Accreditation Board

SITE INSPECTION PREPARATION GUIDE

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Purpose

Your eye bank is about to be inspected for EBAA Accreditation. The purpose of the guide is to familiarize you with the process of accreditation and the EBAA's peer review site inspection process.

Your eye bank will be visited by two (2) inspectors who will review your policies and procedures to ensure that they comply with EBAA Medical Standards. The EBAA Accreditation Board's goal is to make this a constructive learning experience. We want to make the process as comfortable as possible and non-confrontational in nature by sharing information with you that will help you prepare for site inspection.

Confidentiality

Our expressed goal is to keep all information regarding your inspection strictly confidential. Please do not discuss your inspection or inspectors with other banks to ensure continued confidentiality.

Site Inspection Preparation

Following notification from the EBAA office that a site inspection is to be scheduled, your eye bank has thirty (30) calendar days to submit a completed application form, along with the required fees to confirm your request to be inspected.

Prior to the inspection, you should review the EBAA Medical Standards to be certain that you are in compliance with them. The EBAA Procedures Manual may also be reviewed. You are not required to follow procedures as outlined in the Procedures Manual but reviewing it may provide additional useful information for you to ensure that your policies and procedures comply with the Medical Standards. You should also locate documents that will be required at the site inspection (see below).

Scheduling your inspection early will allow your eye bank the maximum amount of time to address any non-compliance with Medical Standards that are identified during the inspection and to submit corrective actions, if necessary. No inspections may be conducted less than one month prior to the Board meeting, without prior approval of the Accreditation Board co-chairs.

The Site Inspection Process

The site inspection team will consist of two individuals who meet the requirements as outlined in Accreditation Board Policies and Procedures and who are familiar with the technical aspects of eye banking. One member of the team will serve as Lead Inspector, coordinating the arrangements for the inspection, such as scheduling. You may be asked to assist with travel arrangements, in recommending to the site inspectors' appropriate accommodations, providing transportation from the airport to their hotel and to and from the hotel to your eye bank. Generally, site inspectors will meet privately prior to the site inspection to discuss your policies and procedures manual, pre-inspection questionnaire responses and other aspects of the inspection. You should not plan any other activities on the day(s) of the site inspection. It is essential that all eye bank personnel, including the Medical Director, be available to the inspectors. The amount of time the inspection will require depends on the scope of eye banking functions performed by your bank. Allow up to 2 days for the inspection. Your Lead Inspector may be able to provide you with more guidance after receiving and reviewing your Application and Pre-Inspection materials.

Pre-Inspection Materials

The following materials must be sent to <u>each</u> of your inspectors at least twenty (20) working days prior to the scheduled date of your inspection:

1. Declaration of Compliance with Governmental Regulations

The declaration of compliance with governmental regulations must be completed and signed by the Director and the Medical Director.

2. Pre-Inspection Questionnaire with Accompanying Documentation

Prior to the inspection, you will be asked to respond to a number of questions in writing. Some of these questions are asked prior to the inspection to give you an opportunity to obtain documentation (such as certification of off-site sterilization or infectious disease testing facilities). Information submitted, such as the above referenced documents, must reflect all agencies, services, certifications, etc. utilized **since the date of your eye bank's last EBAA inspection (maximum of 3 yrs)**. Other questions are designed to identify eye bank personnel which must also be submitted for all personnel performing identified functions **since the date of your eye bank's last EBAA inspection (maximum of 3 yrs.)**. Still others are devised to determine how you might handle specific, difficult situations and to test your knowledge of EBAA Medical Standards. The Pre-Inspection Questionnaire should be completed and the accompanying documentation attached, before the Questionnaire is reviewed and signed by the Director. Deficiencies found in the documentation provided as part of the Pre-Inspection Questionnaire will be cited as part of the inspectors' report to the Accreditation Board and will require formal documentation of corrective actions.

3. Policies and Procedures Manual

The eye bank must have a policies and procedures manual that addresses all eye banking functions performed by the bank. These policies and procedures should be in compliance with Medical Standards, should be current and should reflect actual operations. There must be documentation that the policies and procedures manual has been reviewed by the eye bank Director as well as the Medical Director. One way to accomplish this is for these individuals to initial and date each addition/revision to the policies and procedures manual. Policies and procedures that are revised and/or discarded should be kept on file so that an outside observer could determine the length of time that each policy and procedure was in use.

