

Recommendations for gamete and embryo donation: a committee opinion

The Practice Committee of the American Society for Reproductive Medicine and the Practice Committee of the Society for Assisted Reproductive Technology

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This document provides the latest recommendations for evaluation of potential sperm, oocyte, and embryo donors, incorporating recent information about optimal screening and testing for sexually transmitted infections, genetic diseases, and psychological assessments. This revised document incorporates recent information from the U.S. Centers for Disease Control and Prevention, the US Food and Drug Administration, and the American Association of Tissue Banks, with which all programs offering gamete and embryo donation services must be thoroughly familiar, and replaces the document titled, "2008 Guidelines for Gamete and Embryo Donation: A Practice Committee Report," last published in *Fertil Steril* 2008;90:S30-44. (*Fertil Steril*® 2013;99:47-62. ©2013 by American Society for Reproductive Medicine.)

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The 2012 Recommendations for Gamete and Embryo Donation provide the latest recommendations for evaluation of potential sperm, oocyte, and embryo donors, incorporating recent information about optimal screening and testing for sexually transmitted infections (STIs), genetic diseases, and psychological assessments. The current document represents an effort to make the screening guidelines for donors of embryos and gametes more consistent and incorporates recent information from the US Centers for Disease Control and Prevention (CDC), US Food and Drug Administration (FDA), and American Association of Tissue Banks (AATB). The risks for transmission of STIs via donations of sperm, oocytes, and embryos differ, and leukocyte-rich semen donation poses

unique risks that are reflected in the recommendations.

These guidelines use terminology from the federal agencies in addition to the AATB. In that context, the term "screening" refers to specific historical factors that place an individual at a higher risk for a given disease, such as human immunodeficiency virus (HIV), transmissible spongiform encephalopathy (TSE), or Creutzfeldt-Jakob disease (CJD). "Testing" refers to specific laboratory studies such as serologic tests. The distinction between screening and testing is consistent within the document.

These guidelines for the screening and testing of gamete and embryo donors apply to potential donors in the United States. Because the prevalence of STIs and genetic diseases may vary in other locales, these guidelines may

not be appropriate for other countries or individuals who come to the United States from other countries. Whereas the FDA does not require screening or testing of the recipients of donated gametes, the American Society for Reproductive Medicine (ASRM) recommends testing of recipients as described. Other areas where the ASRM recommendations may be more stringent than the FDA minimum requirements are noted in the text. Additionally, state requirements may be more restrictive than the FDA, and clinics are encouraged to check with government officials in the state where their practice is located to determine minimum screening and testing requirements for their state.

The promulgation of FDA regulations has added considerable oversight to gamete and embryo donation, including mandatory registration of all assisted reproductive technology (ART) programs with the federal government, federal inspections of programs that are performing donation, required documentation, and written

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protocols attendant to donor screening, testing, selection, rejection, and follow-up. Complete records of all donor cycles, including documentation of adherence to FDA regulations, must be made available to FDA inspectors at their request. Federal regulations may be viewed at the following Web sites:

<http://www.fda.gov/cber/tiss.htm>

<http://www.fda.gov/BiologicsBloodVaccines/default.htm>

<http://www.fda.gov/cber/rules/gtp.pdf>

GUIDELINES FOR SPERM DONATION

I. Introduction

Therapeutic donor insemination (TDI) may be used to achieve pregnancy where appropriate indications exist. The clinical procedures should take into account the age and health status of the recipient. The FDA has published requirements for the screening and testing of donors of human cells, tissues, and cellular and tissue-based products (HCT/PS), which are included here. These are the minimum requirements mandated by the federal government. In some instances, the federal requirements may be less rigorous than those in the state in which an individual practice is located or than those recommended by ASRM and the Society for Assisted Reproductive Technology (SART). It is the responsibility of all clinics to know the regulations of their individual states and local municipalities and to comply with those standards.

II. Indications for TDI

- A. The male partner has azoospermia, severe oligozoospermia, or other significant sperm or seminal fluid abnormalities.
- B. The male partner has ejaculatory dysfunction.
- C. The male partner demonstrates significant male factor infertility (i.e., significant oligoasthenospermia or prior failure to fertilize after insemination in vitro and intracytoplasmic sperm injection [ICSI] is not elected or feasible).
- D. The male partner has a significant genetic defect or the couple previously has produced an offspring affected by a condition for which carrier status cannot be determined.
- E. The male partner has a sexually transmissible infection that cannot be eradicated.
- F. The female partner is Rh-negative and severely Rh-immunized and the male partner is Rh-positive.
- G. Females without male partners.

III. Psychological consultation for recipients

The decision to proceed with donor insemination is complex, and patients and their partners (if applicable) may benefit from psychological counseling to aid in this decision. The clinician should strongly recommend psychological counseling by a qualified mental health professional to all donor sperm recipients and their partners. The assessment should include a clinical interview and, where appropriate, psychological testing. The clinician should require psychological consultation for couples in whom factors appear to warrant further evaluation. In cases of directed donation, the potential impact of the relationship between the donor and recipi-

ent should be explored, as well as any plans that may exist relating to disclosure and future contact.

IV. Evaluation of the partner

- A. The partner in any couple that requests TDI should have completed an appropriate clinical evaluation. Medical records should be reviewed before performing the insemination procedure. If appropriate, alternative treatments should be discussed with the couple. While not required by the FDA, infectious disease testing of the male partner is recommended by the ASRM to address any potential medical/legal issues that could arise should the partner seroconvert during or after TDI.
- B. Human immunodeficiency virus (HIV-1 antibody [AB] and nucleic acid testing [NAT]), HIV-2 AB testing and screening, or testing for HIV group O antibodies on the male partner is strongly recommended. If the male partner is HIV infected, he should be referred to an appropriate infectious disease specialist for counseling on safe sex practices for preventing HIV transmission, on treatment options, and on other issues concerning HIV disease. A positive HIV test result for the male partner should not be used as an exclusionary criterion for treatment of a couple with TDI.
- C. Testing for other STIs similar to that recommended for the female partner (detailed in section V) is encouraged. This includes:
 1. Serologic test for syphilis.
 2. Hepatitis B surface antigen.
 3. Hepatitis B core antibody (IgG and IgM).
 4. Hepatitis C antibody and NAT.
 5. *Neisseria gonorrhoeae* and *Chlamydia trachomatis* NAT on urine or a swab obtained from the urethral meatus.

