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2-47	2/10	WC012	100000: The intent of the regulations is described as pursuing research "that protect[s] patient safety, patient rights, and patient privacy." The use of the term "patient" is confusing since many of the "subjects" would not be patients, especially in oocyte, sperm, and somatic cell donors. It seems unfortunate that the preamble focuses solely on patients. Perhaps, patients, donors, and other subjects would be a viable alternative?	The final sentence could be revised: … *that protect the safety, rights, and privacy of donors, human subjects, patients or other participants in CIRM-funded research.*	None needed; this language was not regulatory so it was removed in drafting.
2-48	2/10	WC012	100005(a): The intent of the "public" member is still not met. The current revised regulations still allows an Institution to name a professional scientist as either a patient advocate or "public" member and still meet the letter of the regulation. It seems you could require meet what I understood as the intent of the NAS guidelines for a non-scientist by stating as much.	Recommend that SWG consider intend and modify if necessary.	Forward to SWG
2-49	2/10	WC012	Why is the COI rule restricted to "financial" COI? What if the PI is the SCRO member's spouse, child, or student? What if there are non-financial conflicts? Under the rule as written may the conflicted SCRO member provide information during the SCRO meeting and not participate in the deliberations and the vote? Seems like a good use of time and resources if the question could be answered right there while avoiding undue influence or conflict. The COI rule in 45 CFR 46 seems to give enough flexibility in this area and should be considered as a starting point for this rule: 46.107(e).	CFR language reads: *No IRB may have a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information to the IRB.*	Referred to SWG for 5/3 meeting
2-50	2/10	WC012	It is important to ensure that non-IVF oocyte donors not bear the costs of non-negligent research related injuries. It, however, was my understanding CIRM wanted to mirror the NIH funding system. The requirement that the Institution assume sole responsibility for the "cost of any medical care required as a direct and proximate result of oocyte donation for research" is very inconsistent with NIH rules under A-21 and FDP that allows for budget reallocation that does not substantially change the scope of the project in order to address subject injury. Alternatively, the Institution could ask to rebudget to help cover the cost of medical care for the non-negligent injury. The rebudgeting would occur in the direct costs. It seems that CIRM should share some of the financial responsibility for the cost of care resulting from non-negligent injury, at least through rebudgeting of the grant.	There are no barriers or restriction in the CIRM GAP to prohibit or limit the institutions ability budget for such costs.	None

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2-51	2/10	WC012	The regulations should clearly indicate whether PIs may appeal a SCRO decision to some other Institutional committee or person. Any such appeal process would surely undermine SCRO authority and the importance of PIs and SCROs negotiating the conditions for approval. Again, 45 CFR 46 may be a good beginning in which to craft such a regulation. We prefer the following: "Appeals of ESCRO decisions must return to the ESCRO for additional review. Investigators may request to present responses to ESCRO decisions during a convened meeting. Appeals must be in writing and submitted directly to the ESCRO prior to an investigator's personal presentation to the ESCRO."		
2-52	2/10	WC013	As part of working out conditions, stem cell lines may not always be sustainable in culture. Some cultures may die prematurely or could be lines driven to the last step: terminal differentiation, such as a culture of insulin-producing beta islet cells derived from hESCs. Those cultures will grow temporarily, then die.	As a practical matter it is the intent to derived "covered stem cell lines" that triggers the regulatory requirements, so there appears to be no functional relevance here.	
2-53	2/10	WC013	Not all stem cells are capable of differentiating into multiple lineages. Germ stem cells are unipotent, and can only make oocytes and spermatocytes (but can self-renew). There may be as-yet undiscovered unipotent stem cells.	Similar to 2-5, not clear there is a regulatory relevance to this comment.	
2-54	2/10	WC013	It would help if embryo was a defined term. This would clarify whether to allow (c) a human NSC transplant into a primate in utero "late embryo" at 7 weeks, for example (not exactly sure where monkey embryogenesis ends). For (d) or (e), identifying whether transplants of stem cells into late stages of human embryogenesis is permitted, up to 8 weeks. This would also jibe this section with 06 (b).		
2-55	2/10	WC014	Section 100008(b)(1): The meaning of "shall not compromise the optimal reproductive success" needs to be clarified. First, this statement may be interpreted to mean the researcher must not engage in any activity that poses a health risk. If this is the case, then oocyte retrieval would effectively not be allowed because it is conceivable that her fertility could be impacted by the procedure. At a minimum the language should be changed to state "shall not knowingly compromise." It appears the intent of the Working Group is that oocytes not be committed or diverted to research until the women's fertility goals or	(1) A woman undergoing stimulation to produce oocytes for her own reproductive uses may not donate any eggs to research unless she has conclusively determined that she does not want or need them to optimize her own chances for reproductive success. A woman undergoing stimulation to produce oocytes for donation to	

