

2002 GUIDELINES FOR GAMETE AND EMBRYO DONATION

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- S1 **2002 Guidelines for gamete and embryo donation: a practice committee report**
- S2 **Guidelines for sperm donation**
- S6 **Guidelines for oocyte donation**
- S9 **Guidelines for cryopreserved embryo donation**
- S11 **Psychological assessment of gamete donors and recipients**
- S13 **Psychological guidelines for embryo donation**
- S15 **Appendix A: Minimal genetic screening for gamete donors**



2002 Guidelines for gamete and embryo donation: a practice committee report

Guidelines and minimum standards

The American Society for Reproductive Medicine

Birmingham, Alabama

The *2002 Guidelines 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 embryos and gametes more consistent and incorporates recent information from the Centers for Disease Control (CDC), Food and Drug Administration (FDA), and American Association for Tissue Banks (AATB). The risk of STIs does differ for sperm, oocytes, and embryos, and leukocyte-rich semen donation poses unique risks, which 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 high risk for a given disease such as human immunodeficiency virus (HIV), and transmissible spongiform encephalopathy (TSE), or Creutzfeldt-Jakob disease (CJD). “Testing” refers to specific laboratory studies such as serologic tests. This distinction between screening and testing is consistently made within the document. The guidelines for the testing and screening for gamete and embryo donors are intended for potential donors in the United States. Prevalence of STIs and genetic diseases may vary in other locales and these guidelines may not be appropriate for other countries or individuals who come to the United States from other countries.

Revised by the Ad Hoc Committee of the American Society for Reproductive Medicine: Deborah J. Anderson, Ph.D., Owen K. Davis, M.D., Marc A. Fritz, M.D., David I. Hoffman, M.D., Delores J. Lamb, Ph.D., Larry I. Lipshultz, M.D., Jacob F. Mayer, Ph.D., Steven J. Ory, M.D., Deidra T. Rausch, Ph.D., Joe Leigh Simpson, M.D., Michael R. Soules, M.D., and the Practice Committee of the American Society of Reproductive Medicine. Approved by the Board of Directors of the American Society for Reproductive Medicine in 2001.

Guidelines for sperm donation

The American Society for Reproductive Medicine

Birmingham, Alabama

I. Introduction

Therapeutic donor insemination (TDI) may be employed to achieve conception where appropriate indications exist. The clinical procedures should take into account the age and health status of the recipient.

II. Indications for Considering TDI

- A. The male partner has azoospermia, severe oligospermia, or other significant sperm or seminal fluid abnormalities.
- B. The male partner has ejaculatory dysfunction.
- C. In assisted reproductive technologies (in vitro fertilization, gamete intrafallopian transfer, zygote intrafallopian transfer), the male partner demonstrates significant male factor infertility (i.e., previous failure to fertilize, significant oligoasthenospermia, male immunologic infertility) and in vitro fertilization (IVF) with intracytoplasmic sperm injection (ICSI) is not elected or feasible.
- D. The male partner has a significant genetic defect and the recipient also is known either to be affected or to be a carrier of it; or the recipient has previously produced an offspring affected by a condition and carrier status cannot be determined.
- E. The male partner has an ineradicable sexually transmissible infection.
- F. The female partner is Rh-negative and severely Rh-immunized, and the male partner is Rh-positive.
- G. Females without male partners.

III. The Recipient

- A. The decision to proceed with donor insemination is complex, and patients may benefit from psychological counseling to aid in this decision. The phy-

sician should offer psychological counseling to all couples, and should require psychological consultation for couples in whom factors appear to warrant further evaluation.

- B. Consent forms should be signed by the couple or by the recipient if she is single.

IV. Evaluation of the Male Partner

- A. The male 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.
- B. Human immunodeficiency virus (HIV) testing of the male partner is strongly recommended to address potential medical/legal complications that could arise if his partner seroconverts during or after TDI. In addition, if the male partner is HIV infected, he should be referred to an appropriate infectious disease unit for counseling on safe sex practices for preventing HIV transmission, on treatment options, and on other issues concerning HIV disease. A positive HIV-1 test result for the male partner should not be used as an exclusionary criterion for treatment of a couple with TDI, provided that the semen is provided by an HIV-1 negative donor.
- C. Testing for other sexually transmissible infections (STIs) should be recommended.

