3/2/09

To: ICOC

Fr: CIRM

Re: Consideration of regulatory amendments to the CIRM Medical and Ethical Standards regulations, including oversight and consent requirements for use of blastocysts and somatic cells

Action for ICOC Consideration:

Approval of recommended regulatory language (Attachment 1) so CIRM may initiate rulemaking action under the Administrative Procedure Act.

Background:

On 12/12/08 the Standards Working Group (SWG) met to consider MES revisions to support iPS research using somatic cells and to consider final recommendations for regulations governing consent for and utilization of embryos for CIRM-funded research. On 1/30/09 Dr. Bernard Lo described the recommendations to the ICOC in public session. The transcript of this presentation is included as Attachment 3.

SWG Sense of the Committee:

It was the sense of the SWG that the ICOC should consider the following new revisions:

- Clarify that the oversight (SCRO) committee requires notification for *in vitro* iPS research;
- Revise the standard for use of somatic cells in iPS experiments to allow somatic cells obtained under IRB-approved consent protocols.

It was the sense of the SWG that the ICOC should consider the making permanent the existing interim regulations. These regulations

- Authorize the use of IVF-embryos (created prior to August 2008) for which a gamete donor was paid;
- Authorize the use of embryos donated for research, where consent was obtained prior to enactment of the CIRM regulations, provided the consent conformed to the prevailing standard at time of donation.

Attachment 1 contains the regulatory language designed to support the revisions described above. Attachment 2 is a key designed to describe how the specific revisions correspond to the policy objectives described above.

Amend 17 Cal. Code of Regs. section 100070 to read:

§ 100070. SCRO Committee Review and Notification.

(a) CIRM-funded research involving the procurement or use of human oocytes may not commence without SCRO committee review and approval in writing. For such SCRO committee review and approval, a member of the committee with expertise in assisted reproduction shall be present. The designated SCRO committee may require that modification be made to proposed research or documentation of compliance with the requirements of subdivision (a)(3) of this regulation as a condition of granting its approval. At a minimum, the SCRO committee shall require the investigator to:

(1) Provide an acceptable scientific rationale for the need to use oocytes including a justification for the number needed. If SCNT is proposed a justification for SCNT shall be provided.

(2) Demonstrate experience, expertise or training in derivation or culture of human or nonhuman stem cell lines.

(3) Provide documentation of compliance with any required review of the proposed research by an IRB, Institutional Animal Care and Use Committee (IACUC), Institutional Bioethics Committee (IBC), or other mandated review.

(b) CIRM-funded research involving use of human embryos may not commence without SCRO committee review and approval in writing. The designated SCRO committee may require that modification be made to proposed research or documentation of compliance with the

requirements of subdivision (b)(3) of this regulation as a condition of granting its approval. At a minimum, the SCRO committee shall require the investigator to:

(1) Provide an acceptable scientific rationale for the need to use embryos including a justification for the number needed.

(2) Demonstrate experience, expertise or training in derivation or culture of human or nonhuman stem cell lines.

(3) Provide documentation of compliance with any required review of the proposed research by an IRB, Institutional Animal Care and Use Committee (IACUC), Institutional Bioethics Committee (IBC), or other mandated review.

(c) CIRM-funded research with the aim to derive or create a covered stem cell line from human gametes, embryos or products of SCNT involving a human donor nucleus may not commence without SCRO committee review and approval in writing. The designated SCRO committee may require that modification be made to proposed research or documentation of compliance with the requirements of subdivision (c)(4) of this regulation as a condition of granting its approval. At a minimum, the SCRO committee shall require the investigator to:

(1) Provide an acceptable scientific rationale for the need to derive a covered stem cell line.

(2) If SCNT is proposed as a route to generating human stem cell lines, a justification for SCNT shall be provided.

(3) Demonstrate experience, expertise or training in derivation or culture of

human or nonhuman stem cell lines.

(4) Provide documentation of compliance with any required review of the proposed research by an IRB, Institutional Bioethics Committee (IBC), or other mandated review.

(5) Document how stem cell lines will be characterized, validated, stored, and distributed to ensure that the confidentiality of the donor(s) is protected.

