

Minimum standards for practices offering assisted reproductive technologies: a committee opinion

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

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This document is designed to provide a framework for assisted reproductive technology (ART) programs that meet or exceed the requirements suggested by the Centers for Disease Control and Prevention (CDC) for certification of ART laboratories. This document replaces the document, "Revised Minimum Standards for Practices Offering Assisted Reproductive Technologies: A Committee Opinion," published in 2014. (*Fertil Steril*® 2020;113:536–41. ©2019 by American Society for Reproductive Medicine.)

El resumen está disponible en Español al final del artículo.

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Technical advances in assisted reproductive technology (ART) and expansion in the scope of who is treated are the best examples of our rapidly evolving field. Periodically, the American Society for Reproductive Medicine (ASRM) reviews and publishes updated guidelines, guidance documents and committee opinions to define the minimum standards for ART programs inclusive of human embryology and andrology laboratories. This document is designed to guide ART programs by setting criteria that meet or exceed the requirements suggested by the Centers for Disease Control and Prevention (CDC) for certification of ART laboratories (1). This document replaces the previous document entitled "Revised minimum standards for practices offering assisted reproductive technologies" that was originally published in 2008 and revised in 2014. This document is not designed to cover all clinical situations or practices, but rather should be re-

viewed carefully by ART program and laboratory directors to ensure that their programs' practice reflects current recommendations. More detailed guidance on laboratory procedures is presented in the Practice Committee reports Cryopreserved reproductive tissues: a committee opinion and Comprehensive guidance for human endocrinology, andrology, and embryology laboratories: lab management and operations.

DEFINITIONS

ART encompasses a variety of clinical treatments and laboratory procedures that include the handling of human oocytes, ovarian tissue, sperm, testicular tissue or embryos in vitro, with the intent of establishing a pregnancy immediately or in the future. This includes, but is not limited to, in vitro fertilization (IVF), embryo biopsy, preimplantation genetic testing (PGT), embryo cryopreservation, embryo donation, and gestational carrier IVF (2).

Personnel

There should be a contingency plan in place for all personnel essential to a program in case of illness, absence, or departure of an individual from the program. The purpose of the contingency plan is to ensure that critical operations within the laboratory and practice are covered without interruption. A single individual may fulfill the requirement for expertise in one or more areas. An ART program must include the following personnel:

Directors:

- A designated overall practice director, medical director, and laboratory director. One individual may fulfill more than one of these positions, but the medical director must be a licensed physician.

Physician(s):

- A physician who has completed an American Board of Obstetrics and Gynecology (ABOG) or ACGME (American College of Graduate Medical Education) approved fellowship in reproductive endocrinology and infertility and is board certified or an active candidate for board

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certification in reproductive endocrinology and infertility by the ABOG.

- A physician experienced in male reproduction. If this individual is not a urologist, a consultant urologist with expertise in male reproductive surgery should be available.

Nursing:

- A nurse with training and/or experience in reproductive medicine and coordination of clinical ART care.

Laboratory:

- An embryology laboratory director who meets the requirements described in specialized training and experience.
- An individual experienced in laboratory procedures in andrology.
- An individual with specialized training and experience in gamete, embryo and gonadal tissue cryopreservation techniques respectively when gamete, embryo and/or gonadal tissue cryopreservation is offered.
- An individual with specialized training in gamete biology and micromanipulation techniques, if oocyte, gonadal tissue and/or embryo micromanipulation techniques are offered.
- Appropriate personnel to perform hormonal assays. An outside laboratory that has demonstrated adequate competence, quality control, and service may be used for rapid assays of all the necessary reproductive hormones. Such hormone assays should be performed by a laboratory that meets Clinical Laboratory Improvement Amendments of 1988 (CLIA) standards.

Auxiliary:

- An individual with specialized training and experience in gynecologic ultrasonography who provides the monitoring of follicular development. This role may be filled by a physician, nurse, or ultrasound technician.
- A mental health professional (MHP) with expertise in Fertility Counseling. If a MHP is not employed by the program, a consultant MHP should be available.
- An individual with specialized expertise in genetics and genetic counseling. If the individual is not employed by the program, a consultant geneticist and genetic counselor should be available.

SPECIALIZED TRAINING AND EXPERIENCE

Practice Director

The practice director should be a member in good standing of ASRM. The Practice Director is that individual who will assume responsibility and accountability for the activities of the practice related to Assisted Reproductive Technologies. The Practice Director is the individual responsible for official communication with SART, its registry, or its designees, and for ensuring that the practice follows the SART requirements for membership. The Practice Director does not have to be a physician.

Medical Director

As of January 1, 2000, a program's medical director must be board certified in reproductive endocrinology and infertility by the ABOG or be an active candidate for the same. The medical director is responsible for verification of data reported to SART. The medical director should be a member in good standing of ASRM.

