

Intellectual Property and Revenue Sharing Requirements for Notice of Awards Executed on or after September 5, 2018 FREQUENTLY ASKED QUESTIONS

General:

[1.] Why have the prior CIRM regulations (10000 to 100611, January 27, 2014) been changed to the current 100650, which incorporates by references the IP Policy?

Answer: Regulation 100650 incorporates by reference the Intellectual Property Policy (“IP policy”), which largely retains the provisions of the earlier regulations – with a few important changes.

One of the goals in the IP policy is to standardize the revenue-sharing obligations for both non-profits and for-profits. Under the new IP policy, Commercializing Entities all share the same revenue sharing formula for royalties from commercialized products as opposed to the prior version which took licensing revenue shares from the Awardees (see [5.] and [6.] below). This reduces the workload on the non-profit CIRM grantees to conform their typical finance calculations to the prior CIRM regulations on licensing revenue as well as the enforcement burden on CIRM with regard to such non-profits. In addition, the revenue-sharing formula has been tested by the for-profit Awardees from 2014 to 2018 and was deemed to be a suitable mechanism to apply to all Awardees.

All citations below reference the Sections of the IP policy incorporated by reference in 100650.

[2.] To whom do the CIRM’s regulation apply?

Answer: Obligations arise both directly and indirectly under the CIRM IP regulation. For instance, access and pricing requirements, and revenue-sharing directly apply to Commercializing Entities. (See Sections VII and VIII). Section III, which governs Publication-Related Biomedical Materials sharing, applies only to Awardees. On the other hand, in order to comply with the CIRM’s regulation, Awardees may also enter into agreements compelling certain other identified entities to engage in specified conduct.

CIRM also regulates other entities by virtue of the fact that an Awardee will not be able to comply with the CIRM regulation unless they require certain actions from others. For instance, Section II.A requires Awardees to enter into agreements with Collaborators and Awardee Personnel to ensure disclosure of CIRM Funded Inventions.

Also, the revenue-sharing obligations in the regulation now apply to any Commercializing Entities regardless of the for-profit or non-profit status of the CIRM Awardee.

Finally, the regulation also requires Awardees and Collaborators to ensure their Exclusive and Non-Exclusive Licensees maintain certain records and report certain types of information to the Awardee to ensure compliance with these regulation. For further discussion about the obligations of Collaborators and other partners, see questions [27] and [28] below.

[3.] Is there a threshold dollar amount below which CIRM’s IP regulation do not apply?

Answer: For Drugs, CIRM’s IP revenue sharing regulation is triggered upon the *first royalty dollar received* after an official notice of Drug allowance in a country with a legitimate drug approval agency. CIRM reserves the right to disclaim a first Sale in non-US, non-EU, non-Japan jurisdictions without suitable clinical data. Other portions of the CIRM IP regulation are triggered upon Awardee accepting the award.

IP Ownership

[4.] Who owns IP developed with CIRM Funding?

Answer: CIRM retains no ownership of CIRM-Funded Inventions or other related intellectual property. See Section V.A. Under U.S. law, generally, ownership of IP follows inventorship. So, unless the inventor enters a contractual or other arrangement to transfer or assign ownership, the inventor will own the invention.

Revenue Sharing Requirements:

[5.] Who has an obligation to share revenues from CIRM-Funded Inventions and CIRM-Funded Technologies with the State?

Answer: Whoever commercializes a product (the “Commercializing Entity”) would have such obligation. This could include Awardees, Collaborators (and their successors and assigns), and any downstream third party. For Drugs, the trigger to link the commercialization of such drug to the CIRM IP regulation is whether such Drug falls under a CIRM-Funded Invention or if such drug used non-public CIRM-Funded data in a regulatory filing or submission. For non-Drug products or services, the scope of application is limited to Awardees, Collaborators or Exclusive Licensees and will trigger if any part of a CIRM Award assists in a commercial endeavor.

The definition of Commercializing Entity is not intended to capture resellers.

[6.] How do I calculate the potential financial obligations I will have to the State if I develop a CIRM-Funded Technology or CIRM-Funded Invention?