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			treatment is complete. Therefore, this language needs state in a clear manner that oocytes intended for reproductive purposes are used for such purposes and not used in research unless the fertility treatment is complete.	another person's reproductive efforts may not donate any of these eggs to research unless (a) the donation is permissible under her agreement with the recipient who is receiving her oocytes for reproduction and (b) her donation of oocytes for research is done without valuable consideration.	
2-56	2/10	WC015 WC016	**CONCERN** Proposed definition of what would be required for review: *"Covered stem cell line" means a culture-derived, human stem cell population that is capable of: 1) sustained propagation in culture; 2) differentiation along multiple cell lineages; and 3) self-renewing to produce daughter cells with equivalent developmental potential. This definition includes both embryonic and non-embryonic human stem cell lines regardless of the tissue of origin"* At first glance, the final sentence clearly keeps the door open to all adult stem cells. As I understand it, the argument is that this narrows the definition somewhat less than ALL adult stem cell research because the cells must be "culture-derived" and capable of "differentiation along multiple cell lineages," but this still leaves the door open to cells that we wouldn't otherwise need to consider. In one of the earlier proposed definitions, instead of "multiple cell lineages," the wording spoke of "tri-lineage," which was taken to be mesoderm, ectoderm, and endoderm (i.e., pluripotent cells). My sense is that there is no need to extend ESCRO review to include all adult stem cell research, because this is already required under the California Health and Safety Code to be reviewed by the IRB. Also, many of the ethical concerns are being driven not by the potential uses of the cells, but by their origin in human blastocysts. **PROPOSAL** The definition should revert to an earlier version so that we don't have to	(2)	

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			duplicate a kind of review that is already adequately covered by the IRB. However, whether or not this is the case, the wording of this section should be more explicit about what is actually to be covered. It may help if the text is clear about the reasoning behind what is to be covered. An understanding of the spirit of the regulation would greatly help ESCRO Committees in deciding what needs to be reviewed.		
2-57	2/10	WC015	The worry for many of us is that ESCRO Committees will have their efforts diluted by having to look at adult stem cell research that is already required to be reviewed by the IRBs. I would add that any use of the products of CIRM-funded research in humans and any research with adult stem cells already require IRB review by State and/or Federal regulation. While I agree that IRB's may not have the expertise for some aspects of this research, this is a potential risk for almost any kind of research reviewed by the IRB. However, the system relies on the IRB to recognize when they lack the necessary expertise and seek out the help needed. This is certainly the model already being adopted by the UCSD IRB. It seems to me that there are at least three possible suggestions that might make things clearer and more workable for ESCRO Committees: 1. Explicitly state that the only circumstance in which adult stem cells would need to be reviewed by an ESCRO Committee would be when (a) the experiments will result in de-differentiation to pluripotent cells or (b) the IRB asks for consultation from the ESCRO Committee. 2. Limit ESCRO review to any research that will result in the derivation of cells with tri-lineage (mesoderm, ectoderm, and endoderm) potential. 3. Re-word the definition (and I don't know how this might be done) by changing the focus to defining the ethical concerns to be addressed (e.g., destruction of the human blastocyst), rather than try to anticipate the nature of the products of that research (e.g., multipotent stem cells).	Option 2 seems consistent with the intent of the SWG. It may be that the definition of "covered stem cell line" should be discussed. This definition may be introducing confusion.	
2-58	2/10	WC014	Section 100100(f) existing cord blood donation only requires mother		