Physician Performing Oocyte Retrievals and Embryo Transfers

Physicians performing oocyte retrievals should have adequate training to perform diagnostic ultrasound and have performed an adequate number of aspirations under direct supervision to demonstrate proficiency within a practice that meets these standards. Physicians performing embryo transfer should have performed an adequate number of embryo transfers under direct supervision that demonstrates proficiency within a practice that meets these standards or have successfully completed a certificate course using an embryo-transfer simulator. Satisfactory completion of this training should be documented by the practice or medical director. Each physician should continue performing a minimum number of aspirations and embryo transfers per year to maintain their proficiency.

It is recommended that the physicians involved in the supervision of ovarian stimulation and oocyte-retrieval procedures be responsible for ultrasound monitoring of follicular development. Physicians responsible for ultrasound follicular monitoring should have familiarity with basic ultrasound principles and equipment. These physicians should have evidence of training and the requisite competence to adequately perform diagnostic ultrasound examinations. Completion of an ABOG- or ACGME-approved fellowship program in Reproductive Endocrinology and Infertility satisfies the ultrasound training requirement.

Nursing

Licensed nurses in the ART setting provide or direct education, counseling, support, and nursing care to patients seeking assistance becoming pregnant. This role requires knowledge of anatomy and physiology, the normal menstrual cycle, pathophysiology, treatment options, and diagnostic tests.

Other roles in the ART setting may include personnel such as medical assistants with specialized training in patient-care management and technical procedures for the ART patient.

Embryology Laboratory Director

The embryology laboratory director should be an individual with demonstrated knowledge of all laboratory aspects of ART. To qualify as an embryology laboratory director, the individual should fulfill the following requirements:

- An earned doctorate degree (PhD) from an accredited institution in a chemical, physical, or biological science as the major subject, or a medical degree (MD or DO) from an accredited institution or have qualified as a laboratory director prior to July 20, 1999. Effective January 1, 2006, all new laboratory directors should hold a High-complexity

Clinical Laboratory Director (HCLD) or Embryology Laboratory Director (ELD) certification or its equivalent from the American Board of Bioanalysis (ABB). Laboratories that participate in high-complexity procedures (i.e., quantitative sperm preparations and some hormone analyses) must be supervised by a laboratory director that is certified as an HCLD. The laboratory director should have expertise and/or specialized training in biochemistry, cell biology, and physiology of reproduction with experience in experimental design, statistics, and problem solving. The laboratory director should be responsible for formulating laboratory policies and protocols and for communicating with the medical director regarding patient progress and protocols as they affect the laboratory aspects of treatment.

- Two years of documented pertinent experience in a program performing IVF-related procedures. This experience should include:
 - Familiarity with laboratory quality control, inspection, and accreditation procedures.
 - Detailed knowledge of cell culture, ART, and andrology procedures performed in human systems.
 - At least 6 months of training (may be concurrent with documented experience) and completion of at least 60 ART procedures under supervision. A procedure is defined as a combination of the examination of follicular aspirates, insemination, documentation of fertilization, and preparation for embryo transfer. Satisfactory completion of this period of training should be documented by the laboratory director of the training practice.
- At least 24 hours of accredited continuing education every two years in ART or clinical laboratory practice.
- Demonstrated technical competence in the embryology laboratory by documenting performance of specific procedures and results that are within acceptable standards for that program.

The responsibilities of the embryology laboratory director include:

- Providing accessibility for on-site, telephone, or electronic consultations with on-site laboratory personnel as needed.
- Ensuring that the physical plant (space, facilities, and equipment) and environmental conditions of the laboratory are appropriate and safe.
- Maintaining aseptic conditions in the laboratory.
- Ensuring that patient confidentiality is maintained throughout the laboratory ART process.
- Providing all laboratory personnel unrestricted access to an approved procedural manual (print or electronic) and establishing and maintaining a laboratory quality assurance program.
- Providing consultation to physicians and others in the practice, as appropriate, regarding laboratory aspects of treatment.
- Employing a sufficient number of qualified laboratory personnel to perform the quality laboratory procedures.
- Ensuring that there is a personnel contingency plan in case of emergency.

- Ensuring that all personnel receive appropriate training for the ART laboratory procedures to be performed, obtain the required number of annual continuing education hours, and demonstrate continued competence for the ART laboratory procedures performed.

Off-site Embryology Laboratory Director

An “off-site” laboratory director is one whose primary directorship is at another physical facility, which has a separate identification number (SART number) and a separate medical director. An off-site director has the same responsibilities as an on-site director. While the laboratory is actively treating patients, the off-site director is required to physically visit the laboratory with a frequency that will ensure the proper functioning of the laboratory and assure appropriate patient care. An off-site laboratory director should be physically present at the supervised laboratory no less than four visits per year. The off-site laboratory director should be readily available to on-site laboratory personnel by fax, phone, video conference or email for any issues that may arise. The off-site director must be present on-site for any scheduled accreditation or certification procedures. A laboratory director should direct no more than five separate laboratories of any type.