V. Evaluation of the Female Recipient

- A. Medical and Reproductive History Routine medical and reproductive history 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 insemination. (See Appendix A with respect to genetic screening and testing.)

B. Physical Examination

A complete general physical examination should be performed, including a pelvic examination.

C. Standard Preconception Screening, Testing, and Counseling

1. Recommended tests include blood type, Rh factor, and rubella and varicella titers. Vaccination should be offered if the individual is not immune to either virus. Rh-negative women should undergo antibody screening.

2. HIV-1 testing should be mandatory 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-1 infected before treatment, she should be referred to an appropriate infectious disease unit for counseling on issues concerning HIV-1 disease, including reproductive issues such as safe sex practices for preventing HIV-1 transmission to uninfected partners, and treatment options to reduce the probability of transmission to her child. A positive HIV-1 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 following counseling and is compliant with recommended clinical management for the positive HIV state. Other tests to be obtained include serologic test for syphilis, and serum testing for hepatitis B surface antigen, hepatitis C antibody (HCV), cytomegalovirus (CMV) antibody, HIV-2, human T-cell lymphotropic virus type I (HTLV-I) and HTLV-II. Individuals should be screened for possible exposure to transmissible spongiform encephalopathies (TSEs).

3. Cervical cultures may be obtained for gonorrhea and chlamydia at the discretion of the physician.

4. Guidelines for testing for the cystic fibrosis carrier should be discussed and implemented.

E. Documentation and Timing of Ovulation

Women with regular cyclic menses and minimal symptoms are considered to be ovulating. When doubt exists, an index of ovulation, such as serum progesterone level, may be used. Techniques to time ovulation may include basal body temperature, luteinizing hormone (LH) surge measurements, and ultrasound monitoring of follicular maturation.

F. Evaluation of Possible Tubal or Peritoneal Abnormalities

Patients who fail to conceive after four to six well-timed inseminations may be candidates for hysterosalpingography (HSG), laparoscopy, and other appropriate tests to detect other possible causes of persistent infertility. Consideration may be given to performing an HSG before inseminations, and pre-treatment laparoscopy may be indicated by the history and/or physical findings.

VI. Donors

A. Selection of Donor

1. The main qualities to look for in selecting the donor for TDI are assurance of good health status and absence of genetic abnormalities. Suggestions to follow are provided in Appendix A.

2. The donor should be of legal age but younger than 40 years of age so that potential hazards related to aging are diminished.

3. Selecting donors who have established fertility is desirable but not an absolute requirement.

4. Anonymous donors have traditionally been used, but directed (nonanonymous or known) donation is acceptable if all parties agree. Directed donors should undergo the same evaluations as anonymous donors. Both anonymous and directed-donor specimens should be quarantined for 180 days with appropriate retesting and follow-up evaluation prior to use (see section VI.B.6).

5. Psychological assessment by a qualified mental health professional is recommended for all sperm donors. Psychological consultation should be required for individuals in whom there appear to be factors that warrant further evaluation. In the case of directed donation, psychological evaluation and counseling should be strongly recommended to the donor and his partner, as well as the recipient couple. Issues such as the potential impact of the relationship between the donor and recipient should be explored. The psychological assessment should also address the potential psychological risks and evaluate for evidence of coercion (financial or emotional). It is also important to ascertain whether the donor is knowledgeable about the degree of disclosure and whether any plans exist for future contact.

6. No owner, operator, laboratory director, or employee of a facility performing TDI may serve as a donor in that practice.

7. Neither the patient's physician nor the individual performing the actual insemination can be the provider of the sperm sample.

B. Screening and Testing of Donors

1. Semen testing

a. It is suggested that several samples be examined

TABLE 1

Minimal semen parameters recommended for donors.

Volume	>2 mL
Sperm motility	>50% moving actively in a purposeful direction
Sperm concentration	>50 × 10 ⁶ motile sperm/mL
Sperm morphology	Normal range
Cryosurvival	>50% of initial motility

(abstinence 2 to 3 days) before proceeding with more extensive evaluation.

