

**BioIVT Certification Sources of Human Tissue
Donor Consent and Confidentiality**

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Sources of Human Tissue

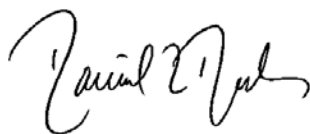
All of the human tissues that BioIVT uses in the manufacture of our products come from sources within the United States. These tissues are procured through a not-for-profit broker (Broker) that works directly with Organ Procurement Organizations (OPO's). The Broker acquires tissues that meet BioIVT specifications while following BioIVT Standard Operating Procedures (SOP's) for obtaining Research Consent and maintaining Donor Confidentiality.

Donor Consent and Confidentiality

Regard for the rights of human donors has been and continues to be a key concern of BioIVT. BioIVT protects donor confidentiality by following approved SOP's which include:

1. Coding all specimens with the UNOS (United Network for Organ Sharing) number and a BioIVT code only.
2. Preventing receipt of or requiring the obscuring or deleting of all information identifying the donor, the physician, and OPO such that this information is unreadable.
3. Collaborating with our Broker to ensure that appropriate consent is obtained for all tissues from all OPO's.
4. Requiring that the Broker review a copy of the donor consent form used by each OPO, to ensure that informed consent is given for research use and does not preclude commercial or international use.
 - a. A copy of the consent form is required before any tissue is accepted by the Broker. A copy of the consent form is retained in the files of the OPO and Broker.
 - b. The Broker trains the OPO's to omit any identifiers of the donor, the donor's physician, and the surgeon procuring the tissue.
 - c. The Broker maintains a copy of the medical records for each donor in order to assist BioIVT with any inquires or investigations while maintaining confidentiality.
 - d. The Broker provides a certification to BioIVT that each tissue received included properly obtained consent.

BioIVT



Dan Dryden
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