# Options for Language CIRM MES Regulations Section 100095

**Section 100095: Additional Requirements for CIRM-Funded Research Involving Ooctyes**

(b) The procurement and disposition for research purposes of oocytes initially provided for reproductive uses, either for use by the donor or another woman, shall not knowingly compromise the optimal reproductive success of the woman in infertility treatment. Pursuant to this requirement, the SCRO shall confirm the following:

**Option 1: Original Language**

(1) The infertility treatment protocol is established prior to requesting or obtaining consent for a donation for research purposes and that the prospect of donation for research does not alter the timing, method, or procedures selected for clinical care.
(2) The woman in infertility treatment makes the determination that she does not want or need the oocytes for her own reproductive success.
(3) The donation of oocytes for research is done without valuable consideration either directly or indirectly.
(4) If the procurement of oocytes involves a donor providing oocytes for another woman's reproductive use, then the donation to research must be expressly permitted by the original donor.

## Option 2: Original Language with Specific Criteria for Fail-to-Fertilize Oocytes

(1) The infertility treatment protocol is established prior to requesting or obtaining consent for a donation for research purposes and that the prospect of donation for research does not alter the timing, method, or procedures selected for clinical care.
(2) The woman in infertility treatment makes the determination that she does not want or need the oocytes for her own reproductive success.
(3) The donation of oocytes for research is done without valuable consideration either directly or indirectly.
(4) If the procurement of oocytes involves a donor providing oocytes for another woman's reproductive use, then the donation to research must be expressly permitted by the original donor.
*(5) If the procurement of oocytes involves use of materials donated for reproductive use by another woman and with valuable consideration in excess of reimbursement for permissible expenses for the oocyte donor, then the oocytes may not be used for CIRM-funded research except when all the following apply:
  (A) The ooctyes fail to fertilize or otherwise are biologically unusable for reproductive purposes.
  (B) The clinician determining that the oocytes are unusable for reproductive purposes does not know whether to donor has consented to donation to research at the time of making such a determination.
  (C) The clinician has no conflict of interest.

* In contrast to option 1, provision (5) focuses on fail-to-fertilize oocytes and provides procedural requirements for making this determination.

## Option 3: Strict Prohibition on Use of Oocytes Where Original Donor Received Valuable Consideration

(1) The infertility treatment protocol is established prior to requesting or obtaining consent for a donation for research purposes and that the prospect of donation for research does not alter the timing, method, or procedures selected for clinical care.
(2) The woman in infertility treatment makes the determination that she does not want or need the oocytes for her own reproductive success.
(3) The donation of oocytes for research is done without valuable consideration either directly or indirectly.
(4) If the procurement of oocytes involves a donor providing oocytes for another woman's reproductive use, then the donation to research must be expressly permitted by the original donor.
*(5) If the procurement of oocytes involves use of materials donated for reproductive use by another woman and with valuable consideration in excess of reimbursement for permissible expenses for the oocyte donor, then oocytes may not be used for CIRM-funded research.

*In contrast to option 1 and 2, provision (5) contains explicit language that would not allow materials from paid donors to be donated to research.

## Attachment 2: Public Comments

14, 2006
RE: CIRM Medical and Ethical Standards Regulations, 17 Cal. Code of Regs 100010-100130
Medical and Ethical Standards Regulations, proposed sections 100010 - 100130,

Dear Members of the ICOC,

The recent CIRM draft regulations regarding egg "donation" which seek to legitimize procuring eggs for research from women undergoing IVF is ill-advised. Women undergoing IVF are in a vulnerable position both psychologically and physically. Their health as well as the integrity of the IVF procedure should not be jeopardized by competing concerns unassociated with their desire to have a child. Suggesting regulations that would facilitate acquiring excessive numbers of eggs from women undergoing IVF only serves to underscore that the aims of SCNT advocates are at odds with women's health and well-being. The most ethical position for the ICOC to adopt is a moratorium on egg donation until such time as independent scientific research establishes that it will cause neither short nor long term harm to women. Medical practitioners should not be asked to compromise their responsibilities to protect their patients' health.

Respectfully,

The Board of Directors of HandsOffOurOvaries:

Diane Beeson Ph.D.
Emilia Ianeva Ph.D.
Jennifer Lahl B.S.N., M.A.
Abby Lippman Ph.D.
Josephine Quintavalle
M.L. Tina Stevens Ph.D.

Dear ICOC members:

We urge the CIRM to adopt regulations that clearly prohibit compensation of egg donors for anything other than out-of-pocket expenses. This means, for example, that eggs donated by women for the purpose of fertility treatments who themselves have been paid could not be used for CIRM research purposes since the existence of an intermediary holder of the eggs would not alter their origin.

Moreover, we strongly urge that no "mixed egg donations" be allowed, whereby egg donors could provide some eggs for infertility purposes and some eggs for CIRM-sponsored research - whether or not compensation is involved. To do so would create an inappropriate incentive to over-hyperstimulate egg donors. It would also reduce optimal outcomes for the women using these eggs for reproductive purposes. In this regard it is ethically critical that a bright line mark the boundary between research and treatment.

Sincerely,

George J. Annas, Chair, Dept. of Health Law, Bioethics & Human Rights, Boston U. School of Public Health

Judy Norsigian, Executive Director, Our Bodies Ourselves

# AMERICAN SOCIETY FOR REPRODUCTIVE MEDICINE

**AGENDA ITEM # 8 B iii**
**8/2/06 ICOC Meeting**

**Administrative Office**
1209 Montgomery Highway
Birmingham, Alabama 35216-2809
Tel 205/978-5000 • Fax 205/978-5005
Email: asrm@asrm.org • Web Site: http://www.asrm.org

**J. Benjamin Younger Office of Public Affairs**
409 12th Street SW, Suite 203
Washington, D.C. 20024-2155
Tel 202/863-4985 • Fax 202/484-4039



Geoffrey Lomax, Dr.PH.
Senior Officer to the Standards Working Group
California Institute of Regenerative Medicine
210 King Street
San Francisco, CA 94107

July 25, 2006

Dear Dr. Lomax:

This letter is in response to your inquiry concerning the practice guidelines and standards governing Society for Assisted Reproductive Technology (SART) members. By requiring clinics performing oocyte retrieval to be a member of SART, the proposed CIRM Medical and Ethical Standards (MES) regulation will serve to ensure a high standard of care.

SART has consistently played an active role in creating practice guidelines and minimum standards of care in an effort to ensure that our member practices can proudly say that they adhere to the highest standards in ART as a requirement for membership. First and foremost, the SART guidelines affirm the doctor-patient relationship by emphasizing an absolute and unwavering commitment to the reproductive needs of patients. Engaging in any clinical procedures intended to create oocytes in excess of clinical need for reproductive treatment would be contrary to SART practice guidelines.

While SART supports and endorses a range of research activities, particularly research aimed at improving the efficacy of ART technologies, our fundamental mission is to set and maintain the standards for ART in an effort to better serve our patients.

Sincerely,

William E Gibbons, MD

William Gibbons, MD
President
Society for Assisted Reproductive Technology