(d) CIRM-funded purely in vitro research utilizing covered stem cell lines or the reprogramming of human somatic cells with the aim to derive or create a covered stem cell line may not commence without written notification to the designated SCRO committee. Research may include animal assays to evaluate pluripotency; however, subsequent introduction of derived covered stem cell lines in non-human animals shall be reviewed in accordance with subdivision (e) of this regulation. At a minimum, the notification shall:

(1) Provide assurance that all covered stem cell lines have been acceptably derived.

(2) Provide documentation of compliance with any required review of the proposed research by an IRB, IACUC, IBC, or other mandated review.

(e) CIRM-funded research introducing covered stem cell lines into non-human animals or introducing neural-progenitor cells into the brain of non-human animals at any state of embryonic, fetal, or postnatal development may not commence without SCRO committee review and approval in writing. The designated SCRO committee may require that modification be

made to proposed research or documentation of compliance with the requirements of subdivision (e)(3) of this regulation as a condition of granting its approval. The SCRO committee may establish guidelines and procedures for expedited review of animal research so that review by the entire SCRO committee is not required. At a minimum, the SCRO committee shall require the investigator to:

(1) Provide an acceptable scientific rationale for introducing stem cells into non-human animals.

(2) Provide assurance that all covered stem cell lines have been acceptably derived.

(3) Evaluate the probable pattern and effects of differentiation and integration of the human cells into the nonhuman animal tissues.

(4) Provide documentation of compliance with any required review of the proposed research by an IRB, IACUC, IBC, or other mandated review.

(f) CIRM-funded research introducing ~~stem~~ cells from covered stem cell lines into a live born human may not commence without SCRO committee review and approval in writing. The designated SCRO committee may require that modification be made to proposed research or documentation of compliance with the requirements of subdivision (f)(4) of this regulation as a condition of granting its approval. At a minimum, the SCRO committee shall require the investigator to:

(1) Provide an acceptable scientific for rationale introducing stem cells into

humans.

(2) Provide assurance that all covered stem cell lines have been acceptably derived.

(3) Evaluate the probable pattern and effects of differentiation and integration of the human cells into the human tissues.

(4) Provide documentation of compliance with any required review of the proposed research by an IRB, IACUC, IBC, or other mandated review.

(g) In cases where SCRO committee approval is required, a SCRO committee shall notify investigators in writing of its decision to approve or disapprove the proposed research activity, or of modifications required to secure SCRO committee approval of the research activity. If the SCRO committee decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.

(h) SCRO committee approvals shall be reviewed no less frequently than once per year. The renewal review shall confirm compliance with all applicable rules and regulations. The SCRO committee may establish guidelines and procedures for expedited review of renewals so that review by the entire SCRO committee is not required.

Note: Authority cited: Article XXXV, California Constitution; Section 125290.40(j), Health and Safety Code. Reference: Sections 125290.40, 12554290.55, Health and Safety Code.

Amend 17 Cal. Code of Regs. section 100090 to read:

§ 100090. ~~Additional Requirements~~ Special Considerations for CIRM-Funded Derivation.

(a) Where CIRM funds are to be used for research intended to derive a covered stem cell line from human gametes, embryos, somatic cells or tissue, the SCRO committee must determine the requirements of Code of California Regulations, title 17, section 100080, subdivision (a)(2) or (a)(3), have been met:. ~~For CIRM-funded derivation occurring after November 22, 2006, the SCRO committee must also confirm that donors provided voluntary and informed consent in accordance with Code of California Regulations, title 17, section 100100, subdivision (b).~~

(1) For embryos created on or before August 13, 2008, "valuable consideration" does not include payments to gamete donors in excess of "permissible expenses," provided the embryo was originally created for reproductive purposes.

~~(2) For embryos created before November 22, 2006 consent exclusively from oocyte donors is sufficient provided the sperm donor cannot be identified and the donation was made in accordance with the legal requirements in force at the place and time of donation.~~

(b) ~~California Code of Regulations title 17, section 100090(a), does not apply to CIRM-funded research intended to derive a covered stem cell line from somatic cells when the SCRO committee has determined the requirements of California Code of Regulations title 17, section 100080, subdivisions (a)(3)(A) and (a)(3)(B), have been met.~~ Where a covered stem cell line is derived from human somatic cells, procured from human subjects after November 22, 2006, and the CIRM-funded research is designed to develop cells for transplantation into a live born

human, the SCRO committee must confirm that donors provided voluntary and informed consent including the requirements of Code of California Regulations, title 17, section 100100, subdivision (b)(1)(E).

