Dear SWG Members:

We have received additional correspondence in advance of the SWG meeting. The original correspondence is attached for your benefit.

With regard to the Center for Genetics and Society correspondence, we offer you a few points of clarification. The commenter has misconstrued the intent of the proposed changes to impact use of oocytes. The public comments we received pertain **exclusively** to use of embryos created for reproductive purposes. Based on these comments, we have developed options modeled after state and federal law and policy. The proposed amendments are responsive to these comments as required by CA law.

In addition, we feel it may be helpful to provide additional clarification:

- **NAS Guidelines as a model**: The language "specifically for research" is a placeholder taken directly from the NAS Guidelines. The SWG has consistently drawn from the NAS guidelines to provide a model for our regulations. This example is no different. This placeholder language is designed to support policy development. Any proposed regulatory language is subject to SWG review, ICOC approval, OAL review and public comment to ensure the regulatory language is consistent with the intent of the policy.
- **Consistent with state law**: The language is consistent with California State law, (SB 1260) which is limited in scope to ovarian retrieval ***"for the purpose of medical research or the development of medical therapies."*** The commenter has publically recognized this appropriate limitation in scope. Again, the intent was to emulate widely accepted language to support policy development.
- **IVF-Embryos only**: The proposed policy amendments are apply exclusively to **embryos** created for reproductive purposes. The CIRM regulations prohibit "diverting eggs for which payments have been made" to research. Public comments pertaining to the proposed policy only address reproductive embryos.
- **Other CA laws support research donation**: California state law not only allows the donation of ALL IVF embryos that would otherwise be discarded, but requires disclosure of the option of donating them to research. The legislative intent here was to make all IVF patients aware of the research option.
- **Sunshine laws require reconsideration of the prior policy**: The July 25, 2008 policy position was approved by the ICOC and it became an interim regulation, and it **has now expired**. CIRM is in the process of promulgating a final regulation. As required by CA law, there must be a public comment. CIRM is obligated by law to address public comments, and the briefing materials are designed to enable the SWG to effectively fulfill this legal obligation prior to submitting revisions to OAL.
- **The proposed modification are consistent with commenter's policy position**: The proposed change allowing IVF-embryos to be donated to research is consistent with CA law and the newly promulgated NIH Guidelines; both of these policies were endorsed by the commenter. For example, in their comments on the NIH Guidelines they raised no objection to this exact policy -- the research donation of embryos that would otherwise be discarded.

AMERICAN SOCIETY FOR REPRODUCTIVE MEDICINE

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September 16, 2009

Dear Members of the Medical and Ethical Standards Working Group:

The American Society for Reproductive Medicine is an organization of national fertility experts, with members including obstetrician/gynecologists, urologists, reproductive endocrinologists, embryologists, mental health professionals, internists, nurses, practice administrators, laboratory technicians, research scientists, and veterinarians. Our affiliated organization, the Society for Assisted Reproductive Technology (SART) represents fertility clinics. We appreciate the opportunity to comment on the recommendations contained in the briefing materials for the September 17 & 18th meetings.

ASRM has been involved with the issue of compensation to oocyte donors for the purposes of research since 2005, when we actively worked on Senate Bill 1260 (Ortiz) to completion. Senator Ortiz introduced the bill to address stem cell research outside of CIRM, therefore not subject to CIRM's statutes or regulations, to address her concern that women would be unduly influenced by compensation when participating in research requiring oocytes.

As physicians treating the patients for infertility, many of whom use compensated oocyte donors for fertility, we wanted to ensure that the prohibition would not interfere with donors for infertility treatment. The law and the record reflect that the legislature intended specifically to exclude reproductive medicine from the scope of this law. SB 1260 does not in any way interfere with donation for infertility treatment. Indeed, the Chapter of the law is entitled – "Procuring of Oocytes for Research".

