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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Some states and other localities may have laws or regulations that pertain to embryo donation; these guidelines may be superseded by such laws and regulations.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 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.

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 spongifirm 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:

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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 consulations 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.

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 for Reproductive Medicine. Approved by the Board of Directors of the American Society for Reproductive Medicine in 2001.