(c) The modification of an acceptably derived stem cell line shall not be considered a CIRM-funded derivation.

Note: Authority cited: Article XXXV, California Constitution; Section 125290.40(j), Health and Safety Code. Reference: Sections 125290.35, 125290.40 and 125290.55, Health and Safety Code.

#	Section Number	Policy Objective	Revised Language	Rationale
1	**§ 100070(c)**	Require SCRO review and approval of research involving human gamates and embryos.	(c) CIRM-funded research with the aim to derive or create a covered stem cell line from human gametes, embryos or products of SCNT involving a human donor nucleus may not commence without SCRO committee review and approval in writing.	The SWG recommended that basic research involving the reprogramming of somatic cells be subject to SCRO notification. This modification limits full SCRO review to derivations involving the use gametes, embryos or SCNT.
2	**§ 100070(d)**	Require SCRO notification (but not full review and approval) of iPS research involving human somatic cells.	CIRM-funded purely in vitro research utilizing covered stem cell lines or the reprogramming human somatic cells with the aim to derive or create a covered stem cell line may not commence without written notification to the designated SCRO committee. Research may include animal assays to evaluate pluripotency; however, subsequent introduction of derived covered stem cell lines in non-human animals shall be reviewed in accordance with section (e).	The SWG recommended that basic research involving the reprogramming of somatic cells be subject to SCRO notification. This modification clarifies that reprogramming is covered under the notification standard including animal assays for the purpose of determining if a line is pluripotent. Stating that subsequent animal transplantation of an established line must be reviewed under the existing standard provides further clarification.
3	**§ 100070(f)**	Require SCRO review of research involving the transplantation of cells derived from pluripotent cell to human subjects.	(f) CIRM-funded research introducing ~~stem~~ cells from covered stem cell lines into a live born human may not commence without SCRO committee review and approval in writing.	The SWG recommended that transplantation research be subject to full SCRO review. This modification clarified that all research proposing to transplant cells from a covered cell line must be reviewed.
4	**§ 100090(a)(1)**	Establish a "baseline" level of consent for use of gametes, embryos and	(a) Where CIRM funds are to be used for research intended to derive a covered stem cell line from human	The SWG recommended that "general" consent for research be allowed for gametes, embryos and somatic cells

		somatic cells.	gametes, embryos, somatic cells or tissue, the SCRO committee must determine the requirements of Code of California Regulations, title 17, section 100080, subdivision (a)(2) or (a)(3), have been met with the following exceptions:	procured prior to the promulgation of the MES regulations. This provision identifies the baseline requirements for consent, payment and oversight. The addition of section 100080(a)(3) allows the use of somatic cell that conform to federal regulations to be utilized.
5	**§ 100090(a)(1)**	Allow embryos created from gamated from which the donors were paid if the embryo was created for reproductive purposes (IVF) and it was created prior to August 2008.	(1)For embryos created on or before August 13, 2008, "valuable consideration" does not include payments to gamete donors in excess of "permissible expenses," provided the embryo was originally created for reproductive purposes.	This provision exempts embryos created from gametes from which the donors were paid from the payment restriction in 100080(a)(2)(A).
6	**§ 100090(b)**	Require comprehensive consent for all gametes and embryos procured after the CIRM regulations take effect.	~~(b)For CIRM-funded derivation occurring after November 22, 2006, the SCRO committee must also confirm that donors provided voluntary and informed consent in accordance with Code of California Regulations, title 17, section 100100, subdivision (b).~~ (b)Where CIRM funds are to be used for research intended to derive a covered stem cell line from gametes or embryos procured from human subjects, after November 22, 2006, the SCRO committee must confirm that donors provided voluntary and	This provision "triggers" the detailed consent requirements for gametes and embryos procured after the CIRM regulations took effect. Excluding somatic cells from this requirement enables the use of somatic cells procured under protocols that deviate from the specific CIRM requirements.

			informed consent in accordance with Code of California Regulations, title 17, section 100100, subdivision (b).	
7	**§ 100090(c)**	Require explicit consent for cell transplantation.	(c) Where a covered stem cell line is derived from human somatic cells, procured from human subjects after November 22, 2006, and the CIRM-funded research is designed to develop cells for transplantation into a live born human; the SCRO committee must confirm that donors provided voluntary and informed consent including the requirements of Code of California Regulations, title 17, section 100100, subdivision (b)(1)(E).	This provision is requires explicit consent for transplantation of cells to humans.