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			consent.		
2-59	2/10	WC016	Section 100009 (c)(4). The language that, "Researchers may meet this requirement by following a process by the designated IRB or SCRO Committee" implies that there is some means to meet this requirement besides such a process. It would be clearer to state, "Researchers must follow a process approved by the designated IRB and SCRO Committee." Also, this section should probably state that it does not apply retroactively to materials collected before the enactment of these regulations.	Recommend adopting the recommended language.	
2-60 Also see 2-59	2/10	WC017	100090(b)(2) The requirement that "the funded research institution has agreed to assume the cost of any medical care…" is phrased in such a way that it seems to preclude arrangements where someone other than the "funded institution" would cover such costs. For example, a commercial sponsor of research may assume such costs. The regulations should be phrased in a manner where the performance objective is clear (the research participant is not responsible for the cost of any required medical care), but does not imply sole responsibility of payment by the funded institution. Rather the funded institution must provide assurance that such costs are covered.	Possible language adapted from SB 1260: *(2) The funded institution shall develop procedures and protocols to ensure access for any medical care required as a direct and proximate result of oocyte donation. The research protocol shall ensure that payment for coverage of resulting medical expenses be provided by the program or project.*	
2-61	2/10	WC017	100100(d)(3) The requirement that donors must initiate recontact with donors seems ineffective. Researchers should have some opportunity to follow up with potential participants. Could the intent of this provision be accomplished by requiring the researchers to wait a minimum time period before recontacting potential participants?		
2-62	2/10	WC029 WC022	100100(d)(3) We endorse the regulatory focus on heightened informed consent. The informed consent requirements make sense because in most cases there will be no direct benefit to the participant. However, in this effort to enhance informed consent the regulations do overreach in one section. Section 100100(d)(3) requires a "deliberative" period in the consent process. Unfortunately, in the reproductive rights field, a similar approach is advocated where states require waiting periods for abortions and/or		

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			waiting periods for parental notification. Therefore, this well intended provision has the unintended consequence of undermining what we have been working for for decades. Fortunately, such a provision may not be necessary. We believe that you're already getting sufficient time to consider the decision to donate with the proposed informed consent process.		
2-63	2/10	WC017	**Lack of clarity regarding applicability to research using existing stem cell lines.** It is not always clear in the draft regulations whether provisions are meant to apply retrospectively to existing stem cell lines and to materials donated prior to the enactment of these regulations. It may be helpful to include some clear guidance as to which sections are meant to apply to research using pre-existing cell lines and donated materials. Otherwise, IRBs and ESCROs may have differing interpretations of what is required by the regulations. For example, is **Section 100100**, setting out specific required informed consent elements, applicable to stem cell lines that were developed prior to the passage of Prop 71? Are researchers precluded from using Prop 71 funds to conduct research using existing stem cell lines if those lines might have been developed from donated materials from donors who were not given the precise elements of information specified by these regulations? Section 100080 requires that all covered stem cells used in CIRM funded research be "acceptably derived." Does that mean the pre-existing stem cell lines, developed prior to the enactment of these regulations, and that are not listed on the NIH registry or one of the other registries, cannot be used in CIRM funded research unless it can be determined that the cell lines were not developed using materials from anonymous sperm donors, or where any donor was compensated for donation?		
2-64	2/10	WC019	It is only advisable to withhold payment to egg donors if no one at any point from procurement to therapeutic application stands to benefit	The SWG is constrained by Proposition 71 which prohibits	