- 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 may vary among laboratories. There are no agreed upon standards, but in general the minimal criteria for semen quality can be used (see Table 1).
2. Genetic Evaluation
Genetic screening of potential donors is important. Some institutions require complete chromosomal analysis before accepting a donor. This analysis is not required if adequate attention is paid to obtaining a proper family history with respect to potential hereditary disorders. (See Appendix A for further details.)
 3. Medical History
 - a. The 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 and other STIs. Prospective sperm donors with any of the following factors should not be accepted:
 - Men with a history of sex with men.
 - Men who have injected drugs for a non-medical reason.
 - Persons who have had sex in exchange for money or drugs.
 - Men who have had sex in the preceding 12 months with any person described in the items above or with any person suspected of having HIV or hepatitis infection.
 - Men who have been exposed through percutaneous inoculation or through contact with an open wound, nonintact skin, or mucous membrane within the last 12 months to blood that is known or suspected to be infected with HIV, hepatitis B, and/or hepatitis C virus.
 - Men who have been incarcerated in jail for more than 72 hours.

- Men who have had close contact within 12 months preceding the donation with another person who has viral hepatitis.
 - Men who have had or have been treated for syphilis or gonorrhea within the preceding 12 months.
 - Persons who within 1 year of donation have undergone acupuncture, body piercing, and/or tattooing procedures in which sterile procedures were not used, or when it is unclear whether sterile procedures were used.
 - Persons with a family history of transmissible spongiform encephalopathy (TSE) such as Creutzfeldt-Jakob disease (CJD); a history of changes in cognition, speech, or gait; or exposure to tissues (e.g., dura mater grafts, corneal transplants) suspected of harboring TSEs.
 - Recipients of human organ or tissue transplants or human extracts.
4. Physical Examination
 - a. The donor should undergo a complete physical examination including evaluation for urethral discharge, genital warts, and genital ulcers as well as routine laboratory testing, including blood type and Rh-factor testing before enlisting him in the practice.
 - b. Donors should have follow-up examinations annually for urethral discharge, genital warts, and genital ulcers. Donors should not be used if any of these findings are present.
 5. Use of Frozen Semen
The use of fresh semen for donor insemination is not justifiable. 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 HIV by fresh semen cannot be eliminated. All frozen specimens should be quarantined for 180 days and the donor should be retested as described below and found to be seronegative before the specimen is released.
 6. Laboratory Testing
There is no method of completely ensuring that infectious agents will not be transmitted by TDI, but the following guidelines, in addition to adequate history taking and exclusion of individuals at high risk for HIV and other STIs should dramatically reduce risks.
 - a. Serologic tests for syphilis should be obtained initially on blood serum and repeated at 6-month intervals.
 - b. Serum hepatitis B antigen (HBsAg) and hepatitis C antibody should be obtained initially

and at 6-month intervals, and individuals who are positive should be excluded.

- c. Semen or urethral tests should be obtained initially for *Neisseria gonorrhoeae*. Either urethral or urinary testing for *Chlamydia trachomatis* should be performed. These tests should be repeated at 6-month intervals or more frequently if clinically indicated. Donors who are found to be positive should be treated and retested before being reconsidered.
- d. The potential donor should be tested for active infection with CMV and retested at 6-month intervals. Those testing positive for active infection should be excluded and all quarantined samples discarded.
- e. Initial serum testing for donors should include HIV-1, HIV-2, HTLV-1, and HTLV-II. These should be repeated at 6-month intervals.

7. Managing Laboratory Results

- a. A positive assay should be verified before notifying the potential donor. If a test is confirmed positive, the individual should be referred for appropriate counseling and management.
- b. If a test is negative, semen samples may be collected and prepared for cryopreservation.
- c. The donor should be retested a minimum of 180 days later and the specimen should be released only if the results are negative.
- d. Additional testing should be performed as dictated by local state requirements.

C. Management of Donors

1. Monitoring health status

The single most important method of diminishing the risk of transmitting infectious agents to women during insemination is to carefully screen 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 in 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 so that they may set a

limit to 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 catchment area that might 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 an increased risk of inadvertent consanguineous conception. This suggestion may require modification if the population using donor insemination represents an isolated subgroup or the specimens are distributed over a wide geographic area.

4. Consent

It is essential for the donor to sign a consent form, which includes a firm denial of having 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 any of these risk factors.

5. Record Keeping

It is essential to maintain permanent records about each donor's initial selection process and subsequent follow-up evaluation. To the extent possible, clinical outcome should be recorded for each insemination cycle. A mechanism must exist to maintain these records as a future medical resource for any offspring produced.

6. Protection of Confidentiality

Individuals participating in donor programs should be assured of protection of confidentiality in so far as local statutes permit. Medical records detailing the donation should be maintained as stipulated by local requirements.