HOW WE'RE GOING TO GET A QUORUM -- NOTHING IS IMPOSSIBLE, JAMES -- WHILE WE TRY AND FIGURE OUT HOW WE'RE GOING TO GET A QUORUM, I THINK IT IS IMPORTANT THAT WE CREATE THE PUBLIC RECORD AND PROVIDE OPPORTUNITY HERE FOR DISCUSSION.

DR. LO: THANK YOU FOR GIVING ME THE CHANCE TO PRESENT ON BEHALF OF THE STANDARDS WORKING GROUP. FIRST, I WANT TO SAY YOU CAN ALL TAKE A DEEP BREATH. THIS SHOULD BE RELATIVELY EASY FOR YOU, I THINK. THIS IS PROBABLY NONCONTROVERSIAL AND IT WON'T COST YOU A PENNY. JUST LISTENING IN THE BACK, I KNOW THERE'S BEEN SOME VERY TOUGH DECISIONS YOU'VE BEEN FACING.

SO WHAT I'M GOING TO PROPOSE TO YOU ARE TWO THINGS. FIRST, NEW RECOMMENDATIONS TO, FIRST, CLARIFY THE CIRM REQUIREMENTS FOR OVERSIGHT OF RESEARCH WITH INDUCED PLURIPOTENTIAL CELLS, IPS CELLS, IN TERMS OF WHAT KIND OF OVERSIGHT DOES THE INSTITUTIONAL SCRO, STEM CELL RESEARCH OVERSIGHT COMMITTEE, HAVE TO DO? AND SECONDLY, TO SUGGEST SOME MEASURES THAT WOULD FACILITATE THE COLLECTION AND USE OF SOMATIC CELLS FOR IPS RESEARCH TO DERIVE NEW CELL LINES.

WE'VE HAD A LOT OF COMMENTS FROM UNIVERSITIES AND INVESTIGATORS WHO ARE VERY

INTERESTED IN PURSUING THIS VERY PROMISING LINE OF STEM CELL RESEARCH TO CLARIFY SEVERAL AMBIGUITIES IN OUR CIRM REGULATIONS.

AND SECONDLY, WE'RE ASKING YOU TO MAKE TWO INTERIM REGULATIONS WHICH WERE PREVIOUSLY DISCUSSED AND APPROVED ON EMBRYONIC STEM CELL RESEARCH DERIVATION USING, QUOTE, GRANDFATHERED, GRANDPARENTED EMBRYOS, MAKE THOSE PERMANENT REGULATIONS AND PUT THEM THROUGH THE REGULATORY PROCESS.

OUR CURRENT CIRM GUIDELINES FOR IPS DERIVATION ARE MORE RESTRICTIVE THAN THE NATIONAL ACADEMY OF SCIENCE 2008 RECOMMENDATIONS AND FOR FEDERAL REGULATIONS, THE COMMON RULE THAT GOVERNS HUMAN SUBJECTS RESEARCH. SO INVESTIGATORS WHO WANT TO ENTER THIS EXCITING FIELD TO DERIVE NEW IPS LINES ARE CAUGHT BETWEEN HAVING TO LIVE WITH MORE RESTRICTIVE CIRM GUIDELINES. AS YOU KNOW, MANY CALIFORNIA INSTITUTIONS ARE APPLYING OUR CIRM GUIDELINES TO ALL STEM CELL RESEARCH AT THEIR INSTITUTION.

THE STANDARDS WORKING GROUP MET AND SUGGESTED THAT THERE IS NO ETHICAL CONCERN REGARDING IPS CELLS THAT WARRANTS A MORE RESTRICTIVE APPROACH IN THE CIRM GUIDELINES. SO WE THINK THIS IS AN

AMBIGUITY, A HISTORICAL SORT OF ANACHRONISM, BUT IT IS CAUSING SOME CONCERNS AMONG INSTITUTIONS AND RESEARCHERS. SO WE'RE ASKING YOU TO CLARIFY AND REMOVE THOSE AMBIGUITIES.