Embryology Laboratory Supervisor

The embryology laboratory may have one or more qualified laboratory supervisors who, under the direction of the laboratory director, provide day-to-day supervision of laboratory personnel performing ART procedures. In small ART programs, an embryology lab director can function as the embryology laboratory supervisor. However, if the medical director is also the laboratory director, there should be a designated laboratory supervisor. If the embryo laboratory director is primarily located off-site, there should be a designated laboratory supervisor. The embryology laboratory supervisor should either meet the qualification requirements designated for laboratory director, or fulfill the following requirements:

- Have an earned bachelor’s or master’s degree in chemical, physical, biological, medical technology, clinical, or reproductive laboratory science from an accredited institution.
- In programs with an off-site laboratory director, the laboratory supervisor must be ELD, TS or GS certified by the ABB (or grandfathered in).
- Have documented training, which includes performing, at a minimum, at least 60 ART procedures under supervision.
- In addition to meeting these requirements, the embryology laboratory supervisor should:
 - Obtain at least 24 hours of accredited continuing education every two years in ART or clinical laboratory practice.
 - Perform at least 20 ART procedures per year to maintain proficiency.

Responsibilities of the embryology laboratory supervisor include the day-to-day supervision and oversight of the embryo laboratory and laboratory director responsibilities as authorized in writing by the embryology laboratory director.

Embryology Laboratory Technologist

Embryology laboratory technologists who perform ART laboratory procedures should either meet the qualification requirements for laboratory supervisor, or fulfill both of the following requirements:

- Have an earned bachelor's or master's degree in chemical, physical, biological, medical technology, clinical, or reproductive laboratory science from an accredited institution.
- Have documented training, which includes performing, at a minimum, at least 30 ART procedures under continuous supervision of the laboratory director or supervisor.
- In addition to meeting these requirements, the embryology laboratory technologist should:
 - Obtain at least 24 hours of accredited continuing education every two years in ART or clinical laboratory practice.
 - Perform a satisfactory number of ART procedures per year to maintain proficiency.

Experience and documented training in cell culture, sperm-egg interaction, or related areas of animal reproduction are desirable. The embryology laboratory technologist works under the supervision of a laboratory director or supervisor. Programs for the appropriate training of embryology laboratory technologists should be in place with documentation of completion for each.

INFORMED CONSENT

ART practices should conform to the ASRM/SART recommendations concerning informed consent (3-10). SART has published consent forms that its members can use or adapt to their medical practice (11). The laboratory must have evidence of informed consent for all procedures prior to their performance. It is expected that practices will comply with all applicable local, state, and federal guidelines.

ETHICAL AND EXPERIMENTAL PROCEDURES

ASRM's Ethics Committee has issued a report on the ethical considerations of ART procedures (12). All ART procedures should be performed in accordance with the recommendations contained in that report, as well as all other reports from the ASRM Ethics Committee.

Procedures considered experimental must be conducted with the approval of an Institutional Review Board or equivalent committee.

RECORDKEEPING

As of the publication of this document, US federal law requires all ART practices to participate in the CDC registry data collection. Furthermore, the law requires that each practice release or permit the release by the registry clinic-specific success rates along with the identity of the clinic. ASRM and SART member practices must adhere to all relevant ASRM, SART, and Federal Trade Commission policies and procedures relating to advertising and the use of ART outcome statistics.

The embryology laboratory must retain records of all its policies and procedures as well as personnel employment, training, evaluations, and continuing education activities. In addition, documentation of the proper identification, outcome, and disposition of all gametes, gonadal tissue and embryos is important. This documentation should identify all clinical and laboratory personnel who have handled gametes, gonadal tissue and embryos during each procedure.

The laboratory must maintain these records for a period of time specified by federal, state, and local laws or for 10 years beyond the final disposition of all specimens obtained during each patient's ART cycle, whichever is later. All paper records must be maintained on-site for 2 years; electronic records must have appropriate safeguards against data loss. In the event that the laboratory ceases operation, provisions must be made for these records to be maintained according to the time frame required.

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Requisitos mínimos para la realización de técnicas de reproducción asistida: dictamen del comité.

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Este documento está diseñado para proporcionar un marco para los programas de tecnologías de reproducción asistida (ART) que cumplan o superen los requisitos propuestos por los Centers for Disease Control and Prevention (CDC) para la certificación de laboratorios de ART. Este documento sustituye al documento "Requisitos mínimos revisados para el ofrecimiento de programas de técnicas de reproducción asistida: dictamen del comité", publicado en 2014.