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			Financially from CIRM funding; in other words, if all players are restricted to direct-cost-compensation-only altruism. As this is not the case, it sets up a prima facie economic disenfranchisement, placing a burden of altruism on egg or tissue donors alone. I thus support compensating women and other tissue donors for their contribution to this vital area of research.	payments to donors. Broader changes to compensation policy would require legislative action or a ballot initiative.	
2-65	2/10	WC019	It is important not to pay anyone what would amount to an undue inducement to undertake medical risk in tissue donation. To make sure that only an appropriate amount is paid in compensation, the following criteria should be met: a) tissue, especially embryos and gametes, should not be valued differently according to eugenic criteria. There should be a flat rate to compensate the work involved in each donation, regardless of donor characteristics, match potential, or earning power of the donor. b) The numbers of eggs retrieved per donation also should not affect the lump sum paid for the effort and contribution of the donation. This would be wrong on two grounds: it would compensate the wrong thing (eggs instead of effort), and it would encourage hyperstimulation protocols that increased yield, potentially substituting yield for the health of the donor. c) payment should be calculated according to civil service pay scales and on the basis of the hours and effort involved, in consultation with area fertility experts and CA government human services.	(a) The compensation criteria in the MES regulations are limited to out of pocket expenses. There may be differential reimbursements based on "earning power," but this decision is made by an IRB, and not prescribed by the regulations. This issue received extensive discussion by the SWG; see: SWG 01/30/06 Transcript P205.L24 (b) Reimbursement policy is related to time spent not number of eggs retrieved. (c) IRBs may establish limits on compensation, but compensation should not exceed out of pocket expenses.	
2-66	2/10	WC019	All ESCRO committees should be charged with investigating alternatives to egg donation before approving applications to conduct human embryonic stem cell research using fresh human eggs from donation. The following alternatives should be considered in all such cases: a) is there a compelling reason not to do this research using already derived embryonic cell lines? Acceptable reasons might include contamination of existing lines, shortage of lines from some populations, need for training in derivation itself, or need to perfect derivation techniques using a bio-engineered matrix rather than mouse or other mammalian feeder cells. b) is there a way to achieve this goal using adult stem cells? Part of this	(a) Research involving existing cell lines is eligible for CIRM funding. New derivation can be a frivolous decision. The SCRO is charged with considering the need for derivation of new cell lines as part of its review and approval process. Could add clarifying language: Optional language for (a): The SCRO committee shall determine there is a compelling scientific reason to utilize	

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			should include a consideration of gender balance: could human sperm progenitor cells be used, for example, for stem cell line derivation and differentiation? Have as many protocols using sperm progenitor cell extraction as egg extraction been approved by this institution? c) could ovarian tissue and in vitro maturation of oocytes be used instead of fresh oocyte harvesting?	oocytes derived from human subjects. (b) All human stem cells are available for achieving the goal. This recognition led to an expansion of the regulation beyond embryonic stem cells. Regulations concerning use of cord blood, fetal tissue and other human tissue have been promulgated in recognition of the value of adult cells. (c) yes, this is why the informed consent provisions apply to a*ll CIRM-funded human subjects research*.	
2-67	2/10	WC019	The following ways to mitigate potential harm to egg donors should be implemented: a) short term risks to donors should be minimized by: i) only permitting SART registered clinics, and qualified fertility physicians to handle stimulation protocols and egg extraction for fresh egg donation ii) best practice monitoring for, and where necessary treatment of, ovarian hyperstimulation syndrome and other potential side effects during and immediately after treatment, provided at no cost to the donor iii) state wide data collection to monitor side effects of egg donation and compare outcomes between egg donation for fertility services and for stem cell research b) long term risks to donors should be minimized by: i) minimizing gonadotropin exposure by restricting limiting donation to not more than one or two donations and fine tuning stimulation protocols according to donor response ii) where possible, use ovarian tissue section rather than oocyte harvesting. The development of protocols to biopsy ovarian surfaces for immature oocytes should be funded. iii) ovarian section should be restricted to women already undergoing pelvic surgery, such as tubal ligation or exploratory laparoscopy, or to	(a)(i) SART represents 85-95% of all IVF clinics in the United States. Their mission is to set and help maintain the standards for ART. Could add provision: Add provision 100090(b)(X): *The clinic performing oocyte retrieval is a member of the Society for Assisted Reproductive Technology..* (a)(ii) addressed in section 100090: see	

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			cadaveric extraction with informed consent according to the prevailing standards for organ donation. There should be a prohibition on the use of abortuses for this purpose. Methods for ovary biopsy by ultrasound aspiration should be explored. iv) Studies to perfect in vitro maturation of human oocytes should be funded. v) data should be collected state wide on the long term effects of egg donation, particularly but not exclusively, the use of gonadotropins. Data on the subsequent health of children born to women who were in their past egg donors should also be monitored. vi) while data is being collected on the possible risk of donation-induced subsequent infertility, this fear should be addressed by requiring egg donors to have at least one living child or by requiring that they attest to the desire not to bear children. Informed consent works poorly to cover the risk of infertility, as it is well known that individuals change their minds radically when faced with infertility.		
2-68	2/10	WC019	The question of familial and friendship coercion should be addressed. Living tissue donations, especially if uncompensated, risk placing undue burdens on some to donate based on kinship or friendship coercion. This is especially important for egg donation, where the burden falls on women, and where women's kinship and caring roles have long been naturalized and subsumed to the realm of altruism. Women have fought long and hard to have their kinship and caring roles appropriately valued and protected, and well as for the right to take on financially compensated workplace risk. The guidelines as they stand at the moment reverse this effort. The following should be considered: a) Autologous donation should be encouraged. According to the well established bio-ethical principle of justice, benefits and risks should be balanced and the potential to benefit is obviously greatest for patients with conditions that could potentially be treated with stem cell therapies. b) all non-autologous kinds of kinship and friendship donations should be monitored very carefully. This will be critical if the asymmetric altruism of current recommendations is left in place.	(a) Autologous donation (in contrast to donation for research) should be viewed preferentially by the IRB; because the risk benefit equations would shift in the direction of benefit to the human subject. Therefore, it is "encouraged" through existing IRB review procedures. (b) SWG should consider whether there should be policies to address non-autologous kinship donations.	