Note: There are no FDA-licensed, approved, or cleared tests for donor screening of these organisms in an asymptomatic, low-prevalence population. Tests using NAT technology adequately and appropriately reduce the risk of transmission of these relevant communicable agents.

6. Human T-cell lymphotropic virus (HTLV) type I and II also may be obtained at the discretion of the clinician in the appropriate clinical setting.

V. Evaluation of the female recipient

- A. Routine medical and reproductive history should be obtained according to the standards that are applied to women anticipating pregnancy. Abnormalities detected from history or physical examination may require more detailed evaluation and treatment before proceeding with insemination.
- B. A complete general physical examination should be performed, including a pelvic examination.
- C. Standard preconceptional screening, testing, and counseling:
 1. Although there are no federal requirements for testing donor sperm recipients, the following tests are recommended:
 - a. Blood type, Rh factor, and antibody screen.

- b. Rubella and varicella titers. Vaccination should be offered if the individual is not immune to either virus.
 - c. *Neisseria gonorrhoeae* and *Chlamydia trachomatis* NAT on urine or a swab obtained from the cervix, urethral meatus, or vagina.
 - d. HIV-1 (AB and NAT), HIV-2 AB testing, and testing or screening for HIV group O antibodies should be performed to address potential medical/legal complications that could arise if the recipient seroconverts during or after treatment. In addition, if the female recipient is found to be HIV-infected before treatment, she should be referred to an appropriate infectious disease specialist for counseling on issues concerning HIV disease, including reproductive issues such as safe sex practices for preventing HIV transmission to uninfected partners and treatment options to reduce the probability of transmission to her child. A positive HIV test of the female recipient should not be used as an exclusionary criterion for treatment with TDI as long as the couple makes an informed decision after counseling and agrees to comply with recommended clinical management for the positive HIV status during pregnancy.
 - e. Serologic test for syphilis.
 - f. Hepatitis B surface antigen.
 - g. Hepatitis B core antibody (IgG and IgM).
 - h. Hepatitis C antibody and NAT.
 - i. Cytomegalovirus (CMV) antibody (IgG and IgM). For women who test positive for active infection (positive urine or throat culture or paired serum samples demonstrating a four-fold rise in IgG antibody and IgM antibody at least 30% of the IgG level), attempts to conceive should be postponed until they no longer exhibit active infection, owing to the risk of transmitting the infection to their fetus and the serious potential consequences of fetal CMV infection.
 - j. HTLV type I and II also may be obtained at the discretion of the clinician in the appropriate clinical setting.
- D. Documentation and timing of ovulation
1. Women with regular cyclic menses and molimina are assumed to be ovulating. When doubt exists, an index of ovulation, such as serum progesterone level, basal body temperature recordings, LH surge detection, and ultrasound monitoring of follicular maturation, may be used to document ovulation. Appropriate timing of the insemination procedure optimizes chances for success.
- E. Evaluation for possible tubal or peritoneal abnormalities
- F. Patients who fail to conceive after 4 to 6 well-timed inseminations may be candidates for hysterosalpingography (HSG), laparoscopy, or other appropriate tests to detect possible causes for their failure to conceive.
- Pretreatment HSG or laparoscopy may be indicated by the history and/or physical findings.
- G. Informed consent should be obtained from the patient (and her partner, if applicable).
- VI. Donors
- A. Selection of donor
1. The main qualities to seek in selecting a donor for TDI are an assurance of good health status and the absence of known genetic abnormalities.
 2. The donor should be of legal age and, ideally, less than 40 years of age.
 3. Selection of donors with established fertility is desirable but not required.
 4. Psychological evaluation and counseling by a qualified mental health professional is strongly recommended for all sperm donors. 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. In cases of directed donation, psychological evaluation and counseling are strongly recommended for the donor and his partner (if applicable) as well as for the recipient female and her 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 information about him might be disclosed and about any plans that may exist relating to future contact.
 5. No owner, operator, laboratory director, or employee of a facility performing TDI may serve as a donor in that practice.
 6. Neither the patient's physician nor the individual performing the actual insemination can be the sperm donor.
- B. Screening and testing of donors
1. Semen testing
 - a. It is suggested that more than one sample be examined (each after a 2- to 5-day abstinence interval) before proceeding with a more extensive evaluation of the donor candidate.
 - b. The sample should be examined within 1 to 2 hours after ejaculation into a sterile container. The criteria used to judge the normality of the sample can vary among laboratories. There are no uniformly accepted standards, but, in general, the minimum criteria for normal semen quality can be applied (1).
 2. Genetic evaluation

Genetic screening for heritable diseases should be performed in potential sperm donors. Testing for cystic fibrosis carrier status should be performed on all donors. Other genetic testing should be performed as indicated by the donor's ethnic

background in accordance with current recommendations after obtaining a proper family history. Chromosomal analyses on all sperm donors are not required (see [Appendix A](#) for further details regarding genetic screening and testing) (2–4).

3. Medical history

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

b. A complete personal and sexual history should be obtained to exclude as donors individuals who might be at high risk for HIV, STIs, or other infections that might be transmissible via gamete donation. Prospective sperm donors with any of the following factors should not be accepted (for a complete list of screening questions, see “Uniform Donor Application” at www.sart.org):

- i. Men with a history of sex with another man in the preceding 5 years.
- ii. Men who have injected drugs for non-medical reasons in the preceding 5 years, including intravenous, intramuscular, and subcutaneous injections.
- iii. Men with hemophilia or other related clotting disorders who have received human-derived clotting factor concentrates in the preceding 5 years.
- iv. Men who received clotting factors once to treat an acute bleeding event more than 12 months ago may be eligible to donate.
- v. Men who have had sex in exchange for money or drugs in the preceding 5 years.
- vi. Men who have had sex in the preceding 12 months with any person meeting any of the criteria described immediately above, or with any person having HIV infection, including a positive or reactive test to HIV virus, hepatitis B infection, or clinically active (symptomatic) hepatitis C infection.
- vii. Men 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.
- viii. Men 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.
- ix. Men who have been incarcerated in lock-up, jail, or prison for more than 72 consecutive hours within the previous 12 months.
- x. Men who have had or have been treated for syphilis, gonorrhea, or chlamydia within

the preceding 12 months. Deferral of donors is not necessary when there is evidence of successful treatment more than 12 months before.