SPECIFICALLY, THE ISSUES ARE HOW MUCH OVERSIGHT DOES THE INSTITUTIONAL SCRO HAVE TO DO FOR A DERIVATION PROJECT OF NEW IPS CELLS AND, SECONDLY, THE CONSENT TO DONATE SOMATIC CELLS. OUR GUIDELINES ACTUALLY EXCLUDE SOME SOMATIC CELLS THAT WOULD BE PERMITTED UNDER IRB APPROVED PROTOCOLS AND THE FEDERAL COMMON RULE.

NEXT SLIDE. I'LL TRY AND SHOW THIS GRAPHICALLY. ON THE ISSUE OF OVERSIGHT, WE'RE SUGGESTING THAT IF A RESEARCHER WANTS TO DERIVE A NEW IPS LINE, THEY MERELY NEED TO NOTIFY THE SCRO THAT THIS IS HAPPENING. THEY WOULD STILL BE SUBJECT TO ANY IRB REQUIREMENTS FOR DONATION OF CELLS, BUT WE DON'T WANT TO PUT THEM THROUGH A FULL SCRO REVIEW. AND, INDEED, THE NAS GUIDELINES DO NOT REQUIRE FULL SCRO REVIEW.

SECOND ISSUE IS CONSENT FROM THE SOMATIC CELL DONOR, THAT WE'RE ASKING THAT GENERAL CONSENT FOR RESEARCH OR A WAIVER OF CONSENT FROM THE IRB WOULD SUFFICE FOR IPS DERIVATION. OUR REASONING IS THIS IS NOT -- OBTAINING THESE CELLS IS NOT

MEDICALLY OR PHYSICALLY DANGEROUS. IT DOESN'T RAISE THE KINDS OF ETHICAL CONCERN THAT COLLECTING OOCYTES OR EMBRYOS DOES. AND THE RESEARCHERS IN OTHER FIELDS ARE COLLECTING MATERIALS WITHOUT SPECIAL SPECIFIC CONSENT.

WE DO, HOWEVER, SAY THAT, AS OPPOSED TO THE DERIVATIONAL LINES, IF YOU ARE GOING TO HAVE A PROTOCOL ACTUALLY TRANSPLANTING IPS CELLS INTO HUMANS, YOU NEED CONSENT FOR THAT TRANSPLANTATION FROM THE DONORS.

SO SWITCHING TO THE -- DO YOU WANT TO DO THEM ONE AT A TIME, CHAIRMAN KLEIN? SO LET'S GO BACK TO THE LAST SLIDE. SO FOR IPS RESEARCH, WE'RE ASKING YOU TO CLARIFY IN INTERIM REGULATIONS THAT THE SCRO ONLY NEEDS TO BE NOTIFIED FOR IPS DERIVATION, AND THE GENERAL CONSENT FOR RESEARCH, UNSPECIFIED RESEARCH, OR WAIVER OF CONSENT SUFFICES FOR IPS DERIVATION. THESE CHANGES WOULD MAKE US CONSISTENT WITH THE COMMON RULE AS IS ENFORCED BY IRB'S THROUGHOUT CALIFORNIA AND WITH THE NAS STANDARDS AS AMENDED IN MAY 2008.

CHAIRMAN KLEIN: SO WITH THAT, AND THIS HAS GONE THROUGH THE STANDARDS COMMITTEE?

DR. LO: YES. WE UNANIMOUSLY SUGGEST YOUR APPROVAL.

CHAIRMAN KLEIN: SO WHAT I WOULD ASK HERE, UNLESS THERE -- FIRST OF ALL, IF THERE'S ANY DISCUSSION OF THIS; BUT ALSO IN YOUR DISCUSSION, I'D ASK THAT IF THERE IS NO OBJECTION, I WOULD LIKE TO PUT THIS ON THE CONSENT CALENDAR FOR THE MARCH MEETING AFTER TAKING THE SENSE OF THIS GROUP TO SEE IF THERE'S GENERAL CONSENT -- GENERAL SUPPORT FOR THIS.

