

Rider 115 TISSUE RIDER

Purpose:

This Tissue Requirement, hereinafter referred to as the "Rider" establishes requirements to govern the provision of tissue products to The University of Texas MD Anderson Cancer Center ("MD Anderson") and clarifies the responsibilities of the individual parties under such an arrangement.

"Tissue Products" are a functional group of human or animal cells or tissues intended for implantation, transplantation, infusion or transfer into a human recipient, including but not limited to, bone, cornea, skin, heart valves/conduits, tendons, fascia, dura, bone marrow, veins, arteries, cartilage, sperm, embryos, eggs, stem cells, cord blood, synthetic tissue (artificially prepared, human and non-human based), amniotic fluid, and other cellular and tissue based transplant or implant products.

Agreement:

The Company ("Contractor") agrees to the following requirements:

A. Representation and Warranty:

Contractor represents and warrants to MD Anderson that it is licensed by the state where it is headquartered and is registered as a "tissue establishment" with the Food and Drug Administration (FDA), or a device manufacturer that is otherwise regulated by the FDA. On an annual basis, Contractor must provide to MD Anderson a written certification certifying that the foregoing representations and warranties are still true. In addition, on an annual basis, MD Anderson will independently confirm Contractor's FDA registration status and state licensure, if applicable.

B. Responsibilities:

Contractor agrees to transport, handle and store Tissue Products according to written directions (package insert) associated with the product and must comply with all applicable laws, standards and regulations of federal and state governments, and any applicable regulating bodies, including without limitation regulations set forth in 21 CFR Part 1271, and regulations and standards promulgated by the American Association of Tissue Banks (AATB) and the FDA.

Contractor agrees to maintain continuous temperature monitoring for storage refrigerators and freezers while the Tissue Product is in its possession.

Contractor must establish a back-up plan for Tissue Product storage in the event of equipment failure. Storage equipment must have functional alarms and emergency backup.

Contractor assumes full responsibility to maintain package integrity until the Tissue Product is received and accepted into inventory at MD Anderson by the Transfusion Medicine department.

Contractor assumes full responsibility for the transportation of the Tissue Product once it leaves the Contractor's facility and until the Tissue Product is received and accepted into inventory at MD Anderson by the Transfusion Medicine department.

Contractor must be able to demonstrate a validated temperature monitoring system for the transportation of Tissue Products that meets all applicable standards and regulations.

MD Anderson reserves the right to return to Contractor any Tissue Products that do not conform to established standards and regulations.

MD Anderson will have the right to inspect and audit Contractor's facility at reasonable times and in a reasonable manner at Contractor's expense to verify Contractor's compliance with applicable laws, regulations and standards as they related to the transportation, handling and storage of Tissue Products.

C. Traceability:

Contractor must be able to demonstrate a methodology for immediately and effectively communicating to MD Anderson any recalls. All communication regarding Tissue Products recalls should be addressed to UTMDACC, Section of Transfusion Medicine; contact the Tissue Coordinator and/or Quality Assurance Coordinator at (713) 792-8630. Effective and timely communication of such recalls is critical to patient safety because it may result in timely response and treatment to recipients affected by the infected Tissue Products and/or may prevent further implantation of infected Tissue Products.

Contractor acknowledges MD Anderson's right to trace any Tissue Products from the donor or source facility to all recipients or other final dispositions, including the discarding of Tissue Products. Additionally,

Contractor acknowledges MD Anderson's right to trace any Tissue Products from the recipient back to the Tissue Products donor or source facility, in the course of an adverse event investigation.

Contractor agrees to provide Tissue Products donor information reasonably necessary in the course of an adverse event investigation.

D. Records:

Contractor shall have policies and procedures for record management that allow the detailed documentation of each significant step in the lifecycle of Tissue Products and must include, but not limited to:

Informed consents; Donor suitability assessment; Cells and/or Tissue Product retrieval, transport, and processing; Quarantine and infectious disease testing; Record review; and Cells and/or Tissue Product labeling, storage, release and distribution; and Quality Control

To facilitate traceability, Contractor agrees to maintain records which must include (but not be limited to) documentation regarding the unique identifier of the Tissue Products, the identity of staff involved in preparing or issuing the Tissue Products, the identity of staff who accept the Tissue Products, the dates and times of the preparation, issuance or acceptance of Tissue Products, storage temperatures and all superseded procedures, manual, and publications, the original numeric or alphanumeric donor and lot identification, and expiration dates. The records must be retained for a minimum of ten years beyond the date of distribution, transplantation, disposition or expiration of Tissue Products (whichever is latest) or longer, if required by state and/or federal laws.

Complete the section below:

Name of Company:

State that Company is Licensed in:

1. Is the Company a registered tissue establishment with the FDA?

Yes No

If yes, please provide the Company's FDA registration number:

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2. Is the Company accredited by the American Associate of Tissue Banks?

Yes No

If yes, please provide the Company's accreditation number:

3. Have you been inspected by the FDA?

Yes No

Date of last inspection: _____

4. If yes, have all deficiencies noted during FDA inspection been corrected to agency's satisfaction (if applicable)?

Yes No

If No, please provide details: _____

5. Have you been inspected by any other external agency in the past 5 years?

Yes No

Name of Agency and date of last inspection:

6. If yes, have all deficiencies noted during the external inspection been corrected to agency's satisfaction (if applicable)?

Yes No

If No, please provide details: _____

7. Have you had any recalls in the past?

Yes No

If Yes, please provide details: _____

8. Does Company provide non-human products that meet the Tissue Product definition in this Rider?

Yes No

If Yes, please provide name of product and details: _____

****Please note that there are non-human Tissue Products that are considered Tissue Products as defined by MD Anderson's Tissue Committee.**

Contractor agrees to notify MD Anderson in writing within thirty (30) days of any changes to the state license or FDA registration status, as well as any adverse events that involve Tissue Products that MD Anderson procures from Contractor. Contractor further agrees to notify MD Anderson in writing within thirty (30) days of any changes in the

affirmations, certifications, and warranties made by Contractor under this Rider.

Any notice required or permitted to be sent under this Agreement will be delivered by hand or mailed by registered or certified mail, return receipt requested, to Contractor at the address below:

Mailing Address: (Via U.S. Mail)
The University of Texas
MD Anderson Cancer Center
Transfusion Medicine - Unit 007
Attn: Marsha Whatley
P O Box 301439
Houston, Texas 77230-1439

AND

Delivery Address: (In person or Via Courier)
Transfusion Medicine
Attn: Marsha Whatley
The University of Texas
MD Anderson Cancer Center
1515 Holcombe Blvd
Houston, Texas 77030

By signing below, Contractor affirms its compliance with the requirements listed in this Rider. Accepted this _____ day of _____, 20____ by:

Contractor

(Authorized Signature)

(Print or Type Name & Title)

(Date)

**The University of Texas
MD Anderson Cancer Center**

(Authorized Signature)

Contract Manager, Sourcing & Contract Management

(Date)