

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)

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**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 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?**

- |   |   |  |
|---|---|--|
| <input type="checkbox"/> Not applicable       | <input type="checkbox"/> Product storage            | <input type="checkbox"/> Product labeling for issuance |
| <input type="checkbox"/> Donor history        | <input type="checkbox"/> Sample collection/labeling | <input type="checkbox"/> Product issuance              |
| <input type="checkbox"/> Donor testing        | <input type="checkbox"/> Test/product order         | <input type="checkbox"/> Product administration        |
| <input type="checkbox"/> Tissue processing    | <input type="checkbox"/> Patient sample testing     | <input type="checkbox"/> Equipment function            |
| <input type="checkbox"/> Product labeling     | <input type="checkbox"/> Documentation              | <input type="checkbox"/> Other (specify) _____         |
| <input type="checkbox"/> Product check-in     | <input type="checkbox"/> Product selection          |  |
| <input type="checkbox"/> Product manipulation | <input type="checkbox"/> Request for pick-up        |  |

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**How was the incident discovered? (check one)**

- |   |  |
|---|--|
| <input type="checkbox"/> Bedside patient identification | <input type="checkbox"/> External audit          |
| <input type="checkbox"/> Reaction                       | <input type="checkbox"/> Computer warning        |
| <input type="checkbox"/> Supervisory review             | <input type="checkbox"/> Historical record check |
| <input type="checkbox"/> Microbial testing              | <input type="checkbox"/> Discordant lab results  |
| <input type="checkbox"/> Subsequent tissue donation     | <input type="checkbox"/> Review of order         |
| <input type="checkbox"/> Internal Audit                 | <input type="checkbox"/> Reported by consignee   |
| <input type="checkbox"/> Other (specify) _____          |  |

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

- |   |   |   |   |
|---|---|---|---|
| <input type="checkbox"/> Collection/recovery site       | <input type="checkbox"/> Tissue processor | <input type="checkbox"/> Storage facility | <input type="checkbox"/> Transplantation facility |
| <input type="checkbox"/> Insemination/implantation site | Other _____                               |   |   |

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

- |   |  |  |
|---|--|--|
| <input type="checkbox"/> Clinical laboratory technologist | <input type="checkbox"/> Registered nurse              | <input type="checkbox"/> House staff         |
| <input type="checkbox"/> Tissue Recovery staff            | <input type="checkbox"/> Clerical/administrative staff | <input type="checkbox"/> Attending physician |
| <input type="checkbox"/> Tissue Processing staff          |  |  |
| <input type="checkbox"/> Other (specify) _____            |  |  |

**Product involved (check all that apply)**

- |   |  |
|---|--|
| <input type="checkbox"/> Cardiovascular tissue  | <input type="checkbox"/> Allogeneic donation |
| <input type="checkbox"/> Musculoskeletal tissue | <input type="checkbox"/> Autogeneic donation |
| <input type="checkbox"/> Skin tissue            | <input type="checkbox"/> Directed donation   |
| Eye tissue                                      |  |
| Reproductive tissue                             |  |
| Human milk                                      |  |
| <input type="checkbox"/> Other (specify) _____  |  |

**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)

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**Was a root cause analysis performed?**  Yes  No

Findings:

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**Corrective action** (attach a separate page if necessary)

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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](mailto: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.