- xi. Men 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).
- xii. Men 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, he 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, he 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.
- xiii. Men 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.
- xiv. Men who have tested positive or reactive for WNV infection using an FDA-licensed or investigational WNV NAT in the preceding 120 days.
- xv. Men who have been diagnosed with variant CJD (vCJD) or any other form of CJD.
- xvi. Men 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.

- xvii. Men 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.
- xviii. Men 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.
- xix. Men who spent 3 months or more cumulatively in the United Kingdom (U.K.) from the beginning of 1980 through the end of 1996.
- xx. Men who are current or former US military members, civilian military employees, or dependants 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.
- xxi. Men who spent 5 years or more cumulatively in Europe from 1980 until present.
- xxii. Men who received any transfusion of blood or blood components in the United Kingdom or France between 1980 and the present.
- xxiii. Men 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).
- xxiv. Men who have received a blood transfusion or any medical treatment that involved blood in the countries listed in xxiii 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.3.b.xxiii and xxiv from their screening procedures. If screening questions VI.B.3.b.xxiii and xxiv also are asked, donor eligibility may be based on the donor test results, regardless of the answers to those two questions.

- xxv. Men 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.

- xxvi. Men who have received human organ or tissue transplants or treatment with human extracts.

4. Physical examination

- a. 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 (see www.sart.org Male Donor Physical Examination Form):
 - i. Physical evidence for risk of sexually transmitted disease such as genital ulcerative lesions, herpes simplex, chancroid, or urethral discharge.
 - ii. Physical evidence for risk of, or evidence of, syphilis.
 - iii. Physical evidence of anal intercourse including perianal condylomata.
 - iv. 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.
 - v. Physical evidence of recent (within 12 months) tattooing, ear piercing, or body piercing where sterile technique was not used.
 - vi. Disseminated lymphadenopathy.
 - vii. Unexplained oral thrush.
 - viii. Blue or purple spots consistent with Kaposi sarcoma.
 - ix. Unexplained jaundice, hepatomegaly, or icterus.
 - x. Large scab consistent with recent history of smallpox immunization.
 - xi. Eczema vaccinatum, generalized vesicular rash, severely necrotic lesion (consistent with vaccinia necrosum), or corneal scarring (consistent with vaccinal keratitis).

5. Laboratory testing

There is no method to ensure completely that infectious agents will not be transmitted by TDI. However, the following guidelines, combined with an adequate history and specific exclusion of individuals at high risk for HIV and other STIs, should significantly reduce these risks. The FDA requires that the following tests be performed, using methods required for purposes of determining donor eligibility, and that negative results are documented before use of the donor's sperm. The list of test methods approved by the FDA for this purpose is available at the following Web sites:

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

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

Clinics using donor sperm from a commercial sperm bank should have documentation from the bank that they adhere to federal and local requirements (5).

- a. HIV-1 antibody as well as NAT.
- b. HIV-2 antibody.
- c. HIV group O antibody. Establishments that do not use an FDA-licensed test for HIV group O antibodies must evaluate donors for risk associated with HIV group O infection with additional screening questions as described in VI.B.3.b.x-xiii and xxiv.
- d. Hepatitis C antibody and NAT.
- e. Hepatitis B surface antigen.
- f. Hepatitis B core antibody (IgG and IgM).
- g. Serologic test for syphilis.
- h. HTLV-1 and HTLV-2.
- i. CMV (IgG and IgM). Men who test positive for active infection (positive urine or throat culture or paired serum samples demonstrating a four-fold rise in IgG antibody and IgM antibody at least 30% of the IgG level) should be excluded. Because CMV is so common, insemination with semen from a CMV-seropositive man (without active infection) is permissible when the female partner is also CMV seropositive. Although the practice is not entirely without risk, because there are many strains of CMV and superinfection is possible, the associated risk of newborn CMV infection is approximately 1%, and such infants appear to have no significant illness or other abnormality.
- j. *Neisseria gonorrhoeae* and *Chlamydia trachomatis* NAT on urine or a swab obtained from the urethral meatus. These tests should be repeated if clinically indicated. Retesting of the donor at 6-month intervals is required as long as the donor remains active.
N.B. There are no FDA-licensed, approved or cleared tests for donor screening of these organisms in an asymptomatic, low-prevalence population. Tests using NAT technology adequately and appropriately reduce the risk of transmission of these relevant communicable agents.
- k. 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. If evidence is presented that treatment occurred more than 12 months ago and was successful, no further deferral is needed as long as current testing does not indicate an active infection.
- l. Abbreviated donor screening documenting no change in the donor's medical and/or social

history should be performed at 6-month intervals.

- m. Additional testing should be performed as dictated by local or state requirements.
 - n. Additional testing not required by the FDA but recommended by the ASRM includes blood type and Rh. If the use of donor oocytes creates the potential for Rh incompatibility, couples should be informed about obstetric significance of this condition.
6. Managing laboratory results
- a. If testing is negative, semen samples may be collected and prepared for cryopreservation.
 - b. 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.
 - c. Individuals who initially test positive (except for treated syphilis, *Neisseria gonorrhoeae*, or *Chlamydia trachomatis* as described earlier) are not eligible for anonymous donation.
 - d. False-positive results for syphilis using non-treponemal assays that are confirmed to be negative using a treponemal-based assay are eligible for donation.
 - e. After donation, anonymous donor specimens must be quarantined for a minimum of 180 days. The donor must be retested (see section VI.B.5) after the required quarantine interval, and specimens may be released only if the results of repeat testing are negative.
 - f. Screening and testing of donors for STIs and genetic risk factors may change over time as tests improve and new tests become available. Therefore, samples of sperm that are cryopreserved and stored for periods of time may not meet existing testing standards at the time they are released for use. In such instances, every effort should be made to have the donor tested in accordance with current standards. In situations where the donor is not available or refuses such additional testing, the sample(s) may be released provided that the recipient is informed that the specimen does not meet current screening and testing guidelines, is informed of what tests have not been performed, and is counseled regarding the clinical implications of the missing information.
7. 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 not prohibited from use according to current FDA rules, provided that the tissue is labeled to indicate any associated increased

risks and that physicians using samples are aware of the status of the results. Although the FDA does not require informing the recipients of the test results, in the opinion of the ASRM the recipients must be informed and counseled appropriately before use of the samples. Directed donor specimens also are exempt from quarantine under the current FDA guidelines, which require only retesting as described earlier (see section VI.B.5) within 7 days before donation. However, in the opinion of the ASRM, directed donor specimens should be treated in the same manner as anonymous donor specimens; results of testing that would exclude an anonymous donor also should exclude a directed donor, and directed donor specimens should be quarantined and released in the same manner required for anonymous donor specimens (see sections VI.B.1–6).

