



Guidelines for Assisted Reproductive Technology (ART) Service Providers - Ova Donation

This document is intended to provide guidance to Assisted Reproductive Technology (ART) Service Providers and other tissue banks regarding oocyte donation, as required by NYS Public Health Law.

Background:

When a woman chooses to donate her eggs, it is the responsibility of the tissue bank to ensure the safety of the donor and any recipients. Oocyte donation requires ovarian stimulation with monitoring and oocyte retrieval, involving inconvenience, discomfort, and risks for the donor. The tissue bank must mitigate risks to the eventual recipient(s), including infectious disease and inherited disorders.

Indications for use of donor oocytes include:

- A. Persons with hypergonadotropic hypogonadism.
- B. Persons of advanced reproductive age.
- C. Persons who have diminished ovarian reserve.
- D. Persons who are known to be affected by or known to be the carrier of a significant genetic defect or who have a family history of a condition for which carrier status cannot be determined.
- E. Persons with poor oocyte and/or embryo quality or multiple previous failed attempts to conceive via Assisted Reproductive Technology (ART).

Purpose:

The purpose of this document is to set forth guidelines related to the oocyte donation process that should be considered in addition to state and federal requirements. For example, psychological evaluation and counseling is recommended as a standard practice for prospective donors.

Reminder regarding Legal and Ethical Considerations:

This document considers certain legal and ethical issues. However, a full discussion of all legal and ethical considerations associated with oocyte donation is beyond the scope of these guidelines. Tissue banks must comply with all applicable laws.

Guidelines:

Donors

- A. Selection of donors

1. Oocyte donation may be undertaken with donors known or unknown to the recipient.

2. Psychological evaluation and counseling by a qualified mental health professional is strongly recommended for the oocyte donor and their partner (if applicable). The assessment should include a clinical interview and, where appropriate, psychological testing. Psychological consultation should be required for individuals in whom there appear to be factors that warrant further evaluation, as determined by the clinician. In circumstances involving directed donors, psychological evaluation and counseling is strongly recommended for the donor and their partner, if applicable, as well as for the recipient and their partner, if applicable. The potential impact of the relationship between the donor and recipient should be explored. The psychological assessment also should address the potential psychological risks and evaluate for evidence of coercion (financial or emotional). It is important to ascertain whether the donor is well informed about the extent to which their information about may be disclosed and about any plans for future contact.
3. Oocyte donors should be of legal age and preferably between the ages of 21 and 34 years.
4. Donors less than 21 years of age should have psychological evaluation by a qualified mental health professional, and the decision to proceed with such a donor should be determined on an individual basis.
5. The age of the donor should be revealed to the recipient as part of the informed consent discussion concerning cytogenetic risks and the effect of donor age on pregnancy rates.
6. Proven fertility in the donor is desirable but not required.
7. The donor should undergo appropriate genetic evaluation based on history, in accordance with ethnic background, current guidelines. Cystic fibrosis testing should be performed on all donors. Very strong consideration should be given to fragile X testing on donors. Guidelines regarding ethnicity and population-based genetic screening are published by the American Congress of Obstetricians and Gynecologists (<http://www.acog.org>) and the American College of Medical Genetics (<http://www.acmg.net/>). All gamete donors should be evaluated by the current tests recommended at the time of the donation.

Note: Donors should be offered appropriate genetic counseling as part of any genetic testing.

8. Sharing of oocytes from an assisted reproduction cycle: If sharing of oocytes is contemplated, informed consent must be obtained before the start of the cycle of retrieval. The conditions governing the sharing of oocytes should be specified in advance, be included in the informed consent, and comply with industry standards such as American Society for Reproductive Medicine (ASRM) Ethics Committee guidelines¹.
9. No owner, operator, laboratory director, or employee of a facility screening for or performing oocyte donation may serve as a donor in that practice.
10. If an agency is used to recruit oocyte donors, no individual who has a financial interest in that agency may be used as an oocyte donor.

