

Agency for Health Care Administration  
Laboratory Unit  
2727 Mahan Drive, Mail Stop 32  
Tallahassee, FL 32308  
Phone #: (850) 414-0359 Fax #: (850) 410-1511

Adverse Reaction Report Form \*

\*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**

Report ID #: \_\_\_\_\_

**I. Procurement Agency Information**

Processing Agency Name: \_\_\_\_\_

AHCA Certification/License #: \_\_\_\_\_ Telephone #: \_\_\_\_\_

Street Address: \_\_\_\_\_  
\_\_\_\_\_

Procurement agency:

Mailing Address, if different: \_\_\_\_\_

**II. Notification**

Date Processing Agency Notified: \_\_\_\_\_

Notifying Official: \_\_\_\_\_

Notifying Institution: \_\_\_\_\_

Institution Street Address: \_\_\_\_\_

Telephone #: \_\_\_\_\_

**III. Nature of Adverse Reaction:**

Bacterial Infection (Specify Type): \_\_\_\_\_

Transmission of Viral Disease (Specify Type): \_\_\_\_\_

Other (Describe): \_\_\_\_\_

#### **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 #: \_\_\_\_\_ Transplantation Date: \_\_\_\_\_

#### **VI. Transplanting Surgeon Information (continued):**

Description of Adverse Reaction: \_\_\_\_\_

Other Significant Information: \_\_\_\_\_

**VII. Quality Management Action Plan**

A. Notification (Include dates of all persons and agencies notified.)

Medical Dir: \_\_\_\_\_

AHCA \_\_\_\_\_

FDA \_\_\_\_\_

Accrediting Body (Specify which one): \_\_\_\_\_

Others: \_\_\_\_\_

B. Initial Findings (List all actions taken and the results):

\_\_\_\_\_

C. Future Actions (List plan of future investigation, if necessary.):

\_\_\_\_\_

**VIII. Person Filing Report**

Name (Print): \_\_\_\_\_

Signature: \_\_\_\_\_

Title: \_\_\_\_\_

Date: \_\_\_\_\_