management training to the IHT Manager(s). This training will include procedures used for managing tissue and documentation in accordance with the Joint Commission requirements, Department of Veteran's Affairs Guidelines, and MCM 112-2.

e) Access to SharePoint and the electronic tissue log shall be approved by Quality Management. A unique research project tab will be created in SharePoint.

RECIEPT OF INVESTIGATIONAL HUMAN TISSUE:

a) The IHT Manager(s) will be assigned to accept delivery of Investigational Human Tissue. The IHT Manager(s) is the only individual(s) who is allowed to accept delivery of the Investigational Human Tissue.

b) Instruct Sponsor to notify IHT Manager in advance of shipment so IHT Manager is prepared and available to accept shipment. Sponsor must accurately label the package with IHT Manager Name, room number, department, and address.

c) Upon delivery of the Investigational Human Tissue from the Sponsor to the warehouse, the warehouse personnel will inspect the condition of the package to ensure it is sealed and free of damage, scan the package barcode into the electronic tracking system, and expedite delivery of the package to the IHT Manager.

d) Upon receipt from the warehouse, the IHT Manager will:
    1) Inspect the package to ensure it is sealed, free of damage, and transported in compliance with manufacturer's guidelines
    2) Perform accountability check to confirm receipt of all items
    3) Keep all paperwork that accompanies shipment (i.e.: receipts, package insert)
    4) Log inventory on Sponsor Worksheet located in Regulatory Binder
    5) Document the following information into Research Tissue log in SharePoint:
        I. Receipt date
        II. Receipt time
        III. Name of person accepting delivery of Investigational Human Tissue
        IV. Tissue type
        V. Source facility (Sponsor)
        VI. Tissue ID number and/or lot number
        VII. Integrity of package
        VIII. Proper transport temperature verification
        IX. Storage location
        X. Expiration date

e) Tissue arriving opened, contaminated, or at the incorrect transport temperature will not be released for use. This will be documented on the Research Tissue log under product integrity, disposition, and reason for disposal or return. Research staff will notify the Sponsor. Tissue shall be disposed of in the red Biohazard waste receptacle unless Sponsor guidelines require that it be returned.

MANAGEMENT OF INVESTIGATIONAL HUMAN TISSUE:

a) Investigational Human Tissue will be stored in a locked cabinet/drawer and in a locked office at all times. It will be stored at appropriate temperature per manufacturer's guidelines. If refrigeration is required, contact the Clinical Studies Center Manager for further instruction.

b) Only designated research staff will have access to the Investigational Human Tissue.

c) Investigational Human Tissue will be stored separately and away from all other human tissue products currently being used for clinical treatment.

d) Investigational Human Tissue will be dispensed and used according to the IRB approved protocol.

e) Investigational Human Tissue will be delivered to a sterile field in an aseptic manner. Staff will adhere to the package insert information regarding:
    1) Instructions for use
    2) Indications and contraindications
    3) Preparation/reconstitution of tissue for use
    4) Expirations dates

f) The Investigational Human Tissue use must be immediately documented in CPRS and documentation should be verified by study staff. The CPRS note can be a Research Study note (if there is a specific research clinic created for the research project), otherwise it must be a VA Clinic Note, depending how the study subject is scheduled. Document the following:
    1) Type of Investigational Human Tissue used
    2) The name of the material used to prepare and/or reconstitute tissue including its lot number and expiration date (i.e.: normal saline)
    3) Tissue disposition – implanted, returned, or disposed of
    4) Date issued or disposed of
    5) Time issued
    6) Person who issued tissue
    7) Patient's full name
    8) Patient's full social security number
    9) If returned or disposed list reason (i.e.: contaminated)

g) The IHT Manager will immediately document in the SharePoint Tissue Log by:
    1) Selecting the Investigational Human Tissue tab created specifically for the research project (*i.e.; Research Epifix*)
    2) Locate the tissue ID number and lot number in SharePoint that corresponds with the tissue used on study participant
    3) Document:
        I. Type of Investigational Human Tissue used
        II. The name of the material used to prepare and/or reconstitute tissue including its lot number and expiration date (i.e.: normal saline)
        III. Tissue disposition – implanted, returned, or disposed of
        IV. Date issued or disposed of
        V. Time issued
        VI. Person who issued tissue

VII. Patient's full name
VIII. Patient's full social security number
IX. If returned or disposed list reason (i.e.: contaminated)

h) Dispose of unused Investigational Human Tissue in a red Biohazard bag located in the clinic.

i) Update sponsor inventory log located in regulatory binder.

ADVERSE EVENTS:

a) The PI and AVAMC clinical staff are responsible for immediately reporting adverse events (AE) such as disease transmission or infection suspected of direct correlation with Investigational Human Tissue use as follows:
   1) To the AVAMC Infection Control Department and the AVAMC Patient Safety/Risk Management Department.
   2) To the AVAMC Research Office via the Reportable Event Form. The research Reportable Event policy and forms are located on the AVAMC research website.
   3) To the study Sponsor.
   4) Enter into the Electronic Patient Event Report (e-PER) system located on SharePoint.
   5) Refer to MCM 112-2 "Dispensing and Use of Solid Tissue" for further instruction.

b) All unused Investigational Human Tissue will be sequestered.

c) An investigation by the medical center will follow.

d) Principal Investigator or Chief of Service will inform recipients of the Investigational Human Tissue of the infectious risk as soon as possible after consulting with AVAMC Medical Center Authorities.