



PARTICIPATION AGREEMENT

Allograft Tracking System

In accordance with FDA's Good Tissue Practices (§1271.290) and the Joint Commission's Standards (QC.5.11.1), _____ agrees to participate in Genesis Biologics, Inc. Source Facilities Allograft Tracking Systems.

Under this agreement, _____ agrees to:

- Document receipt of each allograft and track its location in facility.
- Complete appropriate Allograft Implant Record upon implantation of an allograft.
- Establish a system for returning the record to Source Facilities in a timely and consistent manner.
- Document allograft usage information in an Implant Log Book to clearly identify the allograft being implanted into a specific patient.
- Document allograft usage information into patient's medical records.
- Retain all records relating to the receipt and usage of allograft tissues for a minimum of ten (10) years.

Under this agreement, **Genesis Biologics, Inc.** agrees to:

- Ensure source facilities provide an Allograft Implant Record for each allograft shipped.
- Ensure source facilities provide instructions for filing out the Allograft Implant Record.
- Ensure source facilities provide, with each allograft, a sufficient number of adhesive labels documenting tissue identification number.
- Ensure source facilities provide, on an as needed basis, reports showing hospital's compliance with the allograft tracking system established by source facilities.

Genesis Biologics, Inc.

Participating Facility

Authorized Signature

Date

Authorized Signature