



New York State Tissue Resources Program

Policy – Importation of reproductive tissue from unlicensed, out-of-state tissue banks

Effective date – June 9, 2022

Valid until – Regulatory or policy change supersedes this policy

Reproductive tissue procured by and/or stored at an out-of-state tissue bank that is not licensed by the Department may be distributed to New York State (NYS) without a written exception to 10 NYCRR Part 52-2.1(a) from the Department under the following conditions:

1. The reproductive tissue was collected from a client-depositor, as defined in 52-8.1(d);
2. The reproductive tissue is ordered by a physician or other person authorized by law to perform artificial insemination or assisted reproductive procedures, and/or receive reproductive tissue, who is employed by the receiving tissue bank;
3. The tissue bank receiving the reproductive tissue is responsible for the safety and suitability of the imported tissue;
4. The medical director of the receiving tissue bank documents that the client-depositor and their tissue are acceptable in compliance with all applicable requirements in Part 52;
5. Written policies and procedures for the receipt, storage, and use of such tissue specimens, as well as for the administrative handling of requisite documentation, are developed and approved by the tissue bank director of the receiving tissue bank; and
6. The tissue bank maintains a log of all tissue imported under this policy, including, but not limited to, the following:
 - a. Basic information to identify the client-depositor(s), such as Name and DOB or unique identifier;
 - b. The intended procedure (insemination, IVF, etc.);
 - c. The number of oocytes, embryos, or vials of semen imported;
 - d. Dates of collection, cryopreservation, receipt and usage;
 - e. Any infectious disease testing results;
 - f. Name of the providing tissue bank;
 - g. Basic information to identify the client-depositor(s) and recipient, as applicable, such as Name and DOB or unique identifier.

This policy does not apply to reproductive tissue from donors, including directed donors. Distribution of donor reproductive tissue specimens from an unlicensed, out-of-state tissue bank requires a written exception from the Department prior to any distribution to NYS. Failure to receive a written exception may result in grounds to suspend or revoke the receiving tissue bank's New York State License.

This policy applies only to rare instances of distribution from an unlicensed out-of-state tissue bank. Routine distribution of client-depositor reproductive tissue samples by an out-of-state bank requires a tissue bank license.

This policy supersedes the Department's policy of July 18, 2014 regarding the importation of reproductive tissue from client-depositors and directed donors.