8. Use of fresh semen

In the opinion of the ASRM, the use of fresh semen can be justified only for sexually intimate couples. It is possible for HIV and other infectious organisms to be transmitted by fresh donor semen before the donor has become seropositive. Consequently, the potential for transmission of infections by fresh semen cannot be eliminated. The ASRM recommends that all directed donor specimens be frozen and quarantined for a minimum of 180 days, with the donor then retested as described above (see section VI.B.5) and demonstrated seronegative before the specimen is released.

C. Management of donors

1. Monitoring health status

The single most important method for reducing the risk of transmitting infectious agents to women during insemination is to screen carefully and test the potential donors and to develop an ongoing procedure for monitoring their health status.

2. Payment to donors

Payment to donors varies from area to area but should not be such that the monetary incentive is the primary motivation for donating sperm. However, the donor may be compensated for his time and expenses.

3. Limitations to donor use

Institutions, clinics, and sperm banks should maintain sufficient records to allow a limit to be set for the number of pregnancies for which a given donor is responsible. It is difficult to provide a precise number of times that a given donor can be used because one must take into consideration the population base from which the donor is selected and the geographic area that may be served by a given donor. It has been suggested that in a population of 800,000, limiting a single donor to no more than 25 births would avoid any significant increased risk of inadvertent consanguineous conception. This suggestion may require modification if the population using donor insemination represents an iso-

lated subgroup or if the specimens are distributed over a wide geographic area.

4. Consent

It is essential for the donor to sign a consent form, which should include a firm denial of having any recognized risk factors for STIs and genetic diseases. It is recommended that the donor acknowledge in the consent form his responsibility to notify the donor program of any changes in his health or risk factor status.

5. Record keeping

The FDA requires that records pertaining to each donor (screening and test results) be maintained for at least 10 years. However, in the opinion of the ASRM, a permanent record of each donor's initial selection process and subsequent follow-up evaluations should be maintained. Ideally, the clinical outcome of each insemination cycle should be recorded as well as a mechanism for reporting any adverse outcomes including heritable diseases identified pre-conceptually 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 sperm should be tested and further release of samples from the donor should be prohibited. If the donor is found to be the carrier for the heritable disease, all recipients of that donated sperm 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.

6. 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 federal and local requirements.

VII. Choosing donor characteristics

There are several methods for matching the male partner with the donor. The couple should be encouraged to list the characteristics that they desire in a prospective donor, including race and/or ethnic group, height, body build, complexion, eye color, and hair color and texture. Consideration should be given to blood type and Rh factor, particularly for Rh-negative recipients. If the use of donor sperm creates the potential for Rh incompatibility, recipients should be informed of the obstetric implications of the condition.

GUIDELINES FOR OOCYTE DONATION

I. Introduction

Oocyte donation requires ovarian stimulation with monitoring and oocyte retrieval, involving significant inconvenience, discomfort, and risks for the donor.

II. Indications for use of donor oocytes

- A. Women with hypergonadotropic hypogonadism.
- B. Women of advanced reproductive age.

