

CIRM Stem Cell Grant Regulations

If you would like to be notified when CIRM begins any regulatory action, click here to be added to our Interested Persons List.

Pending Regulations

All documents associated with pending CIRM regulations can be found on the link below.

- [Quick link to pending regulation documents](#)

FAQs for CIRM Awards

CIRM has prepared the FAQs and Primers below to outline the rights and responsibilities associated with CIRM Grants to Potential and Existing Grantees and Licensees

- [Quick link to CIRM Award FAQs](#)

CIRM Regulations:

Chapter 1. Conflicts of Interest

- [\[100000\] - Conflict of Interest Code - CIRM](#)
- [\[100001\] - Definitions for Working Group Conflict of Interest Provisions](#)
- [\[100002\] - Conflicts of Interest - Non-ICOC Members of the Scientific and Medical Accountability Standards Working Group](#)
- [\[100003\] - Conflicts of Interest - Non-ICOC Members of the Scientific and Medical Research Funding Working Group](#)
- [\[100004\] - Conflicts of Interest - Non-ICOC Members of the Scientific and Medical Facilities Working Group](#)

Chapter 2. Scientific and Medical Accountability Standards

- [\[100010\] - Scope of Chapter 2 - Stem Cell Research](#)
- [\[100020\] - Definitions](#)
- [\[100030\] - Activities Not Eligible for CIRM Funding](#)
- [\[100040\] - Institutional Assurance of Compliance](#)
- [\[100050\] - Compliance](#)
- [\[100060\] - SCRO Committee Membership and Function](#)
- [\[100070\] - SCRO Committee Review and Notification](#)
- [\[100080\] - Acceptable Research Materials](#)
- [\[100081\] - Exemption Petition for Lines Derived Prior to November 22, 2006](#)
- [\[100085\] - Use of Fetal Tissue](#)
- [\[100090\] - Additional Requirements for CIRM-Funded Derivation](#)
- [\[100095\] - Additional Requirements for CIRM-Funded Research Involving Oocytes](#)
- [\[100100\] - Informed Consent Requirements](#)
- [\[100110\] - Fairness and Diversity in Research](#)

- [100120] - Record Keeping
- Stem Cell Research Guidance Documents

Chapter 3. Intellectual Property Requirements for Non-Profit Organizations (applicable to grants made before December 17, 2009)

- [100300] - Intellectual Property Requirements for Non-Profit Organizations - Scope
- [100301] - Intellectual Property Regulations - Definitions
- [100302] - Invention Reporting Requirements
- [100303] - Publication Requirements
- [100303] - Publication Requirements - effective July 1, 2013
- [100304] - Biomedical Materials
- [100305] - Patent Applications
- [100306] - Licensing CIRM-Funded Patented Inventions
- 100307 - [Reserved]
- [100308] - Revenue Sharing
- [100309] - Press Release Requirements
- [100310] - March-In Rights

Chapter 4. Intellectual Property and Revenue Sharing Requirements for For-Profit Organizations (applicable to grants made before December 17, 2009)

- [100400] - Intellectual Property and Revenue Sharing Requirements for For-Profit Organizations - Scope
- [100401] - Intellectual Property Regulations - Definitions
- [100402] - Invention and Licensing Reporting Requirements
- [100403] - Publication Requirements
- [100403] - Publication Requirements - Effective July 1, 2013
- [100404] - Publication-Related Biomedical Materials Requirements
- [100405] - Patents
- [100406] - Licensing CIRM-Funded Patented Inventions
- [100407] - Access Requirements for Products Developed by For-Profit Grantees
- [100408] - Revenue Sharing
- [100409] - Press Release Requirements
- [100410] - March-In Rights

Chapter 5. Grants Administration Policies

- [100500] - Grants Administration Policy for Academic and Non-Profit Institutions (for grants made on or after November 2, 2012)
 - [Policy] - Incorporated by 100500

- **[100500] - Grants Administration Policy for Academic and Non-Profit Institutions (for grants made prior to November 2, 2012)**
 - **[Policy] -Incorporated by 100500**
- **[100501] - Grants Administration Policy for For-Profit Organizations**
 - **[Policy] - Incorporated by 100501**
- **[100502] - Definition of California Supplier**
 - **[Policy] - Incorporated by 100502**
- **[100503] - Grants Administration Policy for Clinical Stage Projects**
 - **[Policy] - Incorporated by 100503**
- **[100504] - Grants Administration Policy for Discovery, Translation, and Education Projects**
 - **[Policy] - Incorporated by 100504**

