



SURGEON QUESTIONNAIRE

Surgeon name: _____

Name of practice: _____

Street address: _____

City, State, Zip: _____

Email: _____

Office telephone: _____

Office fax number: _____

Cell phone: _____

Home phone: _____

Pager: _____

Name of medical school attended: _____

(Please attach a copy of your medical license)

Year and degree granted: _____

Are you Board Certified? Yes No

Fellowship? Yes No

Specialty: _____

List hospitals/surgery centers where you currently perform surgery:

**Revised January 26, 2016*



TRACKING METHOD AGREEMENT

In compliance with FDA Final Rule 21CFR Part 1271, Current Good Tissue Practice for Human Cell, Tissue and Cellular and Tissue-Based Product Establishments, Inspection and Enforcement, I have been informed of the requirements of §1271.290, Tracking.

I have received a copy of this section as well as the Eversight policy and procedure for recipient information tracking (M1.511, Recipient Information Tracking Procedure).

I agree to participate in Eversight's tracking methods outlined in the above policy and procedure and will take all necessary steps to ensure compliance with these requirements.

Name (please print): _____

Signature: _____

Date: _____

**Revised January 26, 2016*



INVOICE INFORMATION SHEET

Name of hospital/surgery center for billing: _____

Billing address: _____

Shipping address (if different): _____

City, State, Zip: _____

Telephone: _____

Fax: _____

Facility hours: _____

Delivery instructions: _____

Does this facility require a Purchase Order Number for payment of tissue received?

No Yes - please check all applicable boxes below:

Standing PO Number: _____ Expires: _____

Individual PO Number: _____

PO Number required prior to receipt of tissue

Hospital/surgery center accounts payable contact: _____

Telephone: _____ Email: _____

Hospital/surgery center purchasing dept. contact: _____

Telephone: _____ Email: _____

Hospital/surgery center operating room contact: _____

Telephone: _____ Email: _____

Questions regarding billing? Please contact our Finance Department at (734) 887-2309.

Questions regarding shipping? Please contact our Tissue Placement Department at (866) 900-8119.

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TITLE 21 FOOD AND DRUGS

CHAPTER I - FOOD AND DRUG ADMINISTRATION DEPARTMENT OF HEALTH AND HUMAN SERVICES

SUBCHAPTER L - REGULATIONS UNDER CERTAIN OTHER ACTS ADMINISTERED BY THE FOOD AND DRUG ADMINISTRATION

PART 1271 - HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS

Subpart D - Current Good Tissue Practice Sec.1271.290 Tracking

(a) **General.** If you perform any step in the manufacture of an HCT/P in which you handle the HCT/P, you must track each such HCT/P in accordance with this section, to facilitate the investigation of actual or suspected transmission of communicable disease and take appropriate and timely corrective action.

(b) **System of HCT/P tracking.** (1) You must establish and maintain a system of HCT/P tracking that enables the tracking of all HCT/Ps from:

(i) The donor to the consignee or final disposition; and

(ii) The consignee or final disposition to the donor.

(2) Alternatively, if you are an establishment that performs some but not all of the steps in the manufacture of an HCT/P in which you handle the HCT/P, you may participate in a system of HCT/P tracking established and maintained by another establishment responsible for other steps in the manufacture of the same HCT/P, provided that the tracking system complies with all the requirements of this section.

(c) **Distinct identification code.** As part of your tracking system, you must ensure: That each HCT/P that you manufacture is assigned and labeled with a distinct identification code, e.g., alphanumeric, that relates the HCT/P to the donor and to all records pertaining to the HCT/P; and that labeling includes information designed to facilitate effective tracking, using the distinct identification code, from the donor to the recipient and from the recipient to the donor. Except as described in 1271.55(a)(1), you must create such a code specifically for tracking, and it may not include an individual's name, social security number, or medical record number.

by another establishment engaged in the manufacturing process, or you may assign a new code. If you assign a new code to an HCT/P, you must establish and maintain procedures for relating the new code to the old code.

(d) **Tracking from consignee to donor.** As part of your tracking system, you must establish and maintain a method for recording the distinct identification code and type of each HCT/P distributed to a consignee to enable tracking from the consignee to the donor.

