



New York State Tissue Resources Program

Policy - Donation of embryos created using client-depositor reproductive tissue

Effective Date – January 1, 2020

Valid until – Regulatory or policy change supersedes this policy

Embryos created using client-depositor reproductive tissue may be donated to other recipients only with the informed consent of the depositor(s) and in compliance with applicable donor screening and testing requirements. This policy supersedes all previous policies.

Consent

- Prior to transfer of the embryos to another tissue bank that may subsequently donate them, or donation to a specific recipient, the tissue bank holding the embryos must document informed consent by the client-depositor(s) for this purpose.
- Consent must comply with 10 NYCRR § 52-8.8(a), including § 52-8.8(a)(3), and include donation for reproductive use by others.
- If the consent form originally signed by the client-depositor(s) did not explicitly consent to such donation, the tissue bank holding the embryos must obtain that consent.

Infectious disease risk

- If the client depositor was screened and tested in compliance with 10 NYCRR §§ 52-8.5 and 52-8.6, no further screening or testing is required.
- If the client depositor was not screened and tested in compliance with 10 NYCRR §§ 52-8.5 and 52-8.6, prior to transferring the embryos to another facility that subsequently may donate them for implantation in NYS, or donating them to a specific recipient for implantation in NYS, the tissue bank holding the embryos must:
 - screen the client-depositor for infectious disease, in compliance with 10 NYCRR § 52-8.5; and
 - test the client depositor for infectious disease in compliance with 10 NYCRR § 52-8.6(j), including serology, or arrange for such testing.

Example 1

A client-depositor wishes to donate embryos, created with his/her own gametes, to a specific recipient for implantation in NYS. The consent form originally signed by the client-depositor did not discuss donation to other recipients for reproductive use. The client-depositor has not been screened or tested for any infectious diseases. Prior to releasing the embryos for clinical use, the tissue bank holding the embryos must:

- obtain informed consent from the client-depositor for donation for reproductive purposes, in compliance with the applicable requirements of 10 NYCRR § 52-8.8(a), including § 52-8.8(a)(3);
- screen the client-depositor in compliance with 10 NYCRR § 52-8.5; and

- test the client-depositor in compliance with 10 NYCRR § 52-8.6(j), including serology, or arrange for such testing.

Example 2

A client-depositor stopped paying storage fees for his/her embryos and, as detailed in the original consent signed by the client-depositor, ownership of these embryos transferred to the tissue bank. The tissue bank holding the embryos wants to make them available to a specific recipient for reproductive use in NYS or transfer them to another tissue bank that subsequently may make them available for implantation. The consent form originally signed by the client-depositor did not include donation to other recipients for reproductive use. The client-depositor has not been screened or tested for infectious disease.

Prior to such release or transfer, the tissue bank holding the embryos must

- obtain informed consent by the client-depositor for donation for reproductive purposes, in compliance with applicable requirements of 10 NYCRR § 52-8.8(a), including § 52-8.8(a)(3); and
- if the embryo(s) will be implanted in NYS
 - screen the client-depositor in compliance with 10 NYCRR § 52-8.5; and
 - test the client-depositor in compliance with 10 NYCRR § 52-8.6(j), including serology, or arrange for such testing.