Answer: The calculation is dependent on the amount awarded and received.

The entity selling the product will have to share with the state a royalty on commercial revenue as follows: 0.1% per \$1 Million in award funds, for the earlier of ten (10) years or 9x the award amount. Thus, for an \$8 million award, the commercializing entity will owe less than one percent royalty (.8%) on commercial revenue for ten years (unless payments to the State of California reach \$72 million earlier).

[7.] Does a licensee – exclusive or non-exclusive – have revenue sharing obligations?

Answer: The Licensee of any Awardee will be subject to revenue sharing if it becomes a “Commercializing Entity” (see definition in question [5], above). In addition, CIRM expects the Awardee to incorporate the royalty obligation in the license as a pass-through royalty to be paid to the State of California (see question [11]).

[8.] Are the revenue sharing provisions applicable to an Awardee or Collaborator proportional to CIRM’s investment in a project?

Answer: Yes. CIRM has attempted to develop a revenue-sharing scheme which is easy to implement and fair to the taxpayers of California so the revenue sharing provisions are directly proportional to the CIRM award (.1% per \$1 million of funding).

Example #1: Awardee accepts a \$5 million CIRM Grant and patents a discovery resulting from CIRM funding. No funds from other sources were used in the development of the patented invention. The Awardee’s obligation to the inventor is a 10% share. Awardee licenses the invention to a third party and receives \$1.0 million in licensing revenue the first year.

Result: Zero. There is no longer any revenue sharing of licensing revenue for non-profit or for-profit Awardees.

Example #2: Same scenario above, but CIRM's funding represents 40% of the total project costs of \$12.5 million the Awardee used to develop the invention. The third party commercializes a Drug and receives \$5 million of Net Commercial Revenue (as defined in the CIRM Regulation) in the first year of commercial sale.

Result: The State of California receives zero dollars on the licensing revenue received by Awardee. The third party Commercializing Entity shall owe \$ 62,5000 (0.0125*5,000,000) to the State of California. A more detailed example is outlined in question [10].

[9.] Can you explain Regulatory Use in more detail?

Answer: Since the non-profit revenue-sharing in the CIRM IP regulation has been changed so that the CIRM revenue-sharing applies to a Commercializing Entity, CIRM has drafted the regulation to cover situations in which (i) CIRM funded clinical data may not be licensed or (ii) if the Awardee does not include the pass-through CIRM royalty in a license agreement. Therefore the revenue-sharing is either based on inventions or Regulatory Use. Regulatory Use occurs if any party uses non-public CIRM-funded data in a regulatory filing or submission (in the US or any foreign jurisdiction). For example, any pre-clinical data or proprietary manufacturing data in an IND filing would trigger Regulatory Use if any of such information was obtained through CIRM funding.

[10.] How does one calculate the financial obligation to the state in the event a Drug arising from a CIRM-Funded Invention(s) or CIRM-Funded Technology is commercialized?

Answer: The company marketing the product (the “Commercializing Entity”) will have to share with the State of California a royalty on commercial revenue as follows: 0.1% per \$1 Million in award funds, for the earlier of ten (10) years or 9x the award amount. Thus, for an \$8 million award, the commercializing entity will owe less than one percent royalty (.8%) on commercial revenue for ten years or until payments reach \$72 million.

Example 1: StemCures receives a \$10m grant from CIRM, leading to a CIRM-funded invention (with a patent that expires 15 years after first commercial sale). The revenue share rate for a Commercializing Entity is 1% due to the \$10m grant. In the table below, the Royalty column addresses the 0.1% per million obligation and the Blockbuster column addresses the scenario in Section 100650.VIII.A.2 where there is a “blockbuster” provision for Net Commercial Revenue over \$500 million year after the 9x or 10 year obligation has been reached.