VII. Choosing Donor Characteristics

There are several ways to match 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 with Rh-negative recipients. If the use of donor sperm creates the potential for Rh incompatibility, recipients should be informed of the obstetrical significance of this condition.

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Guidelines for oocyte donation

The American Society for Reproductive Medicine

Birmingham, Alabama

I. Introduction

Sperm from donors has been used in the treatment of male infertility for more than 100 years. The use of eggs from donors has been made possible more recently as a result of in vitro fertilization (IVF) techniques. Procedures for oocyte donation require superovulation with monitoring and oocyte recovery, which present significant inconvenience as well as discomfort and risks to the donor.

II. Indications for Considering the 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 be the carrier of a significant genetic defect or who have a family history of a condition and whose carrier status cannot be determined.
- E. Women with poor oocyte, and/or embryo quality or multiple failures during prior attempts to conceive via one of the assisted reproductive technologies.

III. Evaluation of the Oocyte Recipient

- A. Medical and Reproductive History
Routine medical and reproductive history 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. (See Appendix A with respect to genetic screening and testing.)
- B. Physical Examination
A complete general physical examination should be performed, including a pelvic examination.

C. Standard Preconception Testing and Counseling

The recommended tests include blood type and Rh factor, and rubella and varicella titers. Recipients should be offered immunization if nonimmune.

D. Laboratory Tests

The following laboratory tests should be recommended as part of the evaluation of the female recipients: a serologic test for syphilis along with serum testing for hepatitis B surface antigen, hepatitis C antibody (HCV), cytomegalovirus (CMV) antibody, human immunodeficiency virus 1 (HIV-1).

E. Psychological Evaluation

The decision to proceed with donated oocytes is complex, and patients may benefit from psychological counseling to aid in this decision. The physician should offer psychological counseling to all couples and should require psychological consultation for couples in whom there appear to be factors that warrant further evaluation.

F. Assessment of Uterine Cavity

When clinical evaluation suggests a possible uterine abnormality, hysterosalpingography (HSG) or other suitable procedure should be performed.

IV. Evaluation of the Partner of the Oocyte Recipient

A. Laboratory Tests

1. Semen analysis
2. Blood type and Rh
3. Serologic test for syphilis, hepatitis B surface antigen, hepatitis C antibody (HCV), cytomegalovirus (CMV) antibody, HIV-1
4. Appropriate genetic screening and testing

B. Psychological Evaluation

The decision to proceed with donated oocytes is complex, and patients may benefit from psychological counseling to aid in this decision. The physician should offer psychological counseling to all couples and should require psychological consultation for couples in whom there appear to be factors that warrant further evaluation.

V. Solicitation of Potential Oocyte Donors

Solicitation of donors should be in accordance with the ASRM Ethics Committee Report [*Fertil Steril* 2000; 74:216–20].

VI. Selection of Donors

A. Anonymous versus known donors: Pragmatic considerations such as the difficulty in recruiting suitable donors support the use of known oocyte donors. Psychological evaluation and counseling should be recommended to the donor and her partner. Psychological consultation should be required for individuals in whom there appear to be factors that warrant further evaluation. In the case of known donors, related issues such as the potential impact of the relationship between donor and recipient should be explored.

B. Oocyte donors should have attained their state's age of legal majority and preferably be between the ages of 21 and 34.

C. 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.

D. Proven fertility in the donor is desirable but not required.

E. The donor should undergo appropriate genetic evaluation as outlined in Appendix A.

F. Sharing of oocytes from an assisted reproduction cycle: If sharing of oocytes is contemplated, informed consent must be obtained prior to the cycle of retrieval. The conditions governing the sharing of oocytes should be specified in advance, should be included in the informed consent, and should conform with the ASRM Ethics Committee Guidelines [*Fertil Steril* 1998;70(Suppl 3)].

VII. Screening and Testing of Oocyte Donors

A. A personal and sexual history should be obtained to exclude as donors individuals who might be at high risk for HIV and other sexually transmitted infections (STIs) as well as transmissible spongiform encephalopathies (TSEs). These risk factors include:

1. Women who have injected drugs for a nonmedical reason.
2. Women who have had sex in exchange for money or drugs.

3. Women who have had sex in the preceding 12 months with any person described in the items above or with any person suspected of having HIV or hepatitis infection.