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			Women in family and caring roles for patients will be under emotional pressure to donate, and this will be exacerbated by the shortage of other sources of donation. It will be especially important to monitor cross generational and ther kinds of family power inequities in this regard. Egg donors need to be young and might be particularly vulnerable to these kinds of emotional pressure. The following distinction should be made, and guidelines developed: i) mothers make up one category, and may wish to donate for their children, and should be able to do so with appropriate informed consent that acknowledges their right or need in some medical circumstances to say no or to have a physician say no on their behalf ii) all other kin or friends make up another category, and all potential donors should only make a donation after approval from an IRB or equivalent to establish that they are not being unduly coerced by their relation to a patient. Sample questions might include: do you know anyone who might benefit from your donation? if there were other sources of eggs, or if XXX were not sick, or if YYY had not asked you to consider donating, would you still wish to donate? iii) scientists and physicians should make clear to the best of their knowledge the chances of a donation being used for a therapeutic application, and this information should be communicated to the potential donor as well as to family members if there is any suspicion of emotional pressure to donate.		
2-69		WC017	100100(d)(3): Restriction on recontacting donors after required "deliberation" period could unduly inhibit subject recruitment without significantly enhancing protection for subjects. 100100(d)(3) prohibits researchers from soliciting potential donors until the donors have themselves initiated recontact with the researchers after the requisite "deliberation period." This requirement could unduly inhibit the effectiveness of subject recruitment while offering little or no added protection to subjects. Researchers should have some opportunity to follow up with potential participants. Potential donors who do, indeed, want to participate, may, nonethless be busy and forget to make a phone call; it seems reasonable to give researchers an opportunity to contact them to determine whether, after consideration, they have decided to	Could offer as a choice rather than mandate recontact by prospective donor.	

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			participate in the research. Could the intent of this provision be accomplished by requiring the researchers to wait a minimum time period before recontacting potential participants?		
2-70		WC025	Policies on gamete donation should be extended to include donors of testicular tissue, since recent results indicate that the adult testis is a potential source of pluripotent stem cells (e.g. Guan et al. Nature 440: 1199, 2006) and at least one company in this State is actively conducting research with human tissue in this field.	Possible revisions to 100070 now specifically address derivation of any covered (pluripotent stem cells); also all "donors of ..human tissue" are covered in 100080 & 90.	
2-71		WC025	100020-Is it really necessary to require ESCRO review of research on tissue stem cells, if they are not pluripotent? Review of research protocols involving donation or therapeutic use of tissue stem cells is carried out by IRBs. ESCRO could be notified of such activity with cross reference to IRB approval. Further downstream experimentation in vitro with such cells could be also subject to notification to an ESCRO, as could animal experiments; where a protocol involving introduction of tissue stem cells into experimental animals might raise exceptional ethical issues, the ESCRO could opt to review the protocol. IRB and ESCRO review should not be redundant. The definition here should also explicitly exempt established or immortalized human cell lines other than ES, EG or SCNT/reprogrammed cell lines. Many established cell lines derived from human cancers, and used by thousands of laboratories daily, might be captured by this definition as it stands.	Possible revisions focus ESCRO review to "covered" pluripotent stem cell lines. Possible revised definition of covered stem cell lines also centers around pluripotency.	
2-71		WC025	Section 100020-the definition of somatic cell nuclear transfer should encompass those procedures in which the donor nucleus is introduced prior to oocyte enucleation, (e.g. Munsie et al. Current Biology 10:989, 2000). Arguably the coverage should also extend to reprogramming to pluripotentiality by cell fusion or other means.	Comment seems consistent with intent of SWG.	
2-72		WC025	Section 100030-the embryonic period is generally understood in man to extend to 8 weeks of development. It is conceivable that introduction of stem cells (broadly defined) before this time point into the postimplantation, postgastrulation embryo might be desirable, for example to correct genetic or other congenital disorders. Also, it is		