Under the 2018 Regulation:

Year	Revenue (millions of \$)	Royalty to CA	Blockbuster (1%) to CA
01	10m	100,000	0
02	20m	200,000	0
03	100m	1m	0
04	200m	2m	0
05	300m	3m	0
06	400m	4m	0
07	500m	5m	0
08	600m	6m	0
09	700m	7m	0
10	800m	8m	0
11	800m	0	3m
12	700m	0	2m
13	600m	0	1m
14	500m	0	0
15	300m	0	0

Total	6,530m	36.3m	6m
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Note that after Year 10, the royalty obligation has ceased but there is the “blockbuster” obligation in Section VIII.A.2.

Example 2: The same chart above apply to StemCures if a “California University” Awardee receives a \$10m grant and StemCures uses data from such grant (whether licensed or not) in its IND filing.

[11.] How should an Awardee inform a Licensee of its obligations to the State of California?

The CIRM regulation has the force and effect of state law. CIRM advises any Awardee licensing CIRM-funded Inventions or Technology to incorporate the revenue-sharing royalty as a pass-through obligation to the State of California. However, even if the obligation is not properly documented in a licensing agreement, this regulation still applies to a Commercializing Entity.

[12.] Is the revenue sharing based on the Grant amount received or awarded.

Answer: The royalty calculation is based on the Grant amount received.

Access and Pricing Requirements:

[13.] What is an “access plan” and when is one required?

Answer: Commercializing Entity must submit a plan to afford uninsured Californians access to a Drug that is developed in whole or in part with CIRM funds. CIRM envisions that such a plan will be similar to “patient assistance plans” already prevalent in the pharmaceutical industry. The plan must be provided within 10 business days following final approval of the Drug by the federal Food and Drug Administration, unless, within that timeframe, the Commercializing Entity seeks an extension from CIRM. The plan is subject to approval by CIRM after a public hearing providing for receipt of public comment.

[14.] Does CIRM prescribe what the elements of the plan must be?

Answer: No. The regulation requires that the plan be “consistent with industry standards” at the time of commercialization. Plans may account for the size of the market and the resources of the Commercializing Entity. In addition, the Commercializing Entity is not responsible for any costs of administering the Drug, any associated costs of medical procedures or protocols for the Drug therapy, or for any costs for attendant care.

[15.] Does the CIRM’s regulation seek to ensure Californians pay a fair price for drugs they helped create?

Answer: Yes. A Commercializing Entity must participate in any applicable California state-wide discount prescription program. A Commercializing Entity must also provide Drugs to publicly-funded purchasers at one of the benchmarks described in CalRx or successor statewide prescription drug discount program. The CalRX benchmarks are:

- (1) Eighty-five percent of the average manufacturer price for a drug, as published by the Centers for Medicare and Medicaid Services.
- (2) The lowest price provided to any nonpublic entity in the state by a manufacturer to the extent that the Medicaid best price exists under federal law.
- (3) The Medicaid best price, to the extent that this price exists under Federal law.

[16.] Do the pricing requirements above apply in all circumstances?

Answer: No. The pricing requirements do not apply to products sold outside of California and only apply to certain Californians who are uninsured or underinsured.

March In Rights:

[17.] Are there circumstances where CIRM will force an Awardee to share CIRM-funded intellectual property?

Answer: In rare circumstances, perhaps. Like the federal government, upon the satisfaction of certain conditions CIRM may intercede in certain circumstances on behalf of the State and grant exclusive or nonexclusive licenses if the Commercializing Entity/Awardee/Collaborator/Exclusive Licensee:

- Fails to make reasonable efforts to achieve practical application of the invention or research data;
- Fails to comply with the access plan;
- Fails to use the data or invention to address a public health emergency declared by the **Governor**.

[18.] What if there is disagreement between the Awardee and CIRM over the exercise of march-in rights?

Answer: Prior to exercising march-in under the very limited circumstances described above, Awardees will be notified of CIRM's intentions and will have at least one year to comply before CIRM exercises its march-in rights, except in the case of health emergencies (which may be exercised at any time). If after this period the parties remain in dispute, the Awardee may appeal to the ICOC.

IP Licensing, Rights and Obligations

[19.] Why is there a definition of CIRM-Funded Technology?

