

2008 Guidelines for gamete and embryo donation: a Practice Committee report

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

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The 2008 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. This revised document incorporates recent information from the U.S. Centers for Disease Control and Prevention, the U.S. 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. (Fertil Steril® 2008;90:S30-44. ©2008 by American Society for Reproductive Medicine.)

2008 GUIDELINES FOR GAMETE AND EMBRYO DONATION: A PRACTICE COMMITTEE REPORT

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The 2008 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 U.S. Centers for Disease Control and Prevention (CDC), U.S. 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 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. 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

Guideline

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No reprints will be available.

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 ASRM recommends testing of recipients as described.

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 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/cber/rules/suitdonor.pdf>

<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 the American Society for Reproductive Medicine (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 oligospermia, 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 and Consent

The decision to proceed with donor insemination is complex, and patients and their partners may benefit from psychological counseling to aid in this decision. The physician should offer psychological counseling by a qualified mental health professional to all couples and should require psychological consultation for couples in whom factors appear to warrant further evaluation.

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 recommended strongly to address potential medical/legal issues 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 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 to be used derives from an HIV-negative donor. Current FDA guidelines do not entirely preclude the use of an HIV-positive directed donor. However, in the opinion of the ASRM, HIV-positive directed donors should not be used because the risk of viral transmission cannot be eliminated completely.

- C. Testing for other STIs similar to that recommended for the female partner (detailed in section V) is encouraged.

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 preconception screening, testing, and counseling:
 1. Recommended tests include:
 - 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. Cervical cultures or nucleic acid-based test on urine or a swab obtained from the cervix, urethral meatus, or vagina for *Neisseria gonorrhoeae* and *Chlamydia trachomatis*.
 - d. HIV-1 and HIV-2 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 unit 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-1 or HIV-2 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.
 - 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. Human T-cell lymphotropic virus (HTLV) type I and II may also be obtained at the discretion of the clinician in the appropriate clinical setting.

D. Documentation and timing of ovulation

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, luteinizing hormone (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
Patients who fail to conceive after four to six well-timed inseminations may be candidates for hysterosalpingography (HSG), laparoscopy, or other appropriate tests to detect possible causes for their failure to conceive. Pre-treatment HSG or laparoscopy may be indicated by the history and/or physical findings.

- F. 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 genetic abnormalities.
2. The donor should be of legal age and, ideally, less than 40 years of age, because increased male age is associated with a progressive increase in the prevalence of aneuploid sperm.
3. Selection of donors with established fertility is desirable but not required.
4. Psychological evaluation and counseling by a qualified mental health professional is recommended strongly for all sperm donors. 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 recommended strongly for the donor and his partner 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 should also 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 several samples be examined (each after a 2- to 5-day abstinence interval) before proceeding with a 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 can vary among laboratories. There are no uniformly accepted standards, but, in general, the minimum criteria for normal semen quality can be applied (See: World Health Organization, *Laboratory Manual for the Examination of Human Semen and Sperm-Cervical Mucus Interaction*, 4th ed., New York: Cambridge University Press, 1999).

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. Some institutions perform chromosomal analyses on all donors, but such evaluation is not required. (See Appendix A for further details regarding genetic screening and testing.)

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:
 - 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 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 nucleic acid test (NAT) in the preceding 120 days.
 - xv. Men who have been diagnosed with 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 necessarily be considered 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 U.S. military members, civilian military employees, or dependants of a military member or civilian employee who resided at U.S. 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 U.K. 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 immediately 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.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:
- Physical evidence for risk of sexually transmitted disease such as genital ulcerative lesions, herpes simplex, chancroid, or urethral discharge.
 - Physical evidence for risk of, or evidence of syphilis.
 - Physical evidence of anal intercourse including perianal condylomata.
 - 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.
 - Physical evidence of recent tattooing, ear piercing, or body piercing.
 - Disseminated lymphadenopathy.
 - Unexplained oral thrush.
 - Blue or purple spots consistent with Kaposi sarcoma.
 - Unexplained jaundice, hepatomegaly, or icterus.
 - Large scab consistent with recent history of smallpox immunization.
 - 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 completely ensure 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 dramatically 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 be 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/cber/tissue/prod.htm>

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

- HIV-1 antibody as well as NAT. Establishments that do not use an FDA-licensed test for 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.xxiii-xxiv.
- HIV-2 antibody.
- Hepatitis C antibody and NAT.
- Hepatitis B surface antigen.
- Hepatitis B core antibody (IgG and IgM).
- Serologic test for syphilis.
- HTLV-1 and HTLV-2.
- 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.
- Semen, urine, or a urethral swab should be obtained to test for *Neisseria gonorrhoeae*. Either urine or a urethral swab should be obtained to test for *Chlamydia trachomatis*. 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.
- 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.

- k. Abbreviated donor screening documenting no change in the donor's medical and/or social history should be performed at 6-month intervals.
 1. Additional testing should be performed as dictated by local or state requirements.
 - m. 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 dis-

ease 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 screening or 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. Sexually intimate couples

Although there is no FDA or legal requirement for viral testing of sexually intimate partners undergoing fertility treatment, such testing can help to ensure that appropriate precautions are taken to minimize risk of viral transmission to partners and offspring. Couples in which one or both partners test positive for HIV, HBV, or HCV should be treated by fertility centers having the appropriate laboratory resources.

9. 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. In the opinion of the ASRM, all frozen specimens should be 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 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 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 isolated 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. To the extent possible, the clinical outcome of each insemination cycle should be recorded. A mechanism must exist to maintain such records 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.