

## Submitting L-ESF Reportable Events via Email

### Email Submission Details

**To:** [clis.biobanking@doh.nj.gov](mailto:clis.biobanking@doh.nj.gov)

**Submission Requirement:** Within **7 business days** of discovering the event

**Subject Line:** Reportable Event - [Facility Name] - [MM/DD/YYYY]

**Required Content:** Include all applicable information listed in “Required Information by Event Type” using the Email Format Template provided on page 2.

### Required Information by Event Type

#### 1. Error or Incident Affecting Reproductive Tissue

If reporting an error or incident involving manipulation, handling, cryopreservation, or storage of reproductive tissue, include:

- Description of circumstances: What happened and how it was discovered
- Quantity of reproductive tissue affected: Specific number of samples/specimens impacted
- Corrective actions: Steps being taken to address the error or incident
- Other notifications made: Any notifications to patients, regulatory bodies, or other parties

#### 2. Events Impacting Premises or Operational Continuity

If reporting events such as fire, flood, illness outbreak, HVAC failure, or utility outage, include:

- Description of the event: What occurred and when
- Emergency plan implementation: Whether the Emergency Preparedness and Recovery Plan (N.J.A.C. 8:77-4.5) was activated
- Remediation actions: Steps being taken to address or remediate the event
- Other notifications made: Any notifications to patients, regulatory bodies, or other parties (if applicable)

#### 3. Critical Equipment Failure

If reporting failure of equipment critical to cryopreservation, storage, or staff safety, include:

- Specific equipment identification: Make, model, and function of failed equipment
- Duration of failure: How long the equipment was non-functional
- Remediation actions: Steps being taken to repair or replace equipment
- Other notifications made: Any notifications to patients, regulatory bodies, or other parties (if applicable)

## **Email Format Template**

**To:** clis.biobanking@doh.nj.gov

**Subject:** Reportable Event - [Facility Name] - [MM/DD/YYYY]

**Licensed Embryo Storage Facility Information:**

- **Facility Name:**

- **Physical Address:**

- **License Number:**

**Event Type:** [Error/Incident, Premises/Operational Event, or Equipment Failure]

**Date of Discovery:** [MM/DD/YYYY]

**Detailed Description:**

[Include all required details for your event type as outlined in the “Required Information by Event Type”]

**Attachments:** [If applicable]

**Contact for Follow-up Questions:**

**Name:**

**Title:**

**Email:**

**Phone:**