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			possible that introduction of cells into animal embryos postimplantation, post gastrulation, might be desirable, to determine the developmental potential of the cells. The intent here is to avoid formation of chimeras in which the donor cells contribute extensively to multiple tissues. It is arguable that this is an area better served by a regulatory approach with flexibility rather than proscriptive legislation.		
2-73		WC025	Section 100080-approved cell lines might be extended to include those derived by a licensee of the Australian National Health and Medical Research Council, whose regulations are in line with those of other bodies cited here.		
2-74		WC025	1000100-it is possible that in future human ES cell derivations may not require destruction of embryos (e.g. Chung et al. Nature 439:216, 2006).		
2-75		WC024	**Section 1000400. Institutional Assurance of Compliance** Sec100040 (a) should be modified to read "The Office of President, Chancellor, or equivalent chief executive office shall be responsible for..." the written report. The regulations need to spell out the required content of the written assurance in order to ensure proper accountability. The following should be added: (a) 1. The written assurance must include a report of the data collected as required in the record keeping provisions of Section 1000120. (2) The written assurance must be delivered annually. (3.) The written assurance must be sent to the Secretary of Health, the Assembly and Senate Health Committees and the CIRM. (4) The written assurance will be made available to the public. An exception for public release may be made for data about individually identifiable patients or research subjects and for proprietary information. (5.) The institution must contract with an outside service to audit the institution's compliance with these standards annually. The audits will be released publicly. (6) Failure to comply with these requirements shall result in any or all of the remedies in Section 100050. **Section 10120 Record Keeping** I propose requiring that the following additional records be kept: (e) Summaries of proposed research activities that went before the		

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			SCRO and the IRB, and whether they were approved. (f) Policies and procedures adopted by the SCRO. (g) An overview of any human stem cell research being done at the institution that is not following CIRM standards. (h) An overview of any failures to comply with these standards. (i) The demographics of the providers of oocytes or embryos used in the derivation of each cell line. (j) A summary of the results, both positive and negative, of any CIRM-funded research or clinical trial. (k) Any significant adverse reactions in a clinical trial. (l) A disclosure of the personal, professional, and financial interests in biotechnology or biomedical companies of the SCRO members. (m) Health outcomes of oocyte donors resulting from oocyte retrieval, including adverse health reactions resulting from ovarian stimulation.		
2-76		WC029	Section 100100 on Informed Consent Requirements does an excellent job of ensuring women are well-informed as to the process, including the risks, of oocyte retrieval. In Section 100100(d), the draft regulations go into great detail as to the process involved in completely informing women of the procedure required for oocyte donation, even taking the unusual (but not unwarranted) step of requiring a test to ascertain understanding of "the essential aspects of the research"1[1].		
2-77		WC029	We support the decision to include "actual lost wages" as permissible expenses. In fact, we would request too include some sort of compensation for the 50-60 hours of medical care (blood tests, hormone shots, ultrasounds and the actual oocyte extraction procedure) endured over an approximately one month period, but understand that is not possible given the language of Proposition 71. Especially given that there is no compensation or honorarium for this selfless act, it is only fair to women to have them fully reimbursed whatever expenses they incur when they subject themselves to this process. We understands that some view reimbursement of lost wages as discriminatory as some women make more than others. However, the lack of any reimbursement for lost wages could make it impossible for lower and		

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			middle income women to be able to participate, where an upper income woman could absorb loss of income more easily. In fact, if the upper income woman is a salaried professional, she might not even lose income for the hour here and there when she needs to come in for a blood test, if she is not paid hourly by her employer. If she does not lose wages, she will not be paid for her time by the research project, as the regulations limit reimbursement to "actual lost wages1[2]". As CIRM needs fairness and diversity in research, the language on lost wages should be retained.		