

The CIRM Medical and Ethical Standards (MES) regulations, title 17 California Code of Regulations, section 100010, et seq., govern research review and oversight. These provisions apply to all CIRM-funded research. Depending on the nature of the research proposal, the CIRM Grants Administration Policy (GAP), title 17 California Code of Regulations, section 100500 chapter III (D)(1)(b) requires each grantee organization to have a SCRO, ESCRO committee (or equivalent) that must receive notification of or that must review and approve a proposed use of “covered stem cell lines”.¹

This document recommends elements that should be included in SCRO approval letters consistent with the CIRM GAP. These recommendations are provided for guidance only and do not constitute regulatory requirements.

Requirements for Institutional Review and Approval (Section 100070)

Categories of research requiring SCRO review and approval are identified in title 17 California Code of Regulations section 100070. These categories include:

- Research involving the procurement or use of human oocytes
- Research involving the use of human embryos
- Research intended to derive a covered stem cell line
- Research introducing a covered stem cell line to non-human animals or neural progenitor cells to the brain of a non-human animal
- Research introducing a covered stem cell line into a live born human

Recommended Elements of SCRO Approval Letter

CIRM recommends that SCRO approval letters provide the following information:

- A statement of the category(ies) of research proposed.
- A statement of the level of review (full review or expedited review) conducted by the SCRO, and of the outcome (e.g., approved, not approved).
- A statement identifying any other required review of the proposed research (e.g., IRB, IACUC, etc.), the status of such reviews and reference to any approval number(s).
- Identification of each covered stem cell line approved by the SCRO committee pursuant to CIRM regulations, and of any lines for which approval was sought but not given.
- Statement of the effective date of the SCRO approval and its expiration date.
- Additional administrative information

Recommended Elements of SCRO Approval Letter

- Administrative information
- Identify research category
- Identify level of review and outcomes
- Identify any additional required reviews, status and approval numbers
- Identify each covered stem cell line approved or disapproved
- Dates of approval and expiration

¹ Section III C of the GAP includes CIRM’s public policy requirements for organizations and individuals that receive support from CIRM.
MES FS 2 version 8/27/2008

Model SCRO Approval Letter

Date: 2/27/07

[Administrative Data]

Contact Information: Name and Address of SCRO Chairperson and/or Responsible Person*

Project Title: *Derivation of Disease-Specific hESC Lines & Comparison to Established Lines*

Principal Investigator: Name of PI (if the PI on the approved protocol is not the CIRM-funded PI, then the CIRM-funded PI's name must be included elsewhere on the documentation.)

CIRM Application Number: *RC1-00000-0*

[Identification of Research Category]:

Protocol RC1-0000-0 involves the use of human embryos and the derivation of a covered stem cell line.

[Level of SCRO Review and Outcome]:

Pursuant to Title 17 California Code of Regulations Sections 100070(b) and 100070(c), research may not commence without SCRO committee review and approval. The letter certifies that on February 27, 2008 the SCRO committee reviewed and approved the protocol referenced above.

[Identify Additional Reviews]:

The SCRO committee acknowledges receipt of IRB approval 08-0000-0 protocol entitled "Procurement of Surplus Human Embryos from IVF Clinic," approved 1/1/08 and valid until 1/1/09.

[Identify Approved hESC Line(s), Expiration Date and Signature]

The SCRO approved as "acceptably derived" use of hESC lines H 9, HUES 1 and HUES 14; and did not approve hESC lines H 8 and H 10.

Approval is effective February 2, 2009 and expires February 1, 2011.

Signature of SCRO chairperson

* If a SCRO not directly affiliated with the grantee institution (e.g. another institutions SCRO committee) is utilized, then please identify the name and address of the SCRO committee and the responsible person at the grantee institution.