NEW YORK STATE OF OPPORTUNITY. Department of Health

KATHY HOCHUL
Governor

JAMES V. McDONALD, M.D., M.P.H.
Commissioner

JOHANNE E. MORNE, M.S.
Executive Deputy Commissioner

August 22, 2024

Dear Colleague,

10 NYCRR Part 52 requires that all semen donors be tested and found negative for HIV-1 and HIV-2, and precludes the use of semen from a donor who has tested positive for either virus.

Since 2017, it has been the Department's policy that U = U, or "Undetectable = Untransmittable." As per the policy, "people living with HIV (PLWH) who have achieved and continue to maintain an undetectable viral load do not sexually transmit HIV."

Under Part 52-3.8, the Department may exempt a tissue bank from specific requirements in Part 52 under limited circumstances. Requests for exceptions to allow assisted reproductive procedures[1], using semen from directed (known) donors[2] who are living with HIV, may be provided under the following conditions:

- the semen donor is taking antiretroviral therapy as prescribed and has an undetectable viral load by blood testing concurrent with the collection of the semen specimen(s) to be used;
- the recipient, including a gestational carrier, is fully informed and counseled about the risks by the tissue bank medical director or attending physician, with documentation of such;
- the recipient is offered pre- and post-exposure prophylaxis for HIV, including 20 days preceding embryo transfer and 28 days post-embryo transfer procedure;
- the tissue bank follows CDC's Universal Precautions in handling the reproductive tissues;
- to prevent accidental misuse of the reproductive tissues, the tissue bank sequesters the semen specimens, and any resulting embryos, from other donor samples; and
- if a gestational carrier is used, the tissue bank is registered as an Assisted Reproductive Technology Service Provider, the surrogacy agreement adheres to the requirements of the Child-Parent Security Act, and the gestational carrier is provided with the Gestational Surrogates' Bill of Rights.

As a reminder, FDA requirements, as found in Title 21 of the Code of Federal Regulations (CFR) Part 1271, are applicable to all tissue banks in New York State.

Please contact the Department with any questions at tissue@health.ny.gov or 518 485-5341.

[1] As defined in Part 52-8.1(c), "assisted reproductive procedure" means a medical procedure intended to result in conception, including, but not limited to, in vitro fertilization (including intracytoplasmic sperm injection), embryo transfer and gamete intrafallopian transfer. "Assisted reproductive procedure" does not include artificial insemination.

[2] As defined in Part 52-8.1(e), in this instance "directed donor" means a semen donor who is known to the recipient and who directs his semen for use by the particular recipient.

Sincerely,

Matthew Kohn, Ph.D.
Director
Tissue Resources Program