NEW YORK STATE DEPARTMENT OF HEALTH
Tissue Resources Program

Transplantation/Tissue Bank-related Incident Report

Wadsworth Center
Empire State Plaza
Albany, New York 12237

Facility name/city _____ **Facility #**_____

Date of discovery _____ **Facility incident number**_____

Date of occurrence _____ **Time of occurrence** _____ ◯ **AM** ◯ **PM**

Date of report _____

Person filing report _____ **Title**_____

Telephone number_____ **Email address**_____

Incident summary (attach a separate page if necessary)

_____

Patient effect(s)

☐ Not applicable
☐ No effect apparent
☐ Fatality – likely related to tissue transplantation
☐ Fatality – possibly related to tissue transplantation, cause to be determined
☐ Infectious disease transmission (specify) _____
☐ Sepsis
☐ Insemination or embryo transfer-associated genetic disease disease in an offspring (specify)

_____

☐ Specimen mixup
☐ Other (specify) _____

Living Donor effect(s)

☐ Not applicable
☐ No effect apparent
☐ Significant donor reaction (specify) _____
☐ Other (specify) _____

At what point(s) in the process did the incident occur?

☐ Not applicable
☐ Donor history
☐ Donor testing
☐ Tissue processing
☐ Product labeling
☐ Product check-in
☐ Product manipulation
☐ Product storage
☐ Sample collection/labeling
☐ Test/product order
☐ Patient sample testing
☐ Documentation
☐ Product selection
☐ Request for pick-up
☐ Product labeling for issuance
☐ Product issuance
☐ Product administation
☐ Equipment function
☐ Other (specify)

_____

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How was the incident discovered? (check one)

- ☐ Bedside patient identification
- ☐ Reaction
- ☐ Supervisory review
- ☐ Microbial testing
- ☐ Subsequent tissue donation
- ☐ Internal Audit
- ☐ External audit
- ☐ Computer warning
- ☐ Historical record check
- ☐ Discordant lab results
- ☐ Review of order
- ☐ Reported by consignee
- ☐ Other (specify) _____

Where did the incident occur? (check all that apply)

- ☐ Collection/recovery site
- ☐ Tissue processor
- ☐ Storage facility
- ☐ Transplantation facility
- ☐ Insemination/implantation site
- ☐ Other _____

Job function of the worker(s) involved in the incident (check all that apply)

- ☐ Clinical laboratory technologist
- ☐ Tissue Recovery staff
- ☐ Tissue Processing staff
- ☐ Other (specify) _____
- ☐ Registered nurse
- ☐ Clerical/administrative staff
- ☐ House staff
- ☐ Attending physician

Product involved (check all that apply)

- ☐ Cardiovascular tissue
- ☐ Musculoskeletal tissue
- ☐ Skin tissue
- ☐ Eye tissue
- ☐ Reproductive tissue
- ☐ Human milk
- ☐ Other (specify) _____
- ☐ Allogeneic donation
- ☐ Autogeneic donation
- ☐ Directed donation

Quantity distributed/issued

- ☐ None
- ☐ # of units _____

Quantity transplanted

- ☐ None
- ☐ # of units _____

Was affected tissue distributed to New York? ◯ Yes ◯ No (If yes, identify facility)

_____

Were other tissues from implicated donor distributed to New York? ◯ Yes ◯ No (If yes, identify facility)

_____

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Results of Investigation (attach a separate page, if necessary)

Was a root cause analysis performed? ◯ Yes ◯ No

Findings:

Corrective action (attach a separate page if necessary)

This form is a PDF fillable document. It is possible to enter data and save the document multiple times, even if you have only Adobe Reader. **Please send the completed PDF form, as an e-mail attachment, to tissue@health.ny.gov, with a subject title of Incident Report and your Facility ID number.** Alternatively, it can be faxed to 518-485-5342 or mailed to the Tissue Resources Program at the address above. Questions should be directed to the Tissue Resources Program at (518) 485-5341.