New Jersey Department of Health
Clinical Laboratory Improvement Services
Biobanking Compliance Program

INSTRUCTIONS FOR COMPLETION OF APPLICATION FOR LICENSURE OF AN EMBRYO STORAGE FACILITY

Following are instructions for completion of an application for licensure of an embryo storage facility (ESF), pursuant to N.J.S.A. 26:2A-23, et seq., and N.J.A.C. 8:77.

The application form must be completed in full and returned with requested attachment and the appropriate fee. Fees are non-refundable and incomplete applications will not be processed.

Checks or money orders should be made payable to the *"**Treasurer, State of NJ**"* and include the embryo storage facility code (if available). You may also make your payment using the electronic payment link on the Clinical Laboratory Improvement Services website (https://www.nj.gov/health/phel/clinical-lab-imp-services/). Please include a copy of the Department of Health Payment Confirmation with the application.

The completed application for licensure and all requested attachments should be mailed to:

Regular Mail (US Postal Service)

Biobanking Compliance Program
PHEL/Clinical Laboratory Improvement Services
New Jersey Department of Health
PO Box 361
Trenton, NJ 08625-0361

Overnight Delivery (FedEx, UPS)

Biobanking Compliance Program
PHEL/Clinical Laboratory Improvement Services
Public Health, Environmental and Agricultural Laboratory
New Jersey Department of Health
3 Schwarzkopf Drive
Ewing, NJ 08628-1620

LICENSURE

An applicant for initial, or renewal of, licensure to operate an ESF must complete this form, attach all requested documentation, and submit the application, and the requisite fee, to the appropriate address above.

Upon approving an application, the Department will issue a License.
A License is not transferable.

New Jersey Department of Health
Clinical Laboratory Improvement Services
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APPLICATION FOR LICENSURE OF AN EMBRYO STORAGE FACILITY

FOR NJDOH USE ONLY			
Date Mailed	Date Received	☐ Approved ☐ Denied ☐ Other:_____	
Received By	Check Number	Amount	Check Date

I. APPLICATION

Type of Application

☐ Initial Licensure
☐ Renewal of Licensure | Provide existing ESF Code: _____
☐ Provisional Licensure

II. ESF AND OPERATOR INFORMATION

Name of ESF	Name of Applicant ☐ESF Owner ☐ESF Operator
Mailing Address of ESF	Mailing Address of Applicant
Physical Address of ESF	Name and Address of Registered Agent for Service of Process or other entity authorized to receive official notices on behalf of the ESF
Telephone Number of ESF	Telephone Number of Applicant
ESF Email Address	Email Address of Applicant

Website

Is the applicant/ESF the office of a licensed health care provider that stores fresh human eggs or embryos on a temporary basis for use in assisted reproduction on the same premises?

☐Yes ☐ No

Has applicant been convicted of a crime? If yes, please state the jurisdiction and approximate date of conviction:

III. OWNERSHIP AND ORGANIZATIONAL STRUCTURE

Check all that apply

☐ Reproductive Laboratory ☐ IVF Facility ☐ Hospital ☐ Medical Practice

☐ Individual or Sole Proprietorship

☐ If doing business or trading under another name, state the name: _____

☐ Partnership: Attached sheet listing names, addresses, and telephone numbers of each partner, and respective ownership share of each.

☐ LLC: Attach a sheet listing names, addresses, and telephone numbers of each member, and respective ownership share of each.

☐ Corporation: State of Incorporation (Attach copy of Articles of Incorporation): _____

☐ Other: _____

Name and title of Administrator at ESF who is responsible for operations and is on site full time

Telephone Number	Email Address

Name and title of another individual at ESF who is a designated contact to communicate with NJDOH

List name, address, telephone number of any other ESF that is owned or operated by the applicant or a parent or subsidiary of the applicant in any jurisdiction:

ESF Name	Telephone Number
Address	Email Address
Website	

ESF Name	Telephone Number
Address	Email Address
Website	

IV. ESF MEDICAL DIRECTOR, LABORATORY DIRECTOR, OR PHYSICIAN (IF MEDICAL PRACTICE)	
Name and title of ESF Medical Director, Laboratory Director, or Physician	
Telephone Number	Email Address
Medical License Number	Date Issued
Bioanalytical Laboratory Director License	Date Issued
Please provide photocopy of each of the above licenses, as applicable, and submit with application.	
CLIA Number (if applicable)	NJDOH Clinical Laboratory License (if applicable)
Description of activities performed at facility with respect to human eggs and/ or embryos	

V. ACCREDITING ORGANIZATION

Is the applicant or L-ESF accredited by CAP or Joint Commission

☐ Yes, please attach a copy of the certificate of accreditation with current seal.

☐ No

I, the undersigned, certify that the statements made herein are true and accurate. I am aware that if any of the statements made herein are willfully false, I am subject to punishment.

Signature of Applicant/ ESF Owner or Operator	Date

VI. REQUIRED DOCUMENT CHECKLIST

(please attach copies of requested documents; original documents will not be returned):

ALL APPLICATIONS (Initial and Renewal):

Requisite Fee: Check or money order payable to "Treasurer, State of NJ," or electronic payment at https://www.nj.gov/health/phel/clinical-lab-imp-services (if electronic payment, please attach copy of the Department of Health Payment Confirmation with this application)

INITIAL LICENSURE:

ALL APPLICANTS:

- Copy of applicant's current Certification of Accreditation issued by the accrediting body (unless a licensed health care provider that stores fresh reproductive tissue temporarily for use in ART on site)
- Copy of the Certificate of Occupancy issued by the municipality for premises, if applicable
- Copy of the applicant's lease or deed to the premises
- Evidence of current registration with the FDA as a human cell and tissue establishment, if applicable
- Copy of the Form #483 and Establishment Inspection Report, if any, issued by FDA following its most recent inspection of the applicant as well as documentation of any actions taken or proposed by the applicant in response to Form #483.
- Report of any inspection performed by the jurisdiction in which the ESF is located for each ESF that the applicant and/or a subsidiary or parent of the applicant owns or operates in New Jersey or another jurisdiction during the 10 years preceding this application for initial licensure.

RENEWAL OF LICENSURE

- Copy of applicant's current Certification of Accreditation issued by the accrediting body (unless a licensed health care provider that stores fresh / wet reproductive tissue temporarily for use in ART on site)
- Evidence of current registration with the FDA as a human cell and tissue establishment, if applicable
- Copy of the Form #483 and Establishment Inspection Report, if any, issued by FDA following its most recent inspection of the applicant, if inspected by FDA in the period since current license was issued, as well as documentation of any actions taken or proposed by the applicant in response to Form #483.

Number of additional pages attached: _____