- C. Women who have diminished ovarian reserve.
 - D. Women 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. Women with poor oocyte and/or embryo quality or multiple previous failed attempts to conceive via ART.
- III. Psychological consultation for oocyte donor recipients
- The decision to proceed with donated oocytes is complex, and patients and their partners (if applicable) may benefit from psychological counseling to aid in this decision. The clinician should strongly recommend psychological counseling by a qualified mental health professional to all donor oocyte recipients and their partners. The assessment should include a clinical interview and, where appropriate, psychological testing. The clinician should require psychological consultation for couples in whom there appear to be factors that warrant further evaluation. In cases of directed donation, the potential impact of the relationship between the donor and recipient should be explored, as well as any plans that may exist relating to disclosure and future contact.
- IV. Evaluation of the oocyte recipient
- A. Medical and reproductive history
 1. Routine medical and reproductive histories should be obtained according to the standards that are applied to women anticipating pregnancy. Reproductive abnormalities detected from history or physical examination may require more detailed evaluation and treatment before donor oocytes are used.
 - B. A complete general physical examination should be performed, including a pelvic examination.
 - C. Assessment of the uterine cavity
 1. HSG, saline infusion ultrasonography, or another suitable procedure should be performed to detect any significant uterine abnormality.
 - D. Standard preconceptional testing and counseling
 1. Although there are no federal requirements for testing oocyte recipients, the following tests are recommended:
 - a. Blood type, Rh factor, and antibody screen.
 - b. Rubella and varicella titers. Recipients should be offered immunization if not immune.
 - c. HIV-1 (AB and NAT), HIV-2 AB testing and screening or testing for HIV group O antibodies. HIV testing should be performed to address potential medical/legal complications that could arise if the recipient seroconverts during or after treatment. In addition, if the female recipient is found to be HIV infected before treatment, she should be referred to an appropriate infectious disease specialist for counseling on issues concerning HIV disease, including reproductive issues such as safe sex practices for preventing HIV transmission to uninfected partners and treatment options to reduce the probability of transmission to her child; counseling should be documented in the medical record. A positive HIV test of the female recipient should not be used as an exclusionary criterion for treatment, provided that the couple makes an informed decision after counseling and agrees to comply with recommended clinical management for the positive HIV state.
- V. Evaluation of the partner of the oocyte recipient
- A. Laboratory tests. Although there are no federal requirements for testing the partner of the oocyte recipient, the following tests are recommended:
 1. Semen analysis for male partners.
 2. Blood type and Rh factor.
 3. Serologic test for syphilis.
 4. Hepatitis B surface antigen.
 5. Hepatitis B core antibody (IgG and IgM).
 6. Hepatitis C antibody and NAT.
 7. HIV-1 (AB and NAT), HIV-2 AB testing and screening, or testing for HIV group O antibodies. HIV testing should be performed to address potential medical/legal complications that could arise if the recipient seroconverts during or after treatment. In addition, if the partner is found to be HIV infected before treatment, he should be referred to an appropriate infectious disease specialist for counseling on issues concerning HIV disease, including reproductive issues such as safe sex practices for preventing HIV transmission to uninfected partners. Counseling should be documented in the medical record. A positive HIV test of the partner should not be used as an exclusionary criterion for treatment.
 8. Appropriate genetic screening and testing based on history, in accordance with ethnic background and current recommendations (see [Appendix A](#)) (2–4).
- VI. Donors
- A. Selection of donors
 1. Oocyte donation may be undertaken with known or anonymous donors depending on the clinical circumstances.
 2. Psychological evaluation and counseling by a qualified mental health professional is strongly recommended for the oocyte donor and her 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. In circumstances involving known donors, psychological evaluation and counseling is strongly recommended for the donor and her partner, if applicable, as well as for the recipient and her 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 information about her may be disclosed and about any plans that may exist relating to 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. If a prospective donor is over 34 years of age, 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 and current guidelines. Cystic fibrosis testing should be performed on all donors. Consideration should be given to fragile X testing on donors, but is not required (see [Appendix A](#) (2–4)).
 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 existing ASRM Ethics Committee guidelines (6).
 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. A complete personal and sexual history should be obtained to exclude as donors individuals who might be at high risk for HIV, STIs, or other infections that might be transmissible via gamete donation. Prospective oocyte donors with any of the following factors should not be accepted (for a complete list of screening questions, see “Uniform Donor Application” at www.sart.org):
 - a. Women who have injected drugs for non-medical reasons in the preceding 5 years, including intravenous, intramuscular, and subcutaneous injections.
 - b. Women with hemophilia or other related clotting disorders who have received human-derived clotting factor concentrates in the preceding 5 years.
 - i. Women who received clotting factors to treat an acute bleeding event more than 12 months prior to planned donation may be eligible to donate.
 - c. Women who have had sex with a man who has had sex with another man in the past 5 years.
 - d. Women who have had sex in exchange for money or drugs in the preceding 5 years.
 - e. Women who have had sex in the preceding 12 months with any person meeting any of the criteria described immediately above, or with any person having HIV infection including a positive or reactive test to HIV virus, hepatitis B infection, or clinically active (symptomatic) hepatitis C infection.
 - f. Women 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.
 - g. Women 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.
 - h. Women who have been incarcerated in lock-up, jail, or prison for more than 72 consecutive hours within the previous 12 months.
 - i. Women 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.
 - j. Women 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).
 - k. Women 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.
- l. Women who have had a medical diagnosis or suspicion of 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.
 - m. Women 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.
 - n. Women who have been diagnosed with vCJD or any other form of CJD.
 - o. Women 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.
 - p. Women 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.
 - q. Women 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.
 - r. Women who spent 3 months or more cumulatively in the United Kingdom from the beginning of 1980 through the end of 1996.
 - s. Women who are current or former US military members, civilian military employees, or dependants 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.
 - t. Women who spent 5 years or more cumulatively in Europe from 1980 until present.
 - u. Women who received any transfusion of blood or blood components in the United Kingdom or France between 1980 and the present.
 - v. Women 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).
 - w. Women who have received a blood transfusion or any medical treatment that involved blood in the countries listed 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.
- x. Women 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.
 - y. Women 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 (see female donor physical exam at www.sart.org):
 - 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 vaccinal 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. The FDA requires that the following tests be performed within 30 days of 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 antibody as well as 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 antibody and NAT.
- e. Hepatitis B surface antigen.
- 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, couples 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. If evidence is presented that treatment occurred more than 12 months ago and was successful, no further deferral is needed as long as current testing does not indicate an active infection.

D. Quarantining of oocytes

At this time, oocyte freezing cannot be performed reliably; therefore, the quarantining of oocytes is not

practical. All potential recipient couples 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 (see section VI.B.4). However, couples also should be informed that embryo cryopreservation may significantly reduce implantation rates. The recipient couple 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 not prohibited from use according to current FDA rules, provided that the tissue is labeled to indicate any associated increased risks and that physicians using samples are aware of the status of the results. Although the FDA does not require informing the recipients of the test results, the ASRM recommends that the recipients must be informed and counseled appropriately before use of the samples. Additionally, the ASRM recommends that directed-donor specimens should be treated in the same manner as anonymous-donor specimens; results of testing that would exclude an anonymous donor also should exclude a directed donor.

F. Payment to the donor

1. Compensation to the donor should be in compliance with the ASRM Ethics Committee report on the subject (7).
2. Monetary compensation of the donor should reflect the time, inconvenience, and physical and emotional demands and risks associated with oocyte donation and should be at a level that minimizes the possibility of undue inducement of donors and the suggestion that payment is for the oocytes themselves.
3. 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.
4. Payment may be prorated based on the number of steps completed in the procedure.
5. Payment should not be predicated on clinical outcome.

G. Multiple oocyte donations

This subject is addressed specifically in the ASRM Practice Committee Opinion entitled "Repetitive Oocyte Donation" (8).

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 women 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. However, in the opinion of the ASRM, a permanent record of each donor's initial selection process and subsequent follow-up evaluations should be maintained. Ideally, the clinical outcome for each donation cycle should be recorded as well as a mechanism for reporting any adverse outcomes including heritable diseases identified pre-conceptually 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 women 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. Couples and donors who have legal concerns not addressed in the informed-consent process should be advised to seek 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 her responsibility to notify the donor program of any changes in her health or risk-factor status.

In the majority of ART practices, these embryos may be cryopreserved for later transfer. Couples who become pregnant and do not desire another pregnancy, or have other reasons for choosing not to use their embryos, may have the option of discarding these embryos or donating them to other individuals or to research. It is the purpose of this document to present guidelines for embryo donation. It should be noted that these guidelines represent minimum standards for screening, testing, and counseling of potential embryo donors and recipients. The federal government has published minimum requirements for embryo donation (6). Some states and other localities may have laws or regulations that pertain to embryo donation that may supersede these guidelines.

I. Guidelines for ART practices that offer embryo donation

- A. The practice should be knowledgeable in the storage, thawing, and transfer of frozen embryos.
- B. The practice may charge a professional fee to the potential recipients for embryo thawing, the embryo transfer procedure, cycle coordination and documentation, and infectious disease screening and testing of both recipients and donors. However, the selling of embryos per se is ethically unacceptable.
- C. It is acceptable for a practice or cryostorage facility to have conservatorship of embryos given up for potential embryo donation by patients whose gametes were used to generate the embryos.
- D. Embryos should be quarantined for a minimum of 6 months before the potential donors are screened and tested or retested as noted in section II, with documentation of negative results.
- E. Physicians and employees of an infertility practice should be excluded from participating in embryo donation as either donors or recipients within that practice.

