



CFAS Position Statement Regarding New and Experimental Treatments for Assisted Reproductive Technology (ART)

A new procedure or technology to be introduced into ART treatment shall be considered experimental if:

- 1) it is not already in common clinical use and part of established medical practice, and
- 2) it is more than an incremental modification of current procedures, and
- 3) there is insufficient published evidence in the peer-reviewed literature to demonstrate that the procedure is both safe and effective.

It is the CFAS position that:

an experimental procedure should not be offered or advertised as a treatment outside of a research protocol,

and

research involving experimental procedures in clinical ART settings must be part of a well-designed study that aims to gain knowledge about the procedure's efficacy or safety or to answer other valid research questions.

In addition, counselling that specifies that the procedure is experimental should be provided, and informed consent must be obtained using a form that specifies clearly that the procedure is experimental.

Finally, the introduction of experimental procedures or technologies must be carried out with appropriate protections for research participants in accordance with the policies in the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans" (TCPS2, 2014, <http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/>, as updated) and in accordance with a duly constituted Research Ethics Board (REB).

Published June 11, 2015