Answer: In 2009, as CIRM began to fund later-stage research (pre-clinical and clinical), we recognized that CIRM was funding the creation of data to advance a potential stem cell therapy, rather than an "invention." The definition of CIRM-Funded Technology was intended to extend the CIRM's IP Regulation to the creation of pre-clinical data, Chemistry and Manufacturing Controls work, and clinical data.

[20.] Does CIRM require an Awardee to obtain prior CIRM approval of strategies to exploit CIRM Funded Inventions and Target CIRM-Funded Technology – whether by license, sale or other form of transfer?

Answer: No. While the CIRM regulation requires an Awardee to take reasonable steps to develop, commercialize or otherwise bring to practical application CIRM-Funded Technologies and Inventions, the regulation neither grants CIRM an ownership interest in these discoveries nor requires CIRM approval of an Awardee's decision whether or not to retain or transfer its interest in these discoveries.

The Awardee controls patent prosecution, choice of counsel, selection of claims and all patent prosecution decisions.

[21.] Does CIRM discourage development of CIRM-Funded Inventions and CIRM Funded Technology through Non-Exclusive Licenses?

A: Not for early stage basic research. In fact, CIRM encourages broad sharing of CIRM-Funded Technology for general research. In the context of licensing arrangements, CIRM encourages development by Awardees via Non-Exclusive Licenses. CIRM believes Non-Exclusive Licenses have the greatest potential in many cases to further develop the scientific field and ensure the broadest benefit across all disease-related research.

If an Awardee elects not to self-develop the fruits of its CIRM-Funded Technology and instead determines that licensing the technology is the best path forward, the Awardee must make commercially reasonable efforts to negotiate Non-Exclusive Licenses, unless (i) it would put the Awardee at a disadvantage with a competitor or (ii) in the case of CIRM DISC (or successor program) the Awardee makes the data publically available. (Section VI.B).

CIRM understands, however, that Awardees engaged in pre-clinical and clinical research may choose to enter into an exclusive license in order to advance a project towards commercialization. For non-DISC Awards, the obligations to negotiate Licenses shall only apply to the Target CIRM-Funded Technology.

[22.] What is Target CIRM-Funded Technology?

Answer: Target CIRM-Funded Technology is a **new** defined term in the Definitions. Since there is an obligation to license CIRM-Funded Technology which is not self-commercialized, our non-profit Awardees, who are not in the business of commercialization, requested a mechanism to easily identify which set of information is required to be licensed. Therefore, CIRM-Funded Technology which is defined as Target CIRM-Funded Technology in any non-DISC Notice of Award shall have the licensing efforts obligations. This does not mean that Awardees shall not attempt to license other CIRM-Funded Technology nor that the CIRM IP regulation does not apply to licenses of other CIRM-Funded Technology.

Please note that Regulatory Use is not bound by licenses and if there is CIRM-Funded Technology, including Target CIRM-Funded Technology, incorporated in a commercialized Drug, the CIRM revenue sharing regulation may apply. See question [11].

In addition, the obligations to negotiate Target CIRM-Funded Technology shall not impact nor override the licensing effort obligations for CIRM Funded-Inventions.

[23.] Do I need to obtain CIRM approval of a license of a CIRM-Funded Invention or CIRM-Funded Technology before execution?

Answer: No. Licensing activities are controlled by CIRM Awardees. The CIRM Awardee is free to identify potential licensees, establish the scope and terms of those licenses, and determine and execute the overall strategy for exploitation of those discoveries as it sees fit. CIRM requires Awardees to report these licensing activities to CIRM so that CIRM is able to monitor the progression of CIRM-funded research and ensure research does not stagnate. Specifically, Section II.C notes that an Awardee who enters into an executed license agreement conveying right in CIRM-Funded Inventions or CIRM-Funded Technology shall notify CIRM in the next Utilization Report and provide a copy of the agreement. However, CIRM encourages Awardees to provide draft agreements to CIRM for review prior to execution in order to give CIRM an opportunity to point out any potential discrepancies with CIRM Regulation.

[24.] In determining whether to license CIRM-Funded Invention and CIRM-Funded Technologies on a non-exclusive versus exclusive basis, what are the factors that an Awardee should consider?