II. Embryo donation

Eligibility of donors is determined by the gametes, not the embryos being donated. For embryos derived from gametes obtained from an anonymous donor or donors, the donor or donors must have met all FDA screening and testing requirements and must have been determined eligible for anonymous donation as described above for anonymous sperm and/or oocyte donation. If one or both of the donors is known to the recipient, gametes that were determined to be ineligible still can be used and those embryos are not prohibited from use according to current FDA rules, provided that the tissue is labeled to indicate any associated increased risks and that physicians using samples are aware of the status of the results. Although the FDA does not require informing the recipients of the test results, the ASRM recommends that the recipients be informed and counseled appropriately before transfer of the embryos.

Embryos derived from the gametes of a sexually intimate couple and created for use by that couple are exempt from the requirements for donor screening and testing before creation of the embryos. The following guidelines apply to sexually intimate couples who decide to donate unused embryos that are the product of their own biological gametes:

GUIDELINES FOR CRYOPRESERVED EMBRYO DONATION

Background

In the current clinical practice of ART, more embryos than can be transferred safely at one time commonly are generated.

- A. Embryo donors must provide a medical and genetic history.
- B. The gamete donors used to create the embryos should be screened for relevant risk factors for HIV, other transmissible infections, and TSE (9).
- C. There is no method to ensure completely that infectious agents will not be transmitted, but the following guidelines, combined with an adequate medical history and specific exclusion of individuals at high risk for HIV and other transmissible infections, should dramatically reduce these risks. The practice should determine if the cost of such tests will be borne by the donor couple, by the practice mediating the embryo donation, or by the potential recipients. The following recommended tests should be performed using methods approved by the FDA for use in determining donor eligibility, on both partners, before gamete collection and more than 180 days after cryopreservation of the embryos to be donated.
1. HIV-1 antibody and NAT.
 2. HIV-2 antibody.
 3. HIV group O antibody. Establishments that do not use an FDA-licensed test for group O antibodies should evaluate donors for risk associated with HIV group O infection (see screening questionnaires for anonymous sperm and oocyte donation).
 4. Hepatitis B surface antigen.
 5. Hepatitis B core antibody (IgG and IgM).
 6. Hepatitis C antibody and NAT.
 7. Serologic test for syphilis.
 8. *Neisseria gonorrhoeae* and *Chlamydia trachomatis* NAT.
 9. Although not required by the FDA, recommended tests also include:
 - a. Blood type and Rh factor.
 10. In addition, the male gamete donor should be tested for:
 - a. HTLV-1 and HTLV-2.
 - b. CMV (IgG and IgM) antibody.
 11. If not already performed, appropriate genetic evaluation and testing should be conducted.
- D. Often, screening and testing of the biological source of the gametes used to create the embryos in sexually intimate partners was not done, and the decision to donate embryos occurred subsequent to their creation. If the decision to donate is made more than 180 days after cryopreservation of the embryos, the donors may be rescreened and tested. In this instance, the documentation that accompanies the embryos must include the following label: "Advise recipient that screening and testing of the donors were not performed at the time of cryopreservation of the reproductive cells or tissue but have been performed subsequently."
- E. If the donors are not available or refuse to undergo the required screening and testing, FDA guidelines do not preclude the use of their embryos, provided that the documentation that accompanies the embryos includes the following labels: "NOT EVALUATED FOR INFECTIOUS SUBSTANCES," and "WARNING: Advise recipient of communicable disease risks." However, the ASRM recommends careful counseling regarding the risks of transfer of these embryos.
- F. Embryos that are shipped to another facility must be accompanied by a summary of records and must be appropriately labeled, in accordance with FDA guidelines. The receiving facility should not accept embryos that are not accompanied by a summary of records or that are not appropriately labeled (10).
- G. The embryo donors must sign an informed-consent document indicating their permission to use their embryos for embryo donation. Issues to be addressed in the consent form include:
1. Relinquishing all rights of the donor(s) to the embryo(s) and any child or children that may result from the transfer of such embryo(s).
 2. Inadvertent loss or damage to the embryo(s).
 3. The right of the practice to refuse transfer to an inappropriate recipient.
 4. The length of time that donated embryos will be maintained in cryostorage, and the alternatives for their disposition thereafter.
 5. Jurisdiction and process for medical/legal procedures and/or dispute resolution.
- H. Proper chain-of-custody procedures must be followed and documented for the handling of all test specimens and for donated embryos.
- I. Donors should receive no compensation for the embryos.
- J. The decision to proceed with embryo donation is complex, and patients may benefit from psychological counseling to aid in the decision. Psychological consultation with a qualified mental health professional is strongly recommended for all couples considering donating embryos. The assessment should include a clinical interview and, where appropriate, psychological testing. The clinician should require psychological consultation for couples in whom there appear to be factors that warrant further evaluation. In circumstances involving known donors, psychological evaluation and counseling is strongly recommended for the donor and partner, if applicable, as well as for the recipient and her partner, if applicable. The potential impact of the relationship between the donor and recipient should be explored. It is important to ascertain whether the donor is well informed about the extent to which information about her may be disclosed and about any plans that may exist relating to future contact.
- K. Donors should be advised that additional testing may be necessary prior to releasing embryos for donation.
- III. Guidelines for potential recipients
- A. The recipient(s) must take full responsibility for the embryo(s) and any child or children that may result from the transfer.
 - B. The recipient(s) must release the gamete donors from any and all liability from any potential complications of the pregnancies, congenital abnormalities, heritable

diseases, or other complications of the embryo donation. The ART program should also be absolved of liability from potential complications of pregnancy, congenital abnormalities, and heritable diseases.