IS THERE ANY OBJECTION TO PUTTING THIS ON THE CONSENT CALENDAR FOR THE MARCH MEETING?

DR. HAWGOOD: I HAVE JUST ONE QUESTION THAT MAYBE BERNIE OR MAYBE ALAN. THE COMMON CELL FOR THIS IS A FIBROBLAST AND THAT'S EASY. YOU PRESENTED A OR SHOWED US A PAPER WHERE KERATINOCYTES WERE BECOMING A TARGET PERHAPS PREFERRED. DO YOU SUSPECT THAT ANY MORE DIFFICULT TO OBTAIN CELL MAY BECOME A TARGET FOR IPS, AND DOES IT INFLUENCE WHAT WE'RE THINKING HERE?

DR. TROUNSON: YES. AND ALSO I THINK WE EXPLORED THAT WITH THE COMMITTEE. BUT, FOR EXAMPLE, THERE ARE PUBLICATIONS SAYING THAT LIVER CELLS ARE MUCH MORE EFFECTIVE AS CANDIDATE CELLS FOR COMPLETE REPROGRAMMING. SO IT IS POSSIBLE, SAM, THAT A LIVER CELL MAY BE A PREFERRED CELL OR MAYBE ANOTHER CELL COULD BE PREFERRED IN THE LONGER TERM. SO WE

COULDN'T BE CERTAIN ABOUT THAT. BUT LET'S IMAGINE THAT A LIVER CELL MIGHT BE PREFERRED, ALTHOUGH I DON'T THINK THAT IS THE SENSE OF THE FIELD RIGHT AT THE MOMENT.

DR. LO: IF I COULD SORT OF TAKE THE ETHICAL TWISTS ON THAT QUESTION. THAT PROTOCOL WOULD BE REVIEWED BY THE IRB FOR DONATION OF HUMAN MATERIALS. THEY, I ASSUME, WOULD LOOK VERY CLOSELY AT THE MEDICAL RISK AND THE CONSENT PROCESS. WE'RE JUST SAYING WE DON'T WANT TO ADD ON ANY ADDITIONAL SPECIAL REVIEW BECAUSE IT'S GOING TO BE USED FOR IPS RESEARCH AS OPPOSED TO CANCER RESEARCH OR GENETICS RESEARCH. SO WE'RE NOT TAKING AWAY OVERSIGHT. WE'RE JUST NOT ADDING TO WHAT IS IN PLACE AND WHICH WE FEEL AND THE NAS FELT WAS ADEQUATE FOR THIS KIND OF RESEARCH.

DR. AZZIZ: JUST A PROCESS QUESTION, AND I MAY HAVE LOST TRACK. DO WE OR DO WE NOT HAVE A QUORUM?

CHAIRMAN KLEIN: WE DO NOT HAVE A QUORUM. THE QUESTION IS IF THERE'S ANY OBJECTION, IT WOULD NOT GO ON THE CONSENT CALENDAR. IF THERE'S NO OBJECTION, AND THERE APPEARS TO BE GENERAL OVERSIGHT GIVEN IT UNANIMOUSLY WENT THROUGH STANDARDS, AND IF THERE'S NO PUBLIC OBJECTION, I'M GOING TO ASK FOR

PUBLIC COMMENT, WE'D THEN PUT IT ON THE CONSENT CALENDAR FOR MARCH, THEREFORE, SAVING TIME IN MARCH SINCE IT'S BEEN REVIEWED THOROUGHLY AT THE STANDARDS LEVEL AND THERE DOESN'T APPEAR TO BE OBJECTION.

DR. LO: CHAIRMAN KLEIN, COULD I MAKE A CORRECTION? I MISSPOKE. THAT IT WAS UNANIMOUS, BUT WE DID NOT HAVE A QUORUM AT THE SWG, BUT IT WAS THE UNANIMOUS SENSE OF OUR COMMITTEE.

CHAIRMAN KLEIN: WE LOVE THE SPIRIT OF DISCLOSURE. THANK YOU. ANY PUBLIC COMMENT ON THIS ITEM? SEEING NO PUBLIC COMMENTS AND NO OBJECTION, I THINK THE QUESTION HAS BEEN ANSWERED. AND THANK YOU, DR. LOMAX, FOR ALL THE WORK THAT GOES IN BEHIND THE STANDARDS MEETINGS AND WORKING THROUGH THE VERY TECHNICAL ISSUES IN THIS SUBAREA.

