

**Agreement between
California Transplant Services, Inc.
and**

This should be considered a "blanket document" regarding tissue for transplant exported or imported between either establishment listed below. This document is applicable to transplantable tissue and the following registration, licensing, or regulatory considerations where applicable:

1. Accreditation by the Eye Bank Association of America (EBAA) [Medical Standards A1.100 & B 1.000]
2. Registration with the United States Food & Drug Administration (FDA) [21 CFR 1271-B];
3. Licensing/registration with other state or federal regulatory agency(s) as applicable.
4. EBAA Medical Standard C3.510 (Utilization of Services Provided by Establishments Performing Limited Eye Banking Functions)

Definitions

The *importing establishment* shall be known as the *distributor* if the tissue is sent from that establishment for final distribution to the *end user or consignee*.

The *exporting establishment* shall be known as the *source establishment* or the *recovery/processing establishment*. The source establishment is responsible for determination of donor eligibility to the degree required by current EBAA Medical Standards and FDA regulations. If an establishment receives tissue from a source eye bank and subsequently ships the tissue to another eye bank for end user distribution, that establishment will be considered a trans-shipping or distribution intermediary.

Agreement

- Both establishments listed below perform relevant eye banking activities in accordance with current EBAA Medical Standards and FDA regulations (e.g., relevant activities applicable to the functions/services performed such as recovery, processing, storage, or distribution). Additionally, both establishments agree to maintain registration with the FDA, and if EBAA accredited, notify the other within a reasonable amount of time should accreditation status change.
- Both establishments agree to notify the other as soon as possible of any relevant information that may become available which could potentially affect a tissue recipient in the form of an adverse reaction or recall as required by the current EBAA Medical Standards and FDA regulations.
- The distributor will be responsible for collection and maintenance of recipient information and postoperative follow-up associated with imported tissue. In the case of an audit, agency inspection, adverse reaction, or other complaint, the distributor agrees to share reasonable non-proprietary tissue tracking or recipient information with the source establishment as needed within the reasonable time frame requested.
- The distributor will notify the source establishment as soon as possible of any complaints reported from the end user, which may not be limited to but specifically include tissue related adverse reactions or potential deviations. The distributor agrees to forward these complaints or potential deviations to the source establishment for follow-up and investigation should such activities be necessary according to standards and regulations. If an investigation is warranted, a summary of the investigation will be

forwarded to all establishments involved within a reasonable amount of time.

- If regulatory reporting is necessary due to a complaint or tissue recall the source establishment shall be the designated reporter or shall coordinate reporting with other establishments that may have performed eye banking services where applicable.
- Any other responsibilities or activities not specifically addressed in this document will be carried out according to the most current EBAA Medical Standards and FDA regulations available at the time of activity.

The term of this Agreement shall commence on the effective date which is the date of execution and shall end when either party terminates the Agreement with or without cause by giving one hundred eighty (180) days prior written notice to the other party. For purposes of this Agreement, the effective date shall be the last date executed below. This Agreement becomes legally binding upon signature below by authorized representatives of the parties.

<p>By: California Transplant Services, Inc. 5845 Owens Avenue Carlsbad, California 92008</p> <hr/> <p>Marc Pablo, Vice President</p>	<p>By:</p> <p>_____ (eye bank)</p> <p>_____ (address)</p> <p>_____ (city,state,zip)</p> <p>_____ (signature, date)</p> <p>_____ (printed name, title)</p>
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