- C. The ASRM recommends that the recipient(s) submit to the same blood tests for infectious disease testing as the donors (V.C.1.a-j under Guidelines for Sperm Donation).
 - D. Although not required by the FDA, recommended tests also include blood type and Rh factor. If the use of donor embryos creates the potential for Rh incompatibility, couples should be informed about the obstetric significance of this condition.
 - E. The decision to proceed with embryo donation is complex, and patients may benefit from psychological counseling to aid in this decision. Psychological consultation with a qualified mental health professional is strongly recommended for all individuals receiving donated embryos. The assessment should include a clinical interview and, where appropriate, psychological testing. The physician should require psychological consultation for couples in whom there appear to be factors that warrant further evaluation. In circumstances involving known donors, psychological evaluation and counseling is strongly recommended for the recipient and her partner, if applicable. The potential impact of the relationship between the donor and recipient should be explored. It is important to ascertain whether the recipient is well informed about any plans that may exist relating to future contact.
- IV. Record keeping

The FDA requires that records pertaining to each donor (screening and test results) be maintained for at least 10 years. However, in the opinion of the ASRM, a permanent record of each donor's screening and test results should be maintained. To the extent possible, the clinical outcome should be recorded for each donation cycle. A mechanism must exist to maintain such records as a future medical resource for any offspring produced.

V. 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.

PSYCHOLOGICAL ASSESSMENT OF GAMETE DONORS AND RECIPIENTS

Statement of Purpose

The following recommendations are intended to provide general guidelines for addressing the many complex moral, ethical, and psychosocial issues that confront gamete donors, recipients, and offspring.

I. Donors

- A. The decision to proceed with gamete donation is complex, and individuals may benefit from psychological counseling to aid in the decision. Psychological

consultation with a qualified mental health professional is strongly recommended for all individuals considering gamete donation. The assessment should include a clinical interview and, where appropriate, psychological testing. The physician should require psychological consultation for donors in whom there appear to be factors that warrant further evaluation.

- 1. If indicated, psychological testing should document and validate in a standardized objective manner the information gathered from the clinical interview and should include an objective personality test and other self-report measures to assess potential instability or psychopathology.
- B. A psychosocial history should include:
 - 1. Family history.
 - 2. Educational background.
 - 3. Assessment of stability.
 - 4. Motivation to donate.
 - 5. Current life stressors and coping skills.
 - 6. Difficult or traumatic reproductive history.
 - 7. Interpersonal relationships.
 - 8. Sexual history.
 - 9. Travel history.
 - 10. History of major psychiatric and personality disorders.
 - 11. Substance abuse in donor or first-degree relatives.
 - 12. Legal history.
 - 13. History of abuse or neglect.
- C. The psychological assessment should ensure that the donor has been informed about all relevant aspects of the medical treatment. Donors should be counseled about the number and type of infectious disease tests that will be performed and informed about how that information will be used and shared with others.
- D. The psychological assessment also should address the potential psychological risks and should evaluate for evidence of coercion (financial or emotional). It also is important to ascertain whether the donor is well informed about the extent to which information about him/her might be disclosed and about any plans that may exist relating to future contact. The donor must be aware of all aspects of potential embryo management and disposition applicable to that practice. Donors should be informed about how the information will be used, stored, and secured.
- E. Relative exclusion criteria for a gamete donor include:
 - 1. Presence of significant psychopathology.
 - 2. Positive family history of heritable psychiatric disorders.
 - 3. Substance abuse.
 - 4. Two or more first-degree relatives with substance abuse.
 - 5. Current use of psychoactive medications.
 - 6. History of sexual or physical abuse with no professional treatment.
 - 7. Excessive stress.
 - 8. Marital instability.
 - 9. Impaired cognitive functioning.
 - 10. Mental incompetence.

11. High-risk sexual practices.

- F. Candidates who are excluded from the donor practice should be counseled regarding the reasons for their exclusion and, if appropriate, offered referral.
- G. In cases involving known donors, related issues such as the potential impact of the relationship between the donor and recipient should be explored. The impact on treatment failure also should be addressed.

II. Recipients

- A. The decision to proceed with gamete donation is complex, and patients may benefit from psychological counseling to aid in the decision. Psychological consultation with a qualified mental health professional is strongly recommended for all patients considering gamete donation. The assessment should include a clinical interview and, where appropriate, psychological testing. The physician should require psychological consultation for patients in whom there appear to be factors that warrant further evaluation.
- B. The recipient should be counseled about his/her subsequent feelings concerning the medical conditions that necessitated the use of donor gametes.
- C. Counseling should address the impact of successful treatment: feelings during pregnancy, positive and negative aspects of disclosure and nondisclosure with offspring, potential impact of multiple pregnancy, transition to parenthood, parenting at an older age (if applicable), and nonbiological parenting issues.
- D. The impact of treatment failure also should be addressed: coping with treatment termination, the grieving process, and developing alternatives for the future.
- E. In cases involving known donors, related issues, such as the potential impact of the relationship between donor and recipient, should be explored.
- F. The recipients should be informed about the screening and testing required of the donor. The couple should be made aware that a donor may be deemed unsuitable for donation and that the practice may refuse to use these gametes for treatment. If the recipient couple elects to use a donor who is deemed unsuitable, then additional counseling must involve risk management and an agreement that the recipient couple understands and assumes the risk. Couples should be informed that the records related to the screening and testing of the donor will be stored. The storage of this information is relevant to the recipients because it relates to other information-sharing decisions they may make.

I. Donors

- A. All potential donor couples should be informed about all aspects of their medical treatments and the relevant psychological and ethical issues inherent in donating embryos.
- B. There should be a discussion of embryo disposition options before cryopreservation. After couples have concluded their own reproductive attempts, embryo disposition options should be re-evaluated.
- C. The decision to proceed with embryo donation is complex, and patients may benefit from psychological counseling to aid in the decision. Psychological consultation with a qualified mental health professional is strongly recommended for all patients considering donating embryo(s). The assessment should include a clinical interview and, where appropriate, psychological testing. The clinician should require psychological consultation for patients in whom there appear to be factors that warrant further evaluation. In circumstances involving known donors, psychological evaluation and counseling is strongly recommended for the donors. The potential impact of the relationship between the donor and recipient should be explored. It is important to ascertain whether the donor is informed about any plans that may exist relating to future contact. The assessment should occur after couples have concluded their own reproductive attempts and have clearly indicated their desire to donate embryos.
- D. The clinical interview should include a psychosocial history of both partners, which addresses:
 1. Family history.
 2. Educational background.
 3. Assessment of stability.
 4. Motivation to donate.
 5. Current life stressors and coping skills.
 6. Difficult or traumatic reproductive history.
 7. Interpersonal relationships.
 8. Sexual history.
 9. History of major psychiatric and personality disorders.
 10. Substance abuse in donor or first-degree relatives.
 11. Legal history.
 12. History of abuse or neglect.
 13. Emotional attachment to embryo.
- E. If indicated, psychological testing is recommended to document and validate in a standardized objective manner the information gathered from the clinical interview and should include an objective personality test and other self-report measures to assess potential instability or psychopathology.
- F. Relative exclusion criteria for an embryo donor include:
 1. Presence of significant psychopathology.
 2. Positive family history of heritable psychiatric disorders.
 3. Substance abuse.
 4. Two or more first-degree relatives with substance abuse.
 5. Current use of psychoactive medications.

