

6a. ReproTech: Accounts, Logistics and Donor Eligibility Determination

Section 6. Long Term Storage of Patient and Research Samples

ReproTech: Accounts, Logistics and Donor Eligibility

Estimated Time to Complete: 2 weeks (if no institutional approval is needed for ReproTech agreement)

Background and Why ReproTech?

1. The Oncofertility Consortium recommends that all patient and plasma archive samples obtained by NPC members under their IRB approved research protocol for ovarian tissue cryopreservation be stored at ReproTech, LTD (FL, MN, NV, or TX).
2. The long-term storage of the patient's own tissue and plasma and shipment to any site where she plans to use it will be her responsibility.
3. ReproTech requires at minimum HIV 1&2, Hepatitis B and Hepatitis C results for storage. Tissues will be stored with tissues of like infectious disease status.
4. ReproTech is an FDA registered, AATB, CA State, MD State and NY State accredited long term storage facility specializing in Reproductive tissues.
5. Storage at ReproTech gives the patient maximum flexibility concerning future use of her tissue. She can have it shipped anywhere in the country on a few days notice. The patient maintains control over her own tissues.
6. Many of the patients participating in the ovarian tissue cryopreservation program will require very long term storage for periods of time that exceed the typical accommodations at most IVF centers. (In many cases, more than 5 years).
7. Storage costs at ReproTech compare favorably with those charged at most centers.

Establishing Your Account

1. Access the agreement here: <http://forms.reprotech.com/npc-oncofertility-consortium.html>

Please view the disclaimer here: oncofertility.northwestern.edu/disclaimer
disclaimer Version: 10/2017

2. Please review the agreement; if you have any questions please contact ReproTech directly.
3. Please email completed and signed agreements to infomn@reprotech.com or via FAX to 651-489-0442. ReproTech will execute the agreement and return one copy to you for your records. Please insert the name and address of the person who should receive the signed version of this agreement on the last page of the agreement.
4. Contact information: In the space provided on the agreement please provide contact information for the “point person” for tissue storage at your center. The point person will be someone who can load samples into dry shippers, provide inventory information and other paper work. In most cases, this will be a lab person.
5. Once you have returned the signed copy of your agreement to ReproTech and you have verified that they have received it, the person who you designated as the point person for your center should:
 - Call ReproTech at 888-489-8944
 - Speak to Lea Wilcox or Jill Olson
6. ReproTech staff members will review forms packets for patients, shipping paper work, etc.
7. Even if you already have an account with ReproTech, you must sign this agreement.
8. ReproTech will provide shippers to transport the tissues to their facility and will instruct you on the process and the quality control procedures involved.
9. You will not ship your tissues to ReproTech until infectious disease testing results are available. We recommend that infectious disease tests be drawn intraoperatively. Samples must be stored in liquid nitrogen until shipment.

Donor Eligibility Determination Required Before Shipping Tissue to ReproTech:

1. It is up to each site to determine if patients will be tested as anonymous donors. If your site is doing donor eligibility in case the patient must use a gestational surrogate or other method to establish pregnancy, donor eligibility requirements must be followed to treat the cryopreserved ovarian tissue as though it came from an anonymous donor of leukocyte tissue.
 - a. Therefore, those patients must be subjected to a donor eligibility determination prior to tissue shipping to ReproTech.
 - b. The same procedure should be followed that is used for anonymous egg donors at your facility, including screening for risk of infectious diseases, high risk behaviors, physical exams, etc.
2. Please note that the infectious disease testing required for a tissue donor is different than that for an egg donor (GC and Chlamydia are not required). Please follow the instructions in Section 5 for a complete list of infectious disease tests required.
3. A summary of records based on your donor eligibility determination must accompany all samples shipped to ReproTech. Sample forms are included in this manual.
4. **Please NOTE: Donor Eligibility Determination is NOT based solely on infectious disease results. Please be certain that you have adequate documentation on file to support the donor eligibility determination that you are certifying.**
5. For more detailed information on donor eligibility determination, please refer to [21CFR1271 of the Federal Register](#)

Shipping Your Tissue to ReproTech:

1. All of the following materials should be sent to ReproTech:
 - Patient ovarian tissue
 - Plasma samples
 - Oocytes or embryos derived from this cycle for patient use
2. The following Documents should be provided to ReproTech:
 - Summary of records
 - All ReproTech patient forms:
 - a. Registration
 - b. Storage agreement
 - c. Treatment History
 - d. Addendum (infectious sample)

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e. Transfer agreement

- Copy of the patient's tissue cryopreservation records.
- Instructions for thawing/warming oocytes or embryos that are part of the shipment
- Summary of infectious disease results