

CIRM has proposed three categories of changes to the CIRM Medical and Ethical Standards Regulations. Amendments intended: (1) to align MES Regulations with CIRM 2.0 & the revised Grants Administration Policy (GAP), (2) to make the regulations shorter, clearer and easier to implement and (3) to make changes to regulatory review and oversight policy. This memo identifies major changes. An edited copy of the MES regulations with all the currently proposed changes is attached.

1. Amendments intended to align MES Regulations with CIRM 2.0 & GAP Revisions

These amendments are highlighted in green and include the following:

- Page 1, line 63-66: Add the term “human subjects research” as defined by the Federal Common Rule. By adding this term, reference to the Common Rule can be removed from sections 100070.
- Page 1, lines 67-79: Replace the term “institution” with “awardee.” Awardee is defined in the GAP and may also be defined in the MES regulations for clarity. In addition, this term is inserted in various sections of the document.
- Page 2, lines 41-80: Modify section to recognize responsibilities of (1) all awardees and (2) awardees conducting human subjects research or research requiring SCRO oversight.

2. Amendments intended to make the regulations shorter, clearer and easier to implement

- Page 2, lines 82-107: These requirements are contained in the GAP and do not need to be restated here, the GAP will be cited.
- Page 7, lines 49-103: These are requirements of Public Law 103-43; June 10, 1993 sections (a)-(c), which can be referenced by citation.

3. Amendments intended to make changes to regulatory review and oversight policy

- Page 2, lines 32-35: The current language reflects the 2005 National Academies’ Guidelines for Human Embryonic Stem Cell Research. In the 2008 Amendments to the National Academies’ Guidelines for Human Embryonic Stem Cell Research the language was changed. The proposed amendment to the MES regulations is identical to the NAS 2008 Guidelines.
- Section 100070(e): See brief REVIEW AND OVERSIGHT OF ANIMAL STUDIES