PSYCHOLOGICAL GUIDELINES FOR EMBRYO DONATION

Statement of Purpose

The following recommendations are intended to provide general guidelines for addressing the many complex moral, ethical, and psychosocial issues that confront embryo donors, recipients, and offspring.

6. History of sexual or physical abuse with no professional treatment.
 7. Excessive stress.
 8. Marital instability.
 9. Impaired cognitive functioning.
 10. Mental incompetence.
 11. High-risk sexual practices.
- G. A minimum 3-month waiting period with appropriate follow-up assessment is recommended between the time a couple signs the consent form to donate embryos and the actual donation to a recipient couple.
- H. Physicians and employees of an infertility practice may not participate in embryo donation (as donors or recipients) within that practice.
- I. Donors should not be compensated for their donated embryos.
- J. Donors should be at least 21 years of age.
- K. All potential donor couples should be advised at the time of the IVF procedure that additional screening and testing may be required if they elect to donate their embryos. The couple should be counseled about their possible ineligibility to donate embryos.
- II. Recipients and their partners
- A. Recipients of donor embryos and their partners should receive counseling about the potential psychosocial implications.
- B. The decision to proceed with embryo donation is complex, and patients may benefit from psychological counseling to aid in the decision. Psychological consultation with a qualified mental health professional is strongly recommended for all patients considering embryo donation. The assessment should include a clinical interview and, where appropriate, psychological testing. The physician should require psychological consultation for patients in whom there appear to be factors that warrant further evaluation.
- C. The recipient and her partner should be counseled about their subsequent feelings concerning the medical conditions that made necessary the use of donor embryos.
- D. The impact of treatment failure also should be addressed, including coping with treatment termination, the grieving process, and developing alternatives for the future.
- E. Relative issues, such as the impact of the relationship between known donors, recipients, and offspring, should be explored.
- F. This assessment should attempt to exclude significant psychiatric illness and current substance abuse and to evaluate their ability to cope with the stress of ART.
- G. Recipients of donor embryos should be advised of screening and testing requirements and be prepared either to not use or to assume the risks related to the use of donor embryos.

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Society for Assisted Reproductive Technology (SART) as a service to its members and other practicing clinicians. Although this document reflects appropriate management of a problem encountered in the practice of reproductive medicine, it is not intended to be the only approved standard of practice or to dictate an exclusive course of treatment. Other plans of management may be appropriate, taking into account the needs of the individual patient, available resources, and institutional or clinical practice limitations. The Practice Committees and the Board of Directors of ASRM and SART have approved this report.

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APPENDIX A

MINIMUM GENETIC TESTING FOR GAMETE AND EMBRYO DONORS (2–4)

The American Society for Reproductive Medicine; Birmingham, Alabama

I. The donor

- A. Should not have any major Mendelian disorder. Mendelian disorders fall into the following categories:
 - a. Autosomal dominant or X-linked disorders. Providers should be aware that some autosomal dominant or X-linked disorders can have variable expressivity (meaning that mutation carriers may not have noticeable symptoms) or have an age of onset that extends beyond the age of the donor (one example is Huntington disease).
 - b. Autosomal recessive disorders. Donors who are heterozygous need not necessarily be excluded if the reproductive partner has had appropriate carrier screening. The recipient and reproductive partner (as appropriate) should be counseled about the accuracy of the carrier screening test and the residual risk to be a carrier following a negative test. Counseling regarding residual risk is complex and may be best provided by a genetic counselor.
- B. Should not have (or have had) any major malformation of complex cause (multifactorial/polygenic), such as spina bifida or cardiac malformation. A major malformation is defined as one that carries serious functional or cosmetic handicap. However, the definition of “major” is a matter of judgment.
- C. Should not have any significant familial disease with a major genetic component.

Note: Assessment of hereditary risk factors by family history review is performed best by a genetic counselor. However, this screening may be performed by any professional trained in medical genetics at the discretion of the individual program.
- D. Should not have a known karyotypic abnormality that may result in chromosomally unbalanced gametes. In the general population, the chance of having a chromosomal rearrangement that could be transmitted in unbalanced form to offspring is small, provided the family history is negative for risk factors. Therefore, routine karyotyping of all donors is optional.

- E. Should undergo general population and ethnicity (ancestry)-based genetic screening. Donors should give informed consent prior to carrier screening. Informed consent should include discussion of the natural history of the condition being screened, carrier frequency in the respective ethnic group, detection rate of the test, residual risk to be a carrier when testing negative, and options for persons testing positive. If a prospective donor is identified as a carrier, genetic counseling for both the donor and recipient is recommended (6).

The recommended list of tests may change as tests for other disorders are developed. 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: It is not appropriate to screen gamete donors for adult onset conditions (such as cancer predisposition, Huntington disease, etc.) without full consent of the gamete donor, including formal genetic counseling (7).

- F. Should be generally healthy and young. Advanced maternal age is associated with an increased risk for aneuploid offspring. Advanced paternal age is associated with a moderately increased risk for new mutations in offspring, and an emerging body of evidence suggests an increased risk for complex disorders, including some congenital anomalies, schizophrenia, autism spectrum disorders, and specific forms of cancer.
- II. The donor's first-degree relatives (parents, siblings, and offspring) should be free of:
 - A. Mendelian disorders as described in Section I.A.
 - B. Major malformations as described in Section I.B.
 - C. Significant familial disease with a major genetic component.
 - D. A chromosomal abnormality, unless the donor has a normal karyotype.
 - E. Mental retardation of undocumented etiology.

If family history reveals a disorder for which definitive testing is available, then it is appropriate to refer the prospective donor for genetic counseling for that specific disorder. Testing without a formal genetic consultation would be inappropriate. Genetic test results may determine the appropriateness of using that donor.