At the federal level, the National Institute of Health recognized that allowing gametes obtained with the primary purpose of infertility does not have the have the possibility of undue inducement to participate in research. Simply look at the relationship of the parties and by whom the donor is compensated. The recipient couple desiring a biological family, not a researcher or research organization, is paying the donor out of their own pocket for the donor to undergo ovarian stimulation and oocyte retrieval. The recipient couple is expecting to be able to use this donated tissue for their own purposes. It is only when they are no longer in need – whether the oocyte is not of sufficient quality to be used to create an

embryo or when they have finished their fertility treatment and don't want to have their efforts of time and money be wasted with simply disposing of embryos as medical waste, that they turn to the option of donating for research. The donation process for infertility in no way is motivated by procuring oocytes and embryos for research, and it was the concern of undue inducement in procuring oocytes for research that was behind drafting Proposition 71 to prohibit compensation. Use of gametes obtained for infertility, using a paid donor, is not what motivated the prohibition in Proposition 71.

Our understanding of the proposed changes is that CIRM policy would become consistent with state and federal law and policy regarding the donation of IVF oocytes and embryos that would otherwise be discarded. We believe this is a reasonable approach consistent with the ICOC stated policy to strive for consistency of policy and to not be more restrictive than NIH.

We believe a consistent approach will enhance the myriad of protections of donors by providing a uniform standard of treatment of and consent for potential donors.

We appreciate the care and thoughtfulness with which this Group has approached this issue, and encourage you to adopt the staff recommendations relative to Donors.

Sincerely,

Shannon Smith-Crowley
American Society for Reproductive Medicine and Society

CENTER FOR GENETICS AND SOCIETY

Pro-Choice Alliance *for* Responsible Research

September 16, 2009

Dear Members of the Standards Working Group,

We have reviewed the background materials prepared by CIRM staff for this week's meeting, and we have serious concerns.

The first is the proposed change to CIRM policy about payment to women who provide eggs for research. The proposed new language is: "Limit the payment restriction to donation of oocytes provided *specifically* for research purposes." [Italics ours]

We were startled to see this for two reasons. As you know, both Proposition 71 and California law prohibit paying women to provide eggs for research. This proposed policy would mean that a woman undergoing egg extraction could be compensated or receive other valuable consideration as long as research is not *the specifically stated* purpose of harvesting her eggs. Diverting eggs for which payments have been made from the reproductive to the research context would be contrary to Proposition 71 and state law.

We sincerely hope that this is an oversight. We ask the Standards Working Group to reject the proposed language and to clarify that paying women for eggs that will be used for research (beyond reimbursing their expenses) is contrary to law, and will not be done in California.

Further, we note that the background materials do not address a potential change in CIRM policy on the availability of eggs for research. Therefore, beyond the kind of clarification described above, we ask that no substantive consideration be given to the proposed policy change at this meeting. Neither the Standards Working Group nor the public are prepared for a discussion of the very significant legal and ethical issues raised by a proposal to divert eggs from assisted reproduction to research.

We are also concerned about the issue that the background materials do address: the availability of “paid-gamete IVF embryos” for research. At its July 25, 2008 meeting, this committee discussed that issue at some length. It then recommended policy, which the ICOC adopted at its August 12-13, 2008 meeting.

Those discussions, and the policy decisions based on them, reflected concerns that prospective use for research of paid-gamete IVF embryos could create conflicts of interest for the physician attending an egg provider, and thus put her at increased risk. For that reason, the current policy approves only the retrospective research use of paid-gamete IVF embryos.

That policy is now up for reconsideration. We are disappointed to see that concerns about conflict of interest are nowhere mentioned in the background materials. We do not understand how a change in this policy, adopted by the Standards Working Group and ratified by the ICOC, can be justified unless those concerns can be adequately addressed.

Sincerely,

Marcy Darnovsky and Jesse Reynolds
Center for Genetics and Society

Susan Berke Fogel
Pro-Choice Alliance for Responsible Research