B. Screening and testing of oocyte donors

1. Donors should be healthy and give no history to suggest hereditary disease.

2. In addition to the requirements of 10 NYCRR Section 52-8.5(b), prospective oocyte donors with any of the following factors should not be accepted:
- a. Persons who have had sex in the preceding 12 months with any person having a positive or reactive test to hepatitis B infection, or clinically active (symptomatic) hepatitis C infection.
 - b. Persons who have been exposed within the last 12 months, through percutaneous inoculation or contact with an open wound, non-intact skin, or mucous membrane, to blood that is known or suspected to be infected with HIV, hepatitis B, and/or hepatitis C virus.
 - c. Persons who have had close contact (e.g., living in the same household wherein sharing of kitchen and bathroom facilities occurs regularly) within 12 months preceding the donation with another person who has hepatitis B or clinically active (symptomatic) hepatitis C infection.
 - d. Persons who have been incarcerated in lock-up, jail, or prison for more than 72 consecutive hours within the previous 12 months.
 - e. Persons who have had or have been treated for syphilis, gonorrhea, or chlamydia within the preceding 12 months. Deferral of donors is not necessary if evidence is presented that treatment occurred more than 12 months ago and was successful.
 - f. Persons who have undergone body piercing and/or tattooing procedures within the preceding 12 months in which sterile procedures were not used or it is unclear whether sterile procedures were used (e.g., contaminated instruments and/or ink were used or shared instruments that had not been sterilized between uses were used).
 - g. Persons who have received a smallpox vaccination (vaccinia virus) for 21 days after vaccination or until the scab separates spontaneously and physical examination confirms the absence of a scab at the vaccination site (whichever is later). The donor should be deferred for 2 months if the scab was removed before spontaneous separation. If the donor experienced complications from vaccination, she should be deferred until 14 days after complete resolution of those complications. If the donor became infected as a result of close contact with a person recently vaccinated for vaccinia, she may be considered eligible for donation if the scab spontaneously separated, if 14 days have elapsed since resolution of all the vaccinia-related complications, or 3 months after the scab was otherwise removed.
 - h. Persons who have had a medical diagnosis or suspicion of West Nile Virus (WNV) infection (based on symptoms and/or laboratory results or confirmed WNV viremia) should be deferred for 120 days after the onset of symptoms or diagnosis, whichever is later.
 - i. Persons who have tested positive or reactive for WNV infection using an FDA-licensed or investigational WNV NAT donor-screening test in the preceding 120 days.
 - j. Persons who have been diagnosed with variant Creutzfeld-Jacob Disease (vCJD) or any other form of CJD.
 - k. Persons who have been diagnosed with dementia or any other degenerative or demyelinating disease of the central nervous system or other neurologic disease of unknown etiology. Potential donors who have a diagnosis of delirium (e.g., delirium

caused by toxic/metabolic diseases or recent head trauma) would not be considered necessarily to have a diagnosis of dementia and should be evaluated by the medical director.

- l. Persons who are at increased risk for CJD. Donors are considered to have an increased risk for CJD if they have received a non-synthetic dura mater transplant, human pituitary-derived growth hormone, or have one or more blood relatives diagnosed with CJD.
- m. Persons who have a history of CJD in a blood relative unless the diagnosis of CJD was subsequently found to be in error, the CJD was iatrogenic, or laboratory testing (gene sequencing) demonstrates that the donor does not have a mutation associated with familial CJD.
- n. Persons who spent 3 months or more cumulatively in the United Kingdom from the beginning of 1980 through the end of 1996.
- o. Persons who are current or former US military members, civilian military employees, or dependents of a military member or civilian employee who resided at US military bases in Northern Europe (Germany, Belgium, and the Netherlands) for 6 months or more cumulatively from 1980 through 1990, or elsewhere in Europe (Greece, Turkey, Spain, Portugal, and Italy) for 6 months or more cumulatively from 1980 through 1996.
- p. Persons who spent 5 years or more cumulatively in Europe from 1980 until present.
- q. Persons who received any transfusion of blood or blood components in the United Kingdom or France between 1980 and the present.
- r. Persons or their sexual partners who were born or lived in certain countries in Africa (Cameroon, Central African Republic, Chad, Congo, Equatorial Guinea, Gabon, Niger, or Nigeria) after 1977 (risk factor for HIV group O).
- s. Persons who have received a blood transfusion or any medical treatment that involved blood in the African countries listed in (r) above after 1977 (risk factor for HIV group O).