4. Women who have been exposed through percutaneous inoculation or through contact with an open wound, nonintact skin, or mucous membrane within the last 12 months to blood that is known or suspected to be infected with HIV, hepatitis B, and/or hepatitis C virus.

5. Prisoners.

6. Women who have had close contact with another person having viral hepatitis within 12 months preceding the donation.

7. Women who have had or have been treated for syphilis or gonorrhea within the preceding 12 months.

8. Women who within 1 year of donation have undergone acupuncture, body piercing, and/or tattooing procedures in which sterile procedures were not used, or when it is unclear whether sterile procedures were used.

9. Family history of transmissible spongiform encephalopathy (TSE) such as Creutzfeldt-Jakob disease (CJD); or a history of changes in cognition, speech, or gait; or exposure to tissues suspected of harboring TSEs.

10. Recipients of human organ or tissue transplants or human extracts.

B. Appropriate testing should be performed for STIs, including:

1. Serologic testing for syphilis.
2. Serum hepatitis B surface antigen and hepatitis C antibody.
3. Cervical cultures for *Neisseria gonorrhoeae* and *Chlamydia trachomatis*.
4. Serum testing for HIV-1 and HIV-2.
5. Additional testing as dictated by local state requirements.

C. If the use of donor oocytes creates the potential for Rh incompatibility, couples should be informed about the obstetrical significance of this condition.

VIII. Quarantining of Embryos

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 6 months, with release after the donor has been retested. However, couples should be informed that embryo cryopreservation may significantly reduce implantation rates. The recipient couple should be appropriately counseled in the event of seroconversion of the oocyte donor after cryopreservation of the embryos.

IX. Payment to the Donor

- A. Compensation to the donor should be in compliance with the ASRM Ethics Committee Report [*Fertil Steril* 2000;74:216–20].
- B. 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.
- C. Financial obligations and responsibilities in the event of complications or medical expenses of a donor should be contractually agreed upon prior to initiation of a stimulation cycle.
- D. Payment may be prorated based on the number of steps completed in the procedure.
- E. Payment should not be predicated on clinical outcome.

X. Multiple Oocyte Donations

This is addressed in the ASRM Practice Committee Opinion *Repetitive Oocyte Donation*, January 2001.

XI. Unintended Donor Pregnancies

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

XII. 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 obstetrical consultation before undertaking IVF with donor oocytes.

XIII. Record Keeping

It is necessary to maintain permanent records about each donor's initial selection process and subsequent follow-up evaluation. To the extent possible, clinical outcome should be recorded for each treatment cycle. A mechanism must exist to maintain these records as a future medical resource for any offspring produced.

XIV. Legal Issues/Consent

- A. All individuals involved in ovum donation should be explicitly advised of the risks and adverse effects of ovarian stimulation and retrieval, and this process should be documented by informed consent.
- B. Donors and recipients and their partners should execute documents that define or limit their rights and duties with regard to any offspring.
- C. Couples and donors who have legal concerns not addressed in the informed consent process should be advised to seek legal consultation.
- D. Protection of confidentiality: Individuals participating in donor programs should be assured of protection of confidentiality insofar as local statutes permit. Medical records detailing the donation should be maintained as stipulated by local requirements.
- E. It is recommended that the donor acknowledge in the consent form her responsibility to report any changes in any of her risk factors

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Guidelines for cryopreserved embryo donation

The American Society for Reproductive Medicine

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BACKGROUND

In the current clinical practice of assisted reproductive techniques (ART), more embryos than can be safely transferred at one time are commonly generated. In the majority of ART practices, these embryos may be cryopreserved for later replacement. Couples who become pregnant and do not desire another pregnancy, or have other reasons for not wishing to use their embryos, may have the options 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 minimal standards for screening, testing, and counseling of potential embryo donors and recipients. Some states and other localities may have laws or regulations that pertain to embryo donation; these guidelines may be superseded by such laws and regulations.

I. Guidelines for ART Practices Wishing to 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 ga-

metes 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.

II. Guidelines for Couples Who Wish to Donate Embryos

If donor sperm or donor oocytes were used to create the embryos, it is assumed that the donor gametes met the ASRM standards. The following guidelines apply to embryo donors whose embryos are the product of their own biological gametes.

