

Definition of experimental procedures: a committee opinion

The Practice Committee of the American Society for Reproductive Medicine

American Society for Reproductive Medicine, Birmingham, Alabama

This Practice Committee opinion provides a revised definition of experimental procedures. This version replaces the document, "Definition of Experimental Procedures," that was published most recently in 2009. (Fertil Steril® 2013; ■:■-■. ©2013 by American Society for Reproductive Medicine.)

Key Words: Investigational, evidence-based medicine, routine, informed consent, human subjects

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Procedures (including tests, treatments, or other interventions) for the diagnosis or treatment of infertility will be considered experimental or investigational until the published medical evidence regarding their risks, benefits, and overall safety and efficacy is sufficient to regard them as established medical practice. Relevant medical evidence can derive only from appropriately designed, peer-reviewed, published studies performed by several independent investigators, including a description of materials and methods sufficient to assess their scientific validity and to allow independent verification. The American Society for Reproductive Medicine (ASRM) will state specifically in official publications that a procedure is considered experimental or investigational, will review relevant new scientific evidence at regular intervals, and will remove a procedure from experimental or investigational status when evidence warrants.

Procedures classified by ASRM as experimental or investigational should

not be represented or marketed to patients as established or routine medical practice. Any educational materials, advertisements, or other documents describing or relating to the procedure should state specifically that the procedure is not established medical practice and is classified by ASRM as experimental or investigational. Patients also should receive counseling that specifies the experimental nature of the procedure and have that counseling documented in their permanent medical record.

By definition, procedures classified by ASRM as experimental or investigational require further research. This research may or may not be required to be conducted under the oversight of a properly constituted Institutional Review Board (IRB) (1). The consent form for the intervention should state clearly that the procedure is experimental. The decision or opinion of a local IRB does not affect the status of a procedure or the requirements attached to procedures classified by ASRM as experimental or investigational.

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This document was reviewed by ASRM members and their input was considered in the preparation of the final document. The following members of the ASRM Practice Committee participated in the development of this document. All Committee members disclosed commercial and financial relationships with manufacturers or distributors of goods or services used to treat patients. Members of the Committee who were found to have conflicts of interest based on the relationships disclosed did not participate in the discussion or development of this document.

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