Note: Establishments using an HIV-1/2 antibody donor screening test that has been licensed by the FDA and is specifically labeled in the Intended Use Section of the package insert as sensitive for the detection of HIV group O antibodies may delete items VI.B.2.v and VI.B.2.w from their screening procedures. If screening questions VI.B.2.v and VI.B.2.w also are asked, donor eligibility may be based on the results of the donor test results regardless of the answers to those two questions.

- t. Persons who have received xenotransplants (live cells, tissues, or organs from a nonhuman animal source or human body fluids, cells, tissues, or organs that have had ex vivo contact with live nonhuman animal cells, tissues, or organs) or have been in close contact with a xenotransplant recipient.
 - u. Persons who have received human organ or tissue transplants or treatment with human extracts.
3. Before acceptance, and every 6 months while remaining an active donor, donors should undergo a complete physical examination and should be declined when any of the following findings are present:
- a. Physical evidence for risk of sexually transmitted disease such as genital ulcerative lesions, herpes simplex, chancroid, and urethral discharge.

- b. Physical evidence for risk of or evidence of syphilis.
- c. Physical evidence of anal intercourse including perianal condylomata.
- d. Physical evidence of non-medical percutaneous drug use such as needle tracks; the examination should include examination of tattoos, which might be covering needle tracks.
- e. Physical evidence of recent (within 12 months) tattooing, ear piercing, or body piercing where sterile procedure was not used.
- f. Disseminated lymphadenopathy.
- g. Unexplained oral thrush.
- h. Blue or purple spots consistent with Kaposi sarcoma.
- i. Unexplained jaundice, hepatomegaly, or icterus.
- j. Large scab consistent with recent history of smallpox immunization.
- k. Eczema vaccinatum, generalized vesicular rash, severely necrotic lesion (consistent with vaccinia necrosum), or corneal scarring (consistent with vaccinia keratitis).

4. Laboratory testing

There is no method to ensure completely that infectious agents will not be transmitted via oocyte donation. However, the following guidelines, combined with an adequate medical history and specific exclusion of individuals at high risk for HIV and other STIs, should dramatically reduce these risks. In addition to testing requirements in 10 NYCRR Section 52-8.6, the FDA requires that the following tests be performed within 30 days prior to oocyte collection, using methods required for purposes of determining donor eligibility, and that negative results are documented before use of the donor's oocytes. The list of test methods approved by the FDA for this purpose is available at the following Websites:

<http://www.fda.gov/cber/products/testkits.htm>

<http://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Tissue/ucm091345.pdf>

- a. HIV-1 Nucleic Acid Test (NAT).
- b. HIV-2 antibody.
- c. HIV group O antibody. Establishments that do not use an FDA-licensed test for group O antibodies must evaluate donors for risk associated with HIV group O infection as described in VI.B.2.v and w.
- d. Hepatitis C NAT.
- f. Hepatitis B core antibody (IgG and IgM).
- g. Serologic test for syphilis.
- h. *Neisseria gonorrhoeae* and *Chlamydia trachomatis* NAT on urine or a swab obtained from the cervix, urethral meatus, or vagina.

- i. Although not required by the FDA, recommended tests also include blood type and Rh factor. If the use of donor oocytes creates the potential for Rh incompatibility, recipients should be informed about the obstetric significance of this condition.

C. Managing laboratory results

1. A positive test should be verified before notifying the potential donor. If a test is confirmed positive, the individual should be referred for appropriate counseling and management.
2. Individuals who initially test positive (except for treated syphilis, *Neisseria gonorrhoeae*, or *Chlamydia trachomatis* as described above) are not eligible for anonymous donation.
3. False positive results for syphilis using nontreponemal assays that are confirmed to be negative using a treponemal-based assay are eligible for donation.
4. Donors found to be positive for syphilis, *Neisseria gonorrhoeae*, or *Chlamydia trachomatis* should be treated, retested, and deferred from donation for 12 months after documentation that treatment was successful before being reconsidered.

D. Quarantining of oocytes

All potential recipients should be offered the option of cryopreserving and quarantining embryos derived from donor oocytes for 180 days, with release of embryos only after the donor has been retested with confirmed negative results. However, recipients also should be informed that embryo cryopreservation may significantly reduce implantation rates. The recipient should be counseled appropriately in the event of seroconversion of the oocyte donor after cryopreservation of the embryos or if the donor refuses to be retested.