- A. Embryo donors must provide a medical and genetic history. They should be screened for relevant risk factors for human immunodeficiency virus (HIV) and transmissible spongiform encephalopathy (TSE).
- B. All embryo donors must be willing to submit to blood tests for infectious diseases and blood typing. The practice should determine if the cost of these tests will be absorbed by the donors themselves, the practice facilitating the embryo donation, or the potential recipients. The current recommendations include:
 1. Blood type and Rh
 2. Testing for HIV-1
 3. Testing for hepatitis B surface antigen and hepatitis C antibodies
 4. Testing for syphilis
- C. 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 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.
 3. Stating the right of the practice to refuse transfer to an inappropriate recipient.
 4. Specifying before donation the length of time that donated embryos will be maintained in cryostorage and the alternatives for disposition thereafter.
- D. Donation when one or both partners are unavailable: In the case of death of one partner, the surviving partner generally retains conservatorship of any frozen embryos. In the case of death of both partners or of the sole conservator of the embryos, cryopreserved embryos may be donated if the donor(s) specified their intentions in a will or in the embryo cryopreservation consent. Because postmortem testing for infectious disease is not practical and the risk of infection is small, embryos in these instances may be transferred to recipients without postquarantine testing of the donors. The donor(s) must have undergone infectious disease testing as part of the original in vitro fertilization (IVF) evaluation, and the recipients must be informed and appropriately counseled that postquarantine testing was not possible. Postmortem embryo donation is not appropriate in instances where death is due to HIV, viral hepatitis, a sexually transmitted infection, or TSE such as Creutzfeldt-Jakob disease (CJD).
- E. Minimum screening criteria: Ideally, all embryo donors should have had testing for HIV-1, hepatitis B and C, and syphilis at the time of the IVF treatment cycle and retesting for HIV-1 after 6 months' quarantine. An exception to this rule has been noted above (see item D above). Individuals who did not undergo infectious disease testing at the time of the IVF treatment cycle may be tested for HIV-1, hepatitis B and C, and syphilis after the quarantine period and satisfy minimal testing criteria. Couples who are geographically distant from the practice may have their blood drawn and tested at a location that is convenient to them or may opt to ship the serum to the practice for testing. Embryos of individuals who refuse to undergo appropriate infectious disease testing should not be transferred.
- F. Proper chain-of-custody procedures must be followed and documented for the handling of all test specimens and for donated embryos.
- G. Donors should receive no compensation for the donation other than reimbursement for specific expenses (e.g., obligatory blood tests).
- H. The decision to proceed with embryo donation is complex and patients may benefit from psychological counseling to aid in this decision. Psychological consultation should be offered to all couples. The physician should require psychological consultation for couples in whom there appear to be factors that warrant further evaluation.
- ### III. Guidelines for Potential Recipients
- A. The recipient(s) must take full responsibility for the embryos 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. Recipient(s) must be willing to submit to the same blood tests as the donors.
- D. Recipient(s) must conform to guidelines established by the practice that is performing the embryo transfer.
- E. The decision to proceed with embryo donation is complex and patients may benefit from psychological counseling to aid in this decision. Psychological consultations should be offered to all couples participating in the donor-embryo process. The physician should require psychological consultation for couples in whom there appear to be factors that warrant further evaluation.
- ### IV. Record Keeping
- It is necessary to maintain permanent records about each donation (both donors and recipients). Clinical outcome should be recorded for each donation to the extent possible. A mechanism must exist to maintain these records as a future medical resource for any offspring produced.
- ### V. Protection of Confidentiality
- Individuals participating in donor programs should be assured of protection of confidentiality insofar as local statutes permit. Medical records detailing the donation should be maintained as stipulated by local requirements.

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Psychological assessment of gamete donors and recipients

The American Society for Reproductive Medicine

Birmingham, Alabama

STATEMENT OF PURPOSE

These recommendations are general guidelines for addressing the many complex moral, ethical, and psychosocial issues that confront gamete donors, recipients, and offspring.

I. Donors

A. Psychological assessment by a qualified mental health professional is recommended for all gamete donors.

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. 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

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 should also address the potential psychological risks and should evaluate for evidence of coercion (financial or emotional). It is also important to ascertain whether the donor is knowledgeable about the degree

of disclosure and whether any plans may exist for 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.