Answer: As stated above, CIRM licensing decisions rest with its Awardees. Remote exceptions exist with respect to circumstances enabling CIRM to exercise its march-in rights, described further below.

An Awardee may elect to enter into an Exclusive License under Section VI.C, which requires the Awardee to:

- 1) Document licensee development and commercialization capabilities;
- 2) Include terms addressing all reasonably anticipated therapeutic and diagnostic uses in the license; and
- 3) Include license terms describing a commercial development plan with appropriate benchmarks, remedies for failure to develop, and grounds for modification or termination.

[25.]: Awardees who elect to enter Exclusive Licenses for a CIRM-Funded Invention or CIRM-Funded Technology are required under Section VI.C.1. to “document the development and commercialization capabilities” of the intended licensee before entering the arrangement. Does this prohibit Awardees from extending such licenses to start up companies and other entities which may not have fully developed capabilities at the time the contract is signed?

Answer: No. The CIRM Regulation does not prohibit Awardees from entering Exclusive Licenses with start up companies or other entities that lack well established development and commercialization capabilities at the time the license is entered. However, an Awardee must document the development and commercialization capabilities of any intended exclusive licensee prior to entering into an Exclusive License and must monitor the Licensee’s compliance and progress with the development plan.

[26.] If an invention arises during the CIRM-Funded Project, does the CIRM regulation attach to that invention?

Answer: As noted in Question [5] above, CIRM’s revenue sharing obligations may apply to certain inventions. The answer depends on when the invention was “conceived” and “reduced to practice.” Similar to Bayh-Dole though narrower, the CIRM’s regulation attaches to “CIRM-Funded Inventions.” That term is defined to reach inventions arising from the CIRM-Funded Project that are *either*:

- Reduced to practice by an Awardee, Awardee Personnel or Collaborator during the Grant (see row 2 in the chart below); *or*
- Conceived by the above individuals during the Grant and reduced to practice by these individuals during the Grant or within 12 months of the close of the Grant. (see rows 1 and 4, in the chart below)

**Scope of CIRM Reach
Conception (“C”) or Reduction to Practice (“RTP”)**

Pre-Grant Period	Grant Period	Post Grant Period		CIRM Reach?
		<12 mos.	>12 mos.	
	C + RTP			Yes
C	RTP			Yes
C		RTP		No
C			RTP	No
	C	RTP		Yes
	C		RTP	No

		C + RTP		No
		C	RTP	No
			C+RTP	No

Research Partners and Non-Exclusive Licensees:

[27.] I will be partnering with other scientists from different institutions in my CIRM-Funded Project. Does the CIRM regulation apply to their research that is conducted as part of the CIRM-Funded Project, as well?

Answer: As stated in Question 2, obligations arise both directly and indirectly under the CIRM’s regulation. Obligations relating to access plans and pricing (Section VII) specifically apply to Commercializing Entities. Other obligations directly apply only to CIRM Awardees (Section IV.); however, the Awardee will be required to enter into appropriate agreements with those whose cooperation is required for the Awardee to comply with its obligations. The applicability of the CIRM’s regulation will depend on whether the scientist involved falls within the definition of a Collaborator, Awardee Personnel, an Exclusive or Non-Exclusive Licensee as defined in Section I.

If the partnering scientist licenses any CIRM Funded Technology or CIRM Funded Inventions after the close of the Grant, the scientist may still have the obligations set forth above in Question 2. (See Answer to Question 28, below.)

[28.] Do Collaborators and non-exclusive Licensees have obligations to CIRM?

Answer: A Collaborator is subject to the access and march-in requirements. Awardees must structure their licenses, collaboration agreements and all other arrangements for performing the funded work in a way that permits the Awardee to fulfill its obligations (including reporting obligations) to CIRM. In addition, our Awardees must structure their agreements with licensees to ensure that the Awardee will be able to fulfill its various obligations to CIRM (such as reporting). If the Collaborator or non-exclusive Licensees become a Commercializing Entity then they shall have revenue-sharing obligations.

Mergers and Acquisitions:

[29.] What happens in the event an Awardee merges with or is acquired by another entity?