DR. LOMAX: COULD I JUST STATE FOR THE RECORD, MR. CHAIRMAN, THAT IT WAS A SENSE OF THE ICOC THAT ALL THE RECOMMENDED LANGUAGE PERTAINING TO THE REGULATIONS THAT DR. LO DESCRIBED IN SECTIONS 100070 AND 100090 WAS THE SENSE THAT WE SHOULD MOVE FORWARD. THOSE WERE WHAT YOU APPROVED. I JUST WANTED TO MAKE CLEAR THAT WE'RE DEALING WITH TWO SETS OF REGULATIONS AND HAVE THAT IN THE RECORD. AND YOU HAVE THAT LANGUAGE BEFORE YOU.

CHAIRMAN KLEIN: DOES ANYONE OBJECT TO

THAT WORDING? SEEING NO OBJECTION, THAT APPEARS TO BE THE PROPER COURSE.

DR. LOMAX: THANK YOU.

DR. LO: SO IF I COULD GO TO THE SLIDE, THE ONE AFTER THE ARROW DIAGRAM. SO THE SECOND ITEM IS THAT WE'RE ASKING YOU TO TAKE ITEMS THAT YOU HAD PREVIOUSLY APPROVED AS INTERIM REGULATIONS AT THE MARCH MEETING, MOVE THEM INTO THE REGULATORY PROCESS AS PROPOSED PERMANENT REGULATIONS. AND THESE REGULATIONS PERTAIN TO EMBRYOS THAT A CIRM RESEARCHER PROPOSES TO USE IN CIRM-FUNDED RESEARCH, BUT THEY WERE ORIGINALLY CREATED FOR IVF PURPOSES, FOR REPRODUCTIVE PURPOSES, BEFORE A CUTOFF DATE, WHICH I'LL SHOW YOU ON A TIMELINE ON THE NEXT SLIDE.

THE TWO SPECIFIC ISSUES IS, FIRST, TO AUTHORIZE THE USE OF EMBRYOS CREATED FROM A GAMETE FOR WHICH THE DONOR WAS PAID IN AN IVF CONTEXT. SO THAT THE GAMETE DONOR GAVE AN EGG OR AN OOCYTE IN AN IVF CONTEXT, SUBSEQUENTLY AN EMBRYO THAT WAS FROZEN WAS DEEMED NOT NECESSARY FOR REPRODUCTIVE PURPOSES BY THE WOMAN OR COUPLE IN IVF, AND THEY WANTED TO GIVE IT TO RESEARCH. THE IDEA WAS THAT BECAUSE THE PAYMENT HAD TAKEN PLACE IN AN IVF CONTEXT AND WAS NOT A PAYMENT FOR DONATION IN A RESEARCH CONTEXT, THAT THE LEGAL OPINION WAS THAT THAT DID NOT

CONTRAVENE PROP 71. AND IT WAS THE DECISION OF THE ICOC, ACTING ON THE RECOMMENDATION OF THE SWG, THAT THIS BE PERMITTED AS AN INTERIM REGULATION.

THE SECOND ISSUE WAS, AS YOU RECALL, WE PUT IN VERY STRINGENT AND CAREFUL REGULATIONS FOR OOCYTE DONATION SPECIFICALLY FOR THE PURPOSE OF RESEARCH. AND, AGAIN, WE WANT TO DRAW A DISTINCTION BETWEEN THAT SITUATION AND THE SITUATION OF DONATING OOCYTES FOR IVF, BUT LATER, USUALLY YEARS LATER, THE EMBRYO THAT WAS CREATED, NOT BEING NEEDED FOR REPRODUCTIVE PURPOSES AND THE COUPLE WANTING TO DONATE IT TO RESEARCH, THAT WE NOT REQUIRE THE HEIGHTENED CIRM CONSENT REQUIREMENTS FOR OOCYTE DONATION IN THAT CONTEXT BECAUSE IT OCCURRED NOT IN A REPRODUCTIVE CONTEXT.