The policies and procedures manual should be specific for your eye bank (rather than, for example, a copy of the EBAA Procedures Manual). It should be sufficiently detailed so that a person familiar with eye banking could follow procedures accurately. Eye bank personnel should have easy access to the policies and procedures manual and should be familiar with its content. The inspectors will determine whether the procedures set forth in the policies and procedures manual are, in fact, being followed. Therefore, the policies and procedures manual should be reviewed carefully prior to the inspection to be certain that it reflects accurately the current procedures at your eye bank.

You should be certain that the policies and procedures manual addresses all applicable eye banking functions performed at your bank, such as: tissue acquisition (legal and procedural aspects), donor screening (medical history, plasma dilution policy, physician/nurse interviews, medical and social history interviews, autopsy results) recovery procedures, including inspection of the donor body, tissue evaluation, infectious disease testing, determination of donor eligibility by the Medical Director/designee, a back-up medical director, distribution policies, packaging, labeling and tissue recall. Be certain that these procedures satisfy EBAA Medical Standards and are actually being followed.

In order to facilitate review of the policies and procedures manual by the inspectors, you must either tab your SOPs to correspond with each question in Section 2 of the Site Inspection Questionnaire or provide a separate document (crosswalk) that clearly explains where the inspectors can locate information pertaining to each question in Section 2 of the Site Inspection Questionnaire.

During the Inspection

During the inspection, applicable areas for the eye banking functions performed by your bank will be reviewed, in any order convenient to the eye bank staff, and to the inspectors:

- Medical Director Interview
- Director Interview

- Quality Assurance Director Interview
- Technical staff interview and demonstration of applicable tissue preservation and processing procedures (Refer to the "Accreditation Policies and Procedures" to determine which specific procedures will be required to be performed.)
- Inspection of the laboratory and equipment
- Records review, including donor and recipient records, quality assurance, training and equipment records (See Appendix A)

Each of these aspects of the inspection is described below.

Medical Director

The inspection team will interview the Medical Director to be certain that he/she is familiar with eye bank operations and is personally involved. The Medical Director should have access to the Policies and Procedures Manual and EBAA Medical Standards. The Medical Director should be familiar with staff training, donor screening and recovery procedures, infectious disease testing requirements, tissue distribution policies and should be able to explain his/her role in the QA program. The Medical Director should also be available for consultation with technicians and to hold discussions with transplant surgeons about tissue and review adverse reactions, whenever necessary.

There should be documentation of at least the following:

- The Medical Director is directly involved in eye bank activities (e.g., minutes of meetings, correspondence).
- The Medical Director oversees the eye bank technical staff. For example, the Medical Director might meet regularly with eye bank technicians to review procedures and/or observe them personally at work.
- The Medical Director has observed the designated staff trainer(s) performing the following procedures as applicable on an annual basis:
    - In-situ corneoscleral disc excision or laboratory corneoscleral disc removal from whole eye
    - Posterior lamellar processing that utilizes a microkeratome
    - At least one type of laser-shaped processing procedure
    - Each manual dissection processing procedure(s) for EK and ALK (i.e. DSEK or DMEK)
- The Medical Director has personally reviewed each reported adverse reaction and instituted any corrective action he/she deemed appropriate.
- There must also be written evidence in eye bank records that the Medical Director or his/her designee has reviewed and approved the release of each donor for surgical use.

Medical Standard C1.200 requires Medical Directors to attend the Medical Directors' Symposium at the annual meeting of the EBAA at least once every three years and a Medical Advisory Board meeting at least once every three years, and this should be recorded and made available to inspectors.

Personnel

The site inspection team will interview the eye bank Director, the Quality Assurance Director, as well as employees performing eye banking functions, including certified and non-certified technicians. You will be asked to produce documentation of the qualifications of these individuals, including documentation of their orientation, training, and annual competency reviews. The eye bank Director, QA Director and technicians will be interviewed to be certain that they have a working knowledge of the bank's policies and procedures.