(e) **Tracking from donor to consignee or final disposition.** As part of your tracking system, you must establish and maintain a method for documenting the disposition of each of your HCT/Ps, to enable tracking from the donor to the consignee or final disposition.

The information you maintain must permit the prompt identification of the consignee of the HCT/P, if any.

(f) **Consignees.** At or before the time of distribution of an HCT/P to a consignee, you must inform the consignee in writing of the requirements in this section and of the tracking system that you have established and are maintaining to comply with these requirements.

(g) **Requirements specific to dura mater donors.** You must archive appropriate specimens from each donor of dura mater, under appropriate storage conditions, and for the appropriate duration, to enable testing of the archived material for evidence of transmissible spongiform encephalopathy, and to enable appropriate disposition of any affected non-administered dura mater tissue, if necessary.

*Revised January 26, 2016



SURGERY SCHEDULING INFORMATION

Please return completed form to Eversight Tissue Placement using the contact information below.

Patient name: _____

Street address: _____

City, State, Zip: _____

Telephone number: _____

Patient diagnosis: _____ Date of birth: _____

Patient identifier (SSN or MRN): _____ Sex: Male Female

Surgeon: _____

Surgery location: _____

PO number (if required): _____

Surgery date: _____ Surgery time: _____

Tissue being requested:

- | | |
|--|--|
| <input type="checkbox"/> PKP | <input type="checkbox"/> ALK (processed by eye bank) |
| <input type="checkbox"/> DMEK (processed by eye bank) | <input type="checkbox"/> ALK (processed by surgeon) |
| <input type="checkbox"/> DMEK (processed by surgeon) | <input type="checkbox"/> DALK |
| <input type="checkbox"/> DSAEK (processed by eye bank) | <input type="checkbox"/> Globes for KLA Quantity: _____ |
| <input type="checkbox"/> Ultrathin | <input type="checkbox"/> K-Pro |
| <input type="checkbox"/> Pre-loaded | <input type="checkbox"/> LAK/IEK (processed by eye bank) |
| <input type="checkbox"/> DSAEK (processed by surgeon) | <input type="checkbox"/> Other (please specify): _____ |

- | | |
|---|--|
| <input type="checkbox"/> Sclera - whole | <input type="checkbox"/> Sclera - eighth |
| <input type="checkbox"/> Sclera - half | <input type="checkbox"/> 6mm disc |
| <input type="checkbox"/> Sclera - quarter | <input type="checkbox"/> Other (please specify): _____ |

Person completing form: _____

Contact email: _____ or FAX: _____

**Revised June 9, 2016*

RECIPIENT INFORMATION TRACKING

M1.511

Recipient Information Tracking Procedure

Effective Date: 05/01/2015

Supersedes: 05/01/2014

The eye bank shall obtain the name and address of the consignee on each eye tissue used for transplantation. The eye bank shall seek recipient information from the transplanting surgeon for eye tissue distributed by the eye bank.

Recipient follow-up information is collected by telephone and by written forms from the surgeon. For all surgical tissue provided, Post-Operative Outcome forms will be sent to surgeons three to six months post-operatively, confirming in writing the recipient information. For any forms not received within specified time frame, a second notice will be sent to the surgeon requesting recipient follow-up information.

Completed forms become part of the Case Record. Reports of Post-Operative Outcome forms sent will be maintained.

Regulations

EBAA Medical Standard M1.500 Recipient Follow-Up Information

EBAA Medical Standard L1.200 Package Insert Form 21 CFR § 1271.290 Tracking

State of New York Subpart 52-2.9 Required Records

Procedure

1. Patient information is typically obtained from the surgeon/office and entered into the database at the time of surgery scheduling. If the recipient information is not available at the time of scheduling, a Recipient Information form is sent with the tissue to be completed by the surgeon for return to the eye bank.

Note: Corneas in long-term preservation media and sclera may be stocked at an institution only if it is for single patient use. The distributing eye bank must be able to track the tissue to the consignee.