SO IN THE NEXT SLIDE, I'LL SHOW YOU THE TIMELINE. SO WE'RE SAYING THAT BEFORE THE CUTOFF DATE ESTABLISHED AT THE LAST MEETING, 8/13/08, IVF EMBRYOS FROM PAID DONORS MAY BE USED FOR RESEARCH. BECAUSE THE PAYMENT WAS IN THE REPRODUCTIVE CONTEXT, IT COULD NOT HAVE BEEN AN UNDUE INDUCEMENT, IT COULD NOT HAVE LED TO ANY ADVERSE OUTCOMES FOR THE DONOR, PRESUMABLY IN THE IVF CONTEXT THAT CONSENT WAS FULLY OBTAINED. SO THAT'S ONE TIME, 8/13/08, YOUR LAST MEETING, WHEN THAT WAS AN INTERIM REGULATION.

ON THE NEXT SLIDE, FOR THE CONSENT, WE ACTUALLY HAVE TWO DIFFERENT GRANDFATHER TIME DEADLINES. UP UNTIL THE ACCEPTANCE OF THE NAS REGULATIONS AS CIRM INTERIM GUIDELINES, WE SAY ANY EMBRYOS CREATED BEFORE THAT TIME, IF A DONOR EGG OR SPERM WAS USED, THAT DONOR ONLY NEEDED TO HAVE CONSENTED TO RESEARCH IN GENERAL. THEY DID NOT SPECIFICALLY NEED TO CONSENT TO EMBRYO RESEARCH OR EMBRYONIC STEM CELL RESEARCH BECAUSE THAT REALLY WASN'T, WE BELIEVE, THE STANDARD OF CARE AT THE TIME.

NOW, GOING FORWARD -- THE SAME TIMELINE WITH THE GREEN ARROWS. SHOULD BE MY VERY LAST SLIDE. THE TIME PERIOD BETWEEN THAT DEADLINE AND THE 8/13/08 DEADLINE, WE DO REQUIRE THAT THERE BE CIRM-SPECIFIC RESEARCH CONSENT BECAUSE AT THAT TIME OUR GUIDELINES HAD ALREADY BEEN ADOPTED. NOW, THIS, AGAIN, CAME THROUGH SWG. IT WAS PRESENTED TO ICOC. YOU APPROVED THIS WITH PUBLIC INPUT AS INTERIM REGULATION. WE'RE NOW PROPOSING, ASKING YOU AT YOUR MARCH MEETING TO MOVE THIS THROUGH AS A PERMANENT REGULATION, AND THEN START THE REGULATORY PROCESS WITH PUBLIC COMMENT AND FURTHER APPROVAL.

CHAIRMAN KLEIN: OKAY. LET ME CLARIFY THE STATEMENT YOU JUST MADE. YOU'RE ASKING US TO

APPROVE IT AS A PERMANENT REGULATION?

DR. LO: RIGHT. WHAT YOU APPROVED AS AN INTERIM REGULATION AT THE LAST MEETING.

CHAIRMAN KLEIN: AND START THE COMMENT PERIOD.

DR. LO: RIGHT. START THE PUBLIC COMMENT PERIOD.

CHAIRMAN KLEIN: OKAY.

DR. LO: SO, AGAIN, YOU'LL HAVE A CHANCE TO COME BACK TO THIS IN THE CONTEXT.

CHAIRMAN KLEIN: SO WITHOUT OBJECTION, I'D LIKE TO PUT THIS ON THE CONSENT CALENDAR FOR MARCH. ANY PUBLIC OBJECTION? WE KNOW THIS IS A TREMENDOUS AMOUNT OF EFFORT TO PROCESS THESE VERY IMPORTANT RULES.

WE DO HAVE ONE MORE ITEM AFTER THIS THAT'S VERY IMPORTANT AS A DISCUSSION ITEM, BUT I'D LIKE TO THANK REALLY DR. BERNIE LO AND GEOFF LOMAX FOR ALL THE WORK THEY PUT INTO THIS. THANK YOU.

(APPLAUSE.)

DR. LO: I WANT TO AGAIN THANK THE SWG MEMBERS, SEVERAL OF WHOM ARE MEMBERS OF THE ICOC, AND PARTICULARLY TO SHERRY LANSING, MY CO-CHAIR. THANK YOU.

CHAIRMAN KLEIN: SO THE LAST ITEM FOR