Laboratory

The site inspectors will determine whether you have a laboratory that is dedicated solely to conducting eye bank activities, has restricted access to authorized personnel only, is clean, adequately equipped, well maintained and safe. You will need to produce documentation that the laboratory and laboratory equipment are cleaned regularly and appropriately maintained. You must have an acceptable method for disposal of human tissue and biohazardous material.

The laboratory must meet the requirements in the current EBAA Medical Standards applicable to the eye banking functions performed by your bank. This may include requiring a slit lamp and specular microscope that are in working order, a laminar airflow cabinet or hood or processing room, a refrigerator, appropriate instrumentation for recovery and further tissue processing and workspace adequate for the volume of procedures to be performed. If sterilization, culturing and/or infectious disease testing are performed in the eye bank laboratory, quality control must be documented. If they are performed outside of the laboratory, you must provide documentation to satisfy the inspectors that there is adequate quality control.

If the bank performs processing of tissue in the laboratory, it must be performed in a) a laminar airflow cabinet or hood, b) an accredited operating room, or c) another environment such as a processing/clean room. Each processing environment outlined above must meet EBAA Medical Standards, be currently certified on an annual basis (and each time it is moved, if movable equipment) and have documentation of appropriate cleaning.

The refrigerator must have an alarm system that notifies an appropriate individual in the event of a temperature deviation outside of the acceptable range. A continuous temperature-recording device must be connected to the refrigerator and should reflect the temperature of the stored tissue under normal storage conditions. Calibration, at least annually, is required. The refrigerator should be clean, and no extraneous materials (such as food) should be present in the refrigerator. Areas of the refrigerator must be clearly labeled according to their use (e.g., quarantine tissue, surgical tissue awaiting distribution, research tissue, etc.). Any corneal preservation medium stored in the refrigerator will be checked for expiration dates and that there is documentation of inspection upon arrival.

The eye bank must include in its policies and procedures manual, the monitoring, inspection and cleaning procedures and schedules for each piece of laboratory equipment. Documented cleaning schedules for laboratory equipment must be kept on file for a minimum of three years. SDS sheets, for required products found in the lab, must be made available to the inspectors.

The site inspectors will inspect instrumentation for recovery and processing of ocular tissue. The instruments must be adequate for the purpose, clean, well maintained and sterile. Each instrument package must contain an indicator of successful sterilization as well as an expiration date, unless sterilization is event-related. No instrument packages should be stored beyond their date of expiration, if applicable.

Procedures

Through interviews and observation, the site inspectors will determine whether the eye bank technicians are recovering, evaluating, processing, storing, and distributing tissue and determining donor eligibility according to EBAA Medical Standards, as applicable to the eye banking functions performed by your bank. At least one technician from each category of certification at your eye bank, i.e., CEBT and non-CEBT, as applicable, must be available to demonstrate tissue preservation and processing procedures (e.g. lab excision, in situ, lamellar tissue via microkeratome) in the presence of the inspectors. It is strongly recommended that fresh whole eyes (not frozen) be used for the practical demonstration(s) to provide for the best possible outcome of the procedures. (Refer to the "Accreditation Policies and Procedures" to determine which specific procedures will be required to be performed.) The inspectors will watch carefully to be certain that there is compliance with OSHA Standards, good aseptic and sterile technique, atraumatic surgical technique, appropriate labeling and tissue packaging for shipment. At least one member of the technical staff will be asked to describe the enucleation procedure verbally, including preparation of the operative field, instrumentation, the enucleation procedure itself and donor restoration techniques. Instrument packs will be examined for adequacy. Preparation of sclera will also be discussed verbally, if applicable. You should pay close attention to standards for packaging and labeling of tissue. The inspectors will specifically review each of these procedures.

Records Review

The inspection team will review records applicable to the eye banking functions performed by your bank, including records relating to personnel and governance of the eye bank, donor and recipient information, laboratory equipment cleaning and maintenance, Q/A activities, tissue distribution and documents that accompany donor tissue. (See Appendix A)

The team will review a number of donor records selected by them after they arrive. These records will be selected dating from the time of the last inspection (maximum of 3 years). At least 85% of these donor records shall have had one or more tissues transplanted. The inspectors will evaluate each record to be certain that all tissue is labeled with a unique ISBT 128 Tissue Identifier, that tracking from donor to consignee is always possible, that a medical history, donor

risk assessment interview (DRAI), physical inspection, plasma dilution evaluation and (if performed) autopsy reports are documented, that all appropriate tissue evaluations (pre- and post-processing) have been documented prior to distribution, that required infectious disease testing results are obtained before release of tissue for distribution, and that adverse reactions, if reported, are investigated, tracked, reviewed by the Medical Director and reported to EBAA if applicable, and that reporting is documented. You will need to provide evidence to the inspection team that you have a consistent policy for identifying consignees of tissue and seeking post-operative follow up information for each surgical tissue distributed.