Answer: The obligations of this regulation will follow to the new entity.

Publication-Related Biomedical Materials Requirements:

[30.] What is required of a researcher when the results of a CIRM-Funded Project are published?

Answer: In certain circumstances an Awardee will be required to share materials with other California researchers. This requirement embodies a condition often found in scientific journals.

When an Awardee publishes a scientific paper describing tangible research material of biomedical relevance first produced in CIRM-funded research, such materials must be shared for research purposes for free or at actual cost (exclusive of costs for overhead, research, discovery or other non-direct costs of

providing the materials) to a requestor in California within 60 days. The requirement applies where the publication occurs in a Scientific Journal or in connection with a scientific meeting.

With prior approval from CIRM, an Awardee's obligations to share materials may cease when the materials are made broadly commercially available. In addition, CIRM may provide alternatives to this requirement upon satisfaction of certain conditions. Finally, in lieu of this requirement, an Awardee may provide requestors with the information necessary to reconstruct or obtain identical material. (See Question 32)

[31.] I am in the business of selling iPS screening tools. If the research material I publish is such a screening tool, am I compelled to give away for free the material even though this would drastically undermine my business?

Answer: No. The regulation is not intended to require a business to give away all of its product for free. Instead, and with prior approval from CIRM, an Awardee's obligations to share materials cease when the materials are made broadly commercially available.

[32.] Are there ways to address alternatives to the sharing requirement that meet CIRM's goal of encouraging access to CIRM-Funded Technology?

Answer: Yes. CIRM may approve alternatives if:

- The financial burden becomes onerous;
- The material or its transfer could pose a public health risk;
- The request is otherwise inappropriate, as determined by the CIRM.

In addition, in lieu of sharing, an Awardee may provide the requestor with the information necessary to reconstruct or obtain the material.

With CIRM's prior approval, the obligations to share cease when the materials are broadly commercially available.

Finally, there is no obligation to share third party materials described in publications such as raw materials used to develop the published biomedical material, or materials covered by third party IP rights.

[33.] Does the sharing requirement apply to *all* materials developed as a result of a CIRM-Funded Project?

Answer: No. The term "Publication-Related Biomedical Materials" is defined in Section I.CC. Among other qualifications, only materials first produced in the course of CIRM-funded research and described in a published scientific paper come within the scope of the sharing requirement.

Publication:

[34.] If I wish to publicize the results of CIRM-Funded Project, do I have obligations to CIRM regarding the content or timing of those publications?

Answer: CIRM imposes no restrictions on the publishing schedule of research results or its contents. That said, in the event there is publication in a scientific journal or an abstract in connection with a meeting, (regardless if by Awardee, a Collaborator etc.) of a CIRM-Funded Invention or CIRM-Funded Technology, within 60 calendar days of such publication, Awardees shall notify CIRM of the Grant Number, Awardee Institution, Principal Investigator and the PubMed Central identification number for the manuscript. In addition, Awardees shall provide CIRM with a short paragraph, written for the general public, describing both the importance of the discovery that is the subject of the publication and the approach or methodology employed. In addition, such articles must acknowledge CIRM funding. Finally, Awardees must provide notice in advance of press releases discussing CIRM-Funded Technology. This requirement does not extend to third parties that are not funded by CIRM.

An Awardee must ensure that the final abstract or manuscript includes the URL of a website where a Materials Transfer Agreement (or similar document) can be accessed to facilitate requests for these materials.

[35.] Is an Awardee *required* to publish?

Answer:

The CIRM regulation does not contain an explicit publication requirement. The Agency respects the ability of Awardees to determine what and when to publish. Nonetheless, sharing useful scientific advances is helpful to advance the field of stem cell and regenerative medicine research and CIRM's mission. Hence, Section VI.A requires Awardees to make "reasonable efforts" to bring CIRM-Funded Inventions and CIRM-Funded Technology to practical application. Publication is one possible and reasonable means of making such inventions and technologies publicly available for DISC awards (see Section VI.B) and thereby discharging the obligation to negotiate licenses for third party development of the invention or technology.