Patient information to be documented includes:

- Name (if allowed by law)
 - Age/date of birth
 - Race
 - Sex
 - Address
 - Diagnosis
 - Surgery date
 - Type of surgery
 - Location of use
 - Surgeon's name
 - Unique ID number
 1. Social Security number
 2. Driver's license number
 3. Hospital medical record number
 4. Alien identification
 5. Passport number
 6. Other unique identifier appropriate to the health care delivery system where the surgery is performed.
2. Tissue is offered and accepted; patient to receive transplant is confirmed for domestic recipients and the schedule information is linked to the appropriate tissue ID.
 3. Tissue is shipped to the hospital or facility; a designated area at the hospital or facility (e.g., OR, blood bank, etc.) receives and logs appropriate tissue/patient information in accordance with Joint Commission requirements and FDA regulations.
 4. The Tissue Information Form and Adverse Reaction Report Form remain with patient's medical record.
 5. Corrections and/or changes to recipient information are entered into database.
 6. A Post-Operative Outcome form is sent three to six months post-operatively, seeking recipient information and verifying that the tissue indicated by the unique tissue ID number was used for that patient.
 7. Returned forms are reviewed; any changes with regard to recipient information and/or surgeon's comments are entered into the database. Completed forms are filed in the case record.
 8. For any forms not received within specified time frame, a second notice will be sent to the surgeon requesting recipient follow-up information.

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CHARITABLE SERVICES REQUEST

This form **MUST** be submitted before the scheduled surgery date. Please allow at least one week for this request to be reviewed and approved.

Date: _____ Surgeon name: _____

Patient name: _____

Date & location of surgery: _____

Reason the patient needs gratis or reduced-fee tissue: _____

Does the patient have insurance? Yes No

Does the patient receive Medicare? Yes No

Does the patient receive Medicaid? Yes No State reimbursement: _____

Financial assistance from providers

1) Surgeon's fee reduced by: _____%

2) Hospital/surgery center's fee reduced by: _____%

3) Anesthesiologist's fee reduced by: _____%

3) Requested financial aid from Eversight: _____%

Contact name: _____ Contact phone: _____

I verify that this patient demonstrates financial need for charitable services.

As part of our mission to restore sight, Eversight and its affiliates rely on financial contributions to provide charitable support for uninsured or underinsured patients in need of a cornea transplant. These charitable contributions are used to offset all or a portion of the reimbursement fees related to tissue recovery and processing for transplantation.

For Eversight use only

Request received by: _____

Request reviewed by: _____

Status: Approved Declined Date: _____

Invoice tissue at: _____

Comments: _____

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GIFT OF SIGHT PROGRAM

No one should be denied the gift of sight.

Eversight offers hope for your patients with limited income or inadequate insurance by accepting reduced-fee requests for corneal tissue.

Our Gift of Sight program, funded solely through charitable contributions, waives or reduces the fees associated with transplantation.

Over the years, our program has helped hundreds of grateful recipients. Now, these people can work, care for their family and live an independent life.

Making your request

Requests can be made by completing the Gift of Sight Charitable Services Request Form (available at eversightvision.org) and returning it to the Eversight Tissue Placement Department.

All requests will be reviewed within three business days, and you will be notified of approval.

When approved, Eversight will waive or reduce our tissue processing fee, plus any shipping charges that may be incurred, and bill the hospital/surgery center for the negotiated fee.

Please provide one week's notice for your charitable services request to allow ample time for processing and approval. In the case of an emergency, your request will be reviewed immediately.

As part of our Gift of Sight program, we ask that you join us in providing financial relief to patients in need by reducing your surgery fees, whenever possible.



See the impact

Dan Burton began having problems with his left eye when he was two years old. As a teenager, he underwent a cornea transplant that saved his eye, but did little to improve his vision.

Nearly 60 years later, an infection robbed Burton of his remaining vision, and he was told that another cornea transplant was the only treatment.

For him, the news could not have come at a worse time. Burton was always a hard worker, and owned and operated his own business, building houses and installing flooring. But the years of hard work eventually took their toll on Burton's body, and he suffered a heart attack.

"Everything went down the drain for me," he recalls. "When it started, it was like a big ball rolling down a hill."

When he found out he was going to need another cornea transplant, he was unemployed and had no insurance. He didn't know where to turn.

Much to his surprise, help was on the way. His eye doctor, Dr. Miriam Schteingart, alerted Eversight that she had a patient who urgently needed a cornea transplant, but was unable to afford the costs associated with the surgery.

Eversight quickly made the arrangements to provide the necessary corneal tissue, waiving our usual fees, and Burton underwent a successful cornea transplant.

Today, he is able to live a productive, independent life thanks to his renewed sight.

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