Chapter 6. Intellectual Property and Revenue Sharing Requirements for Non-Profit and For-Profit Grantees

- **Applicable to grants made after September 4, 2018**
 - **CIRM IP FAQ effective September 5, 2018**
- **Applicable to grants made January 27, 2014 to September 4, 2018**
 - **FAQ on Allowable Costs**
 - **The Intellectual Property FAQ**
 - **Revenue Sharing Requirements for For Profits Primer**
 - **Revenue Sharing Requirements for Non-Profits Primer**
 - **Responsibilities of an Exclusive Licensee Primer**
 - **CIRM Access Plan Review Process Primer**
 - **Pricing Primer**
 - **March-in Right Primer**
- **Applicable to grants made before January 27, 2014**

Chapter 7. Facilities Grants Administration Policies

- **[100700]- Grants Administration Policy for Facilities and Equipment Grants**
- **[100701] - Grants Administration Policy for Academic and Non-Profit Institutions - Major Facilities Grants**

Chapter 8. Loan Administration Policy

- **[100800] - Loan Administration Policy (for loans made on or after August 29, 2012)**

- Loan Administration Policy incorporated by regulation 100800
- [100800] - Loan Administration Policy (for loans made before August 29, 2012)
 - Loan Administration Policy incorporated by regulation 100800
- [100801] - Intellectual Property Provisions Applicable to Loan Recipients
- [100802] - Risk Premium Alternative - Interim Regulation

Chapter 9. Repository for Induced Pluripotent Stem Cells and Embryonic Stem Cells

- [100900] - Definitions
- [100901] - Application of specific CIRM policies
- [100902] - Ownership of Intellectual Property and Materials
- [100903] - Revenue sharing
- [100904] - Publication

Authority to adopt regulations:

Health & Safety Code Section 125290.40, subdivision (j), permits the ICOC to adopt, amend and rescind rules and regulations to carry out the purposes and provisions of Proposition 71 ("Act") and to govern the procedures of the ICOC. Properly adopted regulations carry the same force and effect as law.

Types of Regulations:

The Act provides two methods for the ICOC to adopt regulations - either "Interim" regulations or permanent regulations adopted pursuant to the California Administrative Procedures Act ("APA").

Prop 71 Interim Regulations.

The ICOC may adopt interim regulations exempted from compliance with the procedures set forth in the APA. The interim regulations are adopted by the ICOC and remain in effect for 270 days unless earlier superseded by regulations adopted pursuant to the APA. (125290.40, subd. (k).) Not every regulation adopted by the ICOC will be preceded by an "interim" version (see below).

Formal APA Regulations.

The ICOC may also adopt regulations pursuant to procedures described in the APA in the same manner as other state agencies. Unless otherwise provided in the regulations themselves, these regulations remain in effect indefinitely or until they are repealed or amended by the ICOC in procedures established by the office of Administrative Law, the agency that implements the APA. (These procedures are described at the OAL website: www.oal.ca.gov.)

The ICOC will approve a draft policy or regulation(s) for submission to the OAL to begin the regulation adoption process. Staff will place the policy or draft regulations in proper form and will make a formal submission to the OAL, called the "OAL Notice." Links to both documents (when completed) can be found in the chart below.

Except in the case of interim and emergency regulations, the APA establishes a formal rulemaking process which includes a minimum

45 day public-comment period. During that period, comments may be submitted to the CIRM in response to the proposed regulation.

How to submit public comments:

You may submit written statements, arguments, or comments relating to the proposed regulation in writing to the CIRM during the comment period specified for each regulation.

Comments may be submitted electronically to the address indicated, mailed to:

CIRM Proposed Rulemaking (indicate the specific proposed regulation, e.g., Conflict of Interest Code)
1999 Harrison Street Suite 1650
Oakland, CA 94162

Consideration of public comment:

The CIRM will consider all relevant material it receives during a Noticed opportunity to comment before adopting, amending, or repealing any regulation, including comments received via FAX and email (Govt. Code §§11346.8, subd. (a); 11340.8, subd. (a).) Responses to comments received during the public comment period will be provided in the final statement of reasons submitted to the office of Administrative Law along with any modifications made to the proposed regulation responsive to the public comments received.

General Questions?

Please contact the CIRM at info@cirm.ca.gov

Source URL: <https://www.cirm.ca.gov/our-funding/cirm-stem-cell-grant-regulations>