II. Recipients

A. Recipients of donor gametes should receive counseling about the potential psychological implications.

B. The recipient should be counseled about the subsequent feelings relative to 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 off-

spring, 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 should also be addressed: coping with treatment termination, the grieving process, and developing alternatives for the future.
- E. In the case of 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 as it relates to other information-sharing decisions they may make.

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Psychological guidelines for embryo donation

The American Society for Reproductive Medicine

Birmingham, Alabama

STATEMENT OF PURPOSE

These recommendations are general guidelines for addressing the many complex moral, ethical, and psychosocial issues that confront embryo donors, recipients, and offspring.

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 prior to cryopreservation. After couples have concluded their own reproductive attempts, embryo disposition options should be reevaluated.
- C. Psychological assessment is recommended to ascertain appropriateness of potential donors. This assessment should include a clinical interview and, where appropriate, psychological testing. This 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. 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
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 infertile-

ity practice should be excluded from participation 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 in vitro fertilization (IVF) procedure that additional screening and testing will 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 recipient and her partner should be counseled about the subsequent feelings relative to the medical

conditions that made necessary the use of donor embryos.

- C. The impact of treatment failure should also be addressed, including coping with treatment termination, the grieving process, and developing alternatives for the future.
- D. Relative issues, such as the impact of the relationship between known donors, recipients, and offspring, should be explored.
- E. Psychological assessment is recommended to assess appropriateness of the potential recipient and her partner. This assessment would attempt to rule out significant psychiatric illness, current substance abuse, and the ability to cope with the stress of assisted reproductive technologies.
- F. 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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Appendix A: Minimal genetic screening for gamete donors

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:
 1. Autosomal dominant or X-linked disorders in which age of onset extends beyond the age of the donor, such as Huntington disease.
 2. Autosomal recessive inheritance (homozygous). Donors who are heterozygous need not necessarily be excluded if recipients are not also heterozygous.
- B. Should not have (or have had) any major malformation of complex cause (multifactorial/polygenic), such as spina bifida or heart 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. This applies especially to first-degree relatives (parents, siblings, or offspring).
- D. Should not carry a known karyotypic abnormality that may result in chromosomally unbalanced gametes. Among healthy young adults, the chance of having a chromosomal rearrangement that could be transmitted in unbalanced form to offspring is small. For this reason, routine karyotypic testing of all donors is optional.
- E. A member of a high-risk group (see Table A1) should be tested routinely to de-

termine heterozygosity for certain conditions. The list of tests may change as new tests for other disorders are developed. Heterozygosity need not necessarily exclude a donor, but certain donors may be inappropriate in a given case.

- F. New screening guidelines for cystic fibrosis in the general population have been developed recently by the American College of Obstetricians and Gynecologists and other organizations, and are applicable for gamete donors. Functionally, all gamete donors should be evaluated by the current tests recommended at the time of the donation.
 - G. Donors should be generally healthy and young. Males 40 years and older are at increased risk for new mutations. Women 35 years and older are at increased risk for producing offspring with aneuploidy.
- ## II. The donor's first-degree relatives (parents, siblings, or offspring) should be free of:
- A. Mendelian disorders as described in Section I.A.
 - B. Major malformations as described in Section I.B.
 - C. A chromosomal abnormality, unless the donor has a normal karyotype.
 - D. If family history reveals a disorder for which definitive testing is available, and it is important to consider that candidate further as a donor, then it is appropriate to test for that specific disorder. Results will determine appropriateness of donor.

TABLE A1

Genetic screening in various ethnic groups.

Ethnic Group	Disorder	Screening test
Ashkenazi Jews	Tay-Sachs disease	Decreased serum hexosaminidase-A or molecular analysis
	Canavan disease	DNA analysis to detect most common alleles
African American	Sickle cell anemia	Presence of sickle cell hemoglobin, confirmatory hemoglobin electrophoresis
Mediterranean people	β -Thalassemia	Mean corpuscular volume (MCV) < 80%, followed by hemoglobin electrophoresis
Southeast Asians and Chinese (Vietnamese, Laotian, Cambodian, Filipino)	α -Thalassemia	MCV < 80%, followed by hemoglobin electrophoresis
All ethnic groups In Caucasians of European descent and Ashkenazi Jews should be offered; in other ethnic groups (Asians, Hispanics, African-Americans) should be made available	Cystic fibrosis	DNA analysis of specified panel of 25 CFTR mutations (those present in \geq 0.1% of the general U.S. population). Larger panel not recommended for screening.

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