

Elements to be considered in obtaining informed consent for ART

The Practice Committee of the American Society for Reproductive Medicine

American Society for Reproductive Medicine, Birmingham, Alabama

All informed consents must be in writing, signed by all participating parties, and properly witnessed. In addition to information about chance of success and financial obligations, the following issues should be addressed in the process of obtaining consent. It is also important that couples be provided full information concerning alternative procedures available to manage their specific infertility problems, including procedures that are not performed by the treating center, as well as non-medical options such as adoption and non-treatment. Couples must be informed about the federal reporting requirements. Couples must also be informed through consent forms that de-identified cycle-specific data will be provided to the federal government.

I. IVF, GIFT, and ZIFT

A. Description of procedure including:

1. Use of medications including ovulation induction agents, luteal support, antibiotics, etc.
2. Use of monitoring including laboratory tests and ultrasound
3. Collection of sperm
4. Oocyte retrieval
5. Fertilization in the laboratory (IVF and ZIFT) or in the fallopian tubes (GIFT)
6. Monitoring of early pregnancy

B. Barriers to successful pregnancy including:

1. Poor response to ovulation induction agents
2. Unsuccessful oocyte retrieval
3. Abnormal oocytes
4. Inability to produce semen specimens or acquire sperm of sufficient quality or quantity
5. Failure of fertilization
6. Abnormal embryo development
7. Difficult or failed embryo transfer

8. Failure of implantation
9. Loss or damage to oocytes or embryos

C. Success rates and complications of pregnancy including:

1. Factors which affect pregnancy rates
2. Risks of multiple pregnancies, spontaneous abortion, ectopic pregnancies, stillbirths, and congenital abnormalities

D. Possible risks associated with the following procedures:

1. Blood drawing
2. Ovulation induction agents including allergic reactions, injections, hyperstimulation, multiple births, and association with ovarian cancer
3. Antibiotic administration
4. Oocyte retrieval or tubal transfer
5. Laboratory and clinical handling of gametes and embryos
6. Embryo transfer

E. Disposition of oocytes and embryos including:

1. Option to attempt fertilization and/or freeze unused embryos
2. Discarding of unused oocytes and low quality or abnormal embryos

II. Cryopreservation of Embryos

A. Description of procedures including:

1. Benefits of cryopreservation
2. Freezing of embryos
3. Embryo transfer

B. Potential risks including:

1. Mechanical failure or catastrophic event leading to loss of embryos
2. Theoretic risks of congenital malformations
3. Theoretic risks of long-term storage

Committee Opinion

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4. Monitoring of cycle
5. Failure of embryos to survive freezing and thawing
6. Laboratory and clinical handling of embryos
7. Psychological effects

C. Disposition of frozen embryos including:

1. Program's time limit on storage of frozen embryos
2. Disposition of frozen embryos in the event of:
 - a. Death of one or both partners
 - b. Divorce or dissolution of partnership
 - c. Nonpayment of storage fees
 - d. Loss of contact with gamete providers

III. Oocyte Donation

A. Description of procedure including:

1. Medical and psychological screening including genetic and infectious disease testing as applicable
2. Use of ovulation induction agents
3. Monitoring of cycle
4. Oocyte retrieval
5. Fertilization of oocytes
6. Potential cryopreservation of embryos

B. Potential risks and discomforts (donor) including:

1. Blood drawing
2. Ovulation induction agents including allergic reactions, hyperstimulation, and the association with ovarian cancer
3. Antibiotics
4. Oocyte retrieval
5. Laboratory and clinical handling of gametes and embryos
6. Psychological issues

C. Special considerations (recipient) including:

1. Monitoring of cycle
2. Medications
3. Failure to obtain oocytes, sperm, or embryos
4. Laboratory and clinical handling of gametes and embryos
5. Risks of congenital abnormalities
6. Potential Rh incompatibility
7. Transmission of viral infections, including HIV
8. Psychological issues

D. Legal Issues

IV. Microoperative Procedures

A. Description of procedures including:

1. Appropriate candidates
2. Rationale for use of these techniques

B. Possible risks of Intracytoplasmic Sperm Injection including:

1. Glucocorticoids and antibiotics if used
2. Arbitrary selection of sperm with theoretical potential for increased risks of birth defects including infertility
3. Trauma or destruction of oocytes
4. Laboratory and clinical handling of gametes and embryos
5. Abnormal embryo morphology
6. Unknown long-term sequelae including those that could occur in subsequent generations

C. Possible risks of Assisted Hatching including:

1. Glucocorticoids and antibiotics if used
2. Laboratory and clinical handling of embryos
3. Potential for cells or microorganisms to reach the embryo
4. Potential damage to the embryo including loss of blastomeres
5. Potential increased risk of birth defects
6. Unknown long-term sequelae including those that could occur in subsequent generations

V. Embryo Donation

A. Description of procedure including:

1. Medical and psychological screening including genetic and infectious disease testing as applicable
2. Use of medications as necessary
3. Monitoring of transfer cycle
4. Unknown long-term sequelae including those that could occur in subsequent generations

B. Miscellaneous:

1. Donors relinquish rights to embryos and any offspring that may result from embryo donation
2. Reimbursement of medical costs