Adverse Reaction Report Form
Organ Procurement / Tissue Bank / Eye Bank

Adverse reactions are to be reported to AHCA immediately. Part I of the form is to be submitted to AHCA within 2 days of the event. Part II is to be submitted when the final determination of cause has been determined. When the adverse reaction is due to donor organs or tissues, recall procedures shall be instituted in accordance with Ch. 59A-1.005(15), F.A.C., and look back procedures in accordance with Ch. 59A-1.005(16), F.A.C.

Part I

I. PROCUREMENT AGENCY INFORMATION			
AHCA Certification/License Number:			Report ID Number:
Processing Agency Name:			
Street Address:			
City:	State:	Zip:	Telephone Number:
Telephone Number:			
Procurement Agency Name:			
Mailing Address or ☐ Same as above:			
City:	State:	Zip:	

II. NOTIFICATION	
Date Processing Agency Notified	
Notifying Official	
Notifying Institution	
Institution Street Address	
Telephone Number	

III. NATURE OF ADVERSE REACTION	
☐ Bacterial Infection	Specify Type:
☐ Transmission of Viral Disease	Specify Type:
☐ Other	Describe:

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IV. Organ/Tissue/Identification and Recovery		
Type of Organ/Tissue:	Organ/Tissue ID #:	
Procurement Date:	Procurement Time:	
Preservation Method:	Lot #:	
Transportation Method:	Depart Time:	Arrive Time:
Preservation Days:	Surgery Interval Days:	
Donor ID #:	Donor Age:	Donor Sex:
Donor Cause of Death:		
Were Screening Criteria Met?: ☐ Yes ☐ No		
Other Organs/Tissues Recovered:		

V. Recipient Information	
Patient Name:	
Social Security #:	Medical Record #:

VI. Transplanting Surgeon Information	
Name of Surgeon:	
Address:	
Telephone:	Transplant Date:
Description of Adverse Reaction:	
Other Significant Information:	

VII. Quality Management Action Plan
A. Notification (includes dates of all person and agencies notified)
Medical Director:
AHCA:
FDA:
Accrediting Body (specify which one):
Others:
B. Initial Findings (List all actions taken and the results):
C. Future Actions (List plan for future investigation, if necessary):

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VIII. Person Filing Report	
Name (Print):	Signature:
Title:	Date:

Return this form to:
Agency for Health Care Administration Laboratory and In-Home Services Unit 2727 Mahan Drive, MS# 32 Tallahassee, FL 32308 E-mail Report to: Labstaff@ahca.myflorida.com

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Part II

Date:	Report ID Number:

I. Determination of Cause

Cause:

- ☐ Probably due to donor organ or tissue
- ☐ Probably not due to donor organ or tissue

Basis for determination of cause:

II. Action Plan Complete

Describe all actions completed in accordance with the action plan submitted in Part I:

III. Person Filing Report

Name (Print): Signature:

Date:

Return this form to:

Agency for Health Care Administration
Laboratory and In-Home Services Unit
2727 Mahan Drive, MS# 32
Tallahassee, FL 32308

E-mail Report to: Labstaff@ahca.myflorida.com