E. Directed donation

Directed (non-anonymous or known) donation is acceptable if all parties agree. Directed donors must undergo the same screening and testing as anonymous donors. Directed donors who test positive or demonstrate a risk factor for a relevant communicable disease are prohibited from donating by New York State regulations.

F. Payment to the donor

1. Compensation may be paid to the donor based on medical risks, physical discomfort, inconvenience and the responsibilities she is undertaking in connection with participation in the assisted reproduction.
2. Compensation should be in compliance with industry standards such as guidelines published by the ASRM Ethics Committee².
3. Monetary compensation of the donor should be at a level that minimizes the possibility of undue inducement of donors and the suggestion that payment is for the oocytes themselves.
4. Financial obligations and responsibilities in the event of complications or medical expenses of a donor should be agreed upon contractually before initiation of a stimulation cycle.
5. Payment may be prorated based on the number of steps completed in the procedure.

6. Payment should not be predicated on clinical outcome, the purported quality or genome-related traits of the gametes or embryos, nor on actual genotypic or phenotypic characteristics of the donor or of any resulting children.

G. Tissue banks should adhere to industry standards such as the guidelines established by the ASRM Practice Committee Opinion in its publication entitled "Repetitive Oocyte Donation"³.

H. Unintended donor pregnancies

The donor should be counseled about the possibility of unintended pregnancy and offered options for prevention.

I. Age of the recipient

In view of the concerns about pregnancy in persons of advanced reproductive age, it is recommended that potential recipients over the age of 45 undergo thorough medical evaluation (including cardiovascular testing) and a high-risk obstetric consultation before undertaking IVF with donor oocytes.

J. Record keeping

The FDA requires that records pertaining to each donor (screening and test results) be maintained for at least 10 years. New York State requires that records be maintained for 25 years for live births. However, a permanent record of each donor's initial selection process and subsequent follow-up evaluations should be maintained. The clinical outcome for each donation cycle should be recorded and reported to the reproductive tissue bank releasing the tissue, as well as a mechanism for reporting any adverse outcomes including heritable diseases identified preconceptually or post-natally. In the event that a previously unidentified heritable disease is encountered in a child produced from anonymous donation, the donor as well as the recipient of the donated oocytes should be tested, and the donor should be prohibited from further donation until the results of such testing are known. If the donor is found to be the carrier for the heritable disease, all persons who received oocytes from that donor as well as the clinics performing the procedures should be notified and counseled. A mechanism must exist to maintain records on the donor as a future medical resource for any offspring produced.

K. Legal issues and informed consent

1. All oocyte donors should be advised explicitly of the risks and adverse effects of ovarian stimulation and retrieval, with such counseling documented by informed consent in the patient's permanent medical record.
2. Donors and recipients and their partners, if applicable, should execute documents that define or limit their rights and duties with regard to any offspring.
3. Recipients, their partners, if applicable, and donors should consider seeking legal consultation.
4. Protection of confidentiality: Individuals participating in donor programs should be assured that their confidentiality will be protected insofar as federal and local statutes permit. Medical records detailing the donation should be maintained as stipulated by local requirements.

5. It is recommended that the donor acknowledge in the consent form their responsibility to notify the donor program of any changes in their health or risk factor status, and any financial responsibility they bear.

IV. State and Federal Requirements

Certain state and federal requirements apply to ova donation. For example, 21 CFR 1271 and 10 NYCRR Part 52. The requirements therein supersede any guidance given here.

References:

¹ Ethics Committee of the American Society for Reproductive Medicine. Financial “risk-sharing” or refund programs in assisted reproduction: an Ethics Committee opinion. *Fertil Steril* 2016;106:e8–11.

² Ethics Committee of the American Society for Reproductive Medicine. Financial compensation of oocyte donors: an Ethics Committee opinion. *Fertil Steril* 2016; 106:e15–9.

³Practice Committee of the American Society for Reproductive Medicine and Practice Committee of the Society for Assisted Reproductive Technology. Repetitive oocyte donation: a committee opinion. *Fertil Steril*. 2020;113:1150–3.