Exit Summation Conference

1. Following the inspection, the inspection team will hold a summation conference to provide immediate notice of inspection findings. The eye bank Director may invite other eye bank staff to attend this meeting. The inspectors will discuss any potential threats or other items not in compliance that they found during the inspection. They will leave a photocopy of their handwritten Inspection Summation Report. If you are unsure of the basis for their comments, the site inspectors will be happy to review the relevant portions of the EBAA Medical Standards and site inspection questionnaire with you. The findings from the Inspection Summation Report will be presented to the Accreditation Board for a final determination of accreditation status.

2. Corrective actions regarding non-compliance must be prepared and submitted to the Lead Inspector and non-MD Accreditation Board Co-Chair. Corrective actions and supplemental materials must be received by the Lead Inspector and non-MD Accreditation Board Co-Chair within ten (10) working days following the summation conference for consideration by the Accreditation Board at the meeting where inspection results are presented.

3. You will also have an opportunity to provide feedback to the site inspection team at the Summation Conference. You have a right to a courteous, professional inspection and clear communication of the team's findings. If you feel that this has not occurred, please let the inspection team know this in the post-inspection interview. You will receive an evaluation form that should be completed and submitted to the EBAA Office. You are encouraged to make suggestions about the inspection process if you can think of ways it can be improved.

4. During their inspection, the inspection team may encounter conditions at your eye bank that could, in the opinion of the team, be improved even though they are not violations of the Medical Standards. They may make comments and recommendations in this regard. However, the inspection team will distinguish clearly between non-compliance with Medical Standards and comments about possible improvements.

After the Site Inspection

The inspection team will prepare a report of their findings. This report will be presented at the next meeting of the Accreditation Board. Eye bank identifying information is masked so that the full Board can make a decision on accreditation without knowledge of the eye bank being evaluated. After the report has been presented and questions answered, the Accreditation Board, by secret ballot, will determine the accreditation status of your eye bank. (Refer to "Accreditation Policies and Procedures" for the criteria for accreditation status.) After the meeting, your bank's accreditation status and any recommendations of the Board will be presented and discussed with you. Official written notification about your eye bank's accreditation status, identified deficiencies and any additional required corrective actions will come from the Accreditation Board Chair(s).

We want the accreditation process to be as comfortable and confidential as possible. Our goal is to ensure quality and safety of eye tissue provided for transplantation, not to deny accreditation. You can facilitate this process by preparing for the inspection well in advance. If you review the EBAA Medical Standards and this guide carefully, there should be no surprises.

Appendix A

Eye Bank Records to Have Available for Accreditation Site Inspection

- Personnel records
  - Orientation and training
  - Release to perform tasks individually
  - Annual competency reviews
  - Designation to determine suitability for transplant
- Medical Director Records
  - Interaction with administrative and technical staff
  - Involvement with QA Program
  - Adverse Reaction Review
- QA Records / Corrective Actions
  - Credentials for testing labs utilized
  - Cleaning, maintenance and environmental control records / logs for laboratory and equipment, including processing/clean rooms (if applicable)
  - Refrigerator records, including temperature monitor records, logs, calibration and alarm testing
  - Autoclave records, including documentation of biological testing
  - Corneal storage solution inspection
  - Donor chart audits
  - Adverse Reaction file
- SDS sheets
- Tissue distribution records
- Donor / consignee / recipient records
- Archive of outdated policies and procedures
- Credentials for other establishments performing eye banking functions, including copies of contracts/agreements, audits and audit plans

Eye Bank Records must be available dating from the time of the last inspection (maximum of 3 years).

***Please note that this list is not to be considered all-inclusive, and that other documents and records may be requested by your inspectors throughout the inspection process.*