

Adverse Reaction Report

The Receiving Surgeon is responsible for reporting any adverse reaction to the appropriate eye bank facility within 30 days of the occurrence. A reportable adverse reaction is any communicable or other disease transmissible by, and attributable to, transplantation of donor eye tissue, including infection (as manifested by endophthalmitis, keratitis, or systemic viral disease) and biologic dysfunction (such as immediate donor endothelial failure or donor corneal dystrophy). The Distributing Eye Bank is responsible for verifying completion of all the items below and reporting information to the EBAA within a reasonable time.

<p>SURGERY INFORMATION</p> <p>Surgeon Name: _____</p> <p>Surgery Location: _____</p> <p>Phone: _____</p>	<p>RECIPIENT INFORMATION</p> <p>Patient Name: _____</p> <p>Patient ID/ SSN: _____</p> <p>Age: _____ Gender: _____</p> <p>Pre-Operative Diagnosis: _____</p> <p>Surgery Date: _____</p> <p>Procedure: _____</p> <p>Lamellar Cut Source _____</p> <p>Lamellar Cut Type _____</p>
<p>DONOR INFORMATION</p> <p>Distributing Eye Bank: SightLife</p> <p>Tissue ID: _____</p> <p>Cell Count (per mm²): _____</p> <p>Donor Age: _____ Gender: _____</p> <p>Race: _____</p> <p>Cause of Death: _____</p> <p>Death-Preservation Interval (hrs): _____</p> <p>Death-Cooling Interval: _____</p> <p>Death-Surgery Interval: _____</p> <p>Recovery Method: _____</p> <p>Preservation Method: _____</p> <p>Media Lot Number: _____</p>	<p>ADVERSE REACTION</p> <p>Date of Diagnosis: _____ (month, day, year)</p> <p><i>(Check One)</i></p> <p><input type="checkbox"/> Primary Graft Failure Did graft ever clear post-operatively? _____ Duration of Clarity _____ Did surgical manipulation have a role in the graft failure? _____ If EK, did the lamellar tissue dislocate from the recipient? _____ If EK, was the tissue rebubbled? _____</p> <p><input type="checkbox"/> Intraocular Infection (microbial endophthalmitis)</p> <p><input type="checkbox"/> Corneal Infection (microbial or viral keratitis)</p> <p><input type="checkbox"/> Transmission of Systemic Disease</p> <p><input type="checkbox"/> Evidence Suggestive of Prior Refractive Surgery</p> <p><input type="checkbox"/> Other _____</p> <p><i>(Check One)</i></p> <p><input type="checkbox"/> Probably due to donor tissue</p> <p><input type="checkbox"/> Probably not due to donor tissue</p> <p><input type="checkbox"/> Reportable to EBAA <input type="checkbox"/> Reportable to FDA</p> <p>Comments: _____</p>
<p>TISSUE SOURCE INFORMATION</p> <p>Tissue Obtained From: _____</p> <p>Recipient ID: _____</p> <p>Tissue Distributed: _____</p> <p>Imported Tissue</p> <p> Origin Eye Bank: _____</p> <p> Origin Eye Bank #: _____</p> <p>TISSUE MATE STATUS</p> <p><i>(Check One)</i></p> <p><input type="checkbox"/> Healthy</p> <p><input type="checkbox"/> Adverse Reaction</p> <p><input type="checkbox"/> Tissue Not Used (reason: _____)</p>	<p>MICROBIOLOGY</p> <p>Donor Cultures <i>(Check Applicable)</i>:</p> <p><input type="checkbox"/> Preservation Medium <input type="checkbox"/> Corneoscleral</p> <p><input type="checkbox"/> Other _____ <input type="checkbox"/> Not Done</p> <p>Results: _____</p> <p>Patient Cultures <i>(Check Applicable)</i>:</p> <p><input type="checkbox"/> Aqueous <input type="checkbox"/> Cornea</p> <p><input type="checkbox"/> Vitreous <input type="checkbox"/> Other _____</p> <p><input type="checkbox"/> Not Done</p> <p>Results: _____</p> <p>Tissue Mate Culture</p> <p><input type="checkbox"/> Done <input type="checkbox"/> Not Done</p> <p>Results: _____</p>
<p>RECIPIENT OUTCOME</p> <p>Additional Surgery <i>(Check Applicable)</i>:</p> <p><input type="checkbox"/> Regraft</p> <p><input type="checkbox"/> Enucleation</p> <p><input type="checkbox"/> Other _____</p> <p>Recent Vision <i>(Check Applicable)</i>:</p> <p><input type="checkbox"/> NLP</p> <p><input type="checkbox"/> LP-CF / 20 - 400 <input type="checkbox"/> 20/200 or better</p>	<p>CONTACT INFORMATION</p> <p>Contact Name: _____ Phone: _____</p> <p>Signature: _____ Date: _____</p> <p>Date Rec'd by EBAA (if appl.): _____ Date Rec'd by Registry (if appl.): _____</p>