

Intellectual Property and Revenue Sharing Requirements for Notice of Awards Executed on or after January 27, 2014 FREQUENTLY ASKED QUESTIONS

General:

[1.] Which set of intellectual property regulations apply?

The answer depends on whether the Awardee has a Grant or a Loan.

All Grants with a Notice of Grant Award executed on or after January 27, 2014, are governed by sections 100600-100611.

For Notice of Loan Awards executed after December 17, 2009, sections 100600-100611 (“Chapter 6”) apply, EXCEPT Sections 100602(c)(3) and (5) and 100608 (Revenue Sharing).

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

Answer: Obligations arise both directly and indirectly under CIRM’s regulations. For instance, access and pricing requirements directly apply to Awardees, Collaborators and Exclusive Licensees. (See section 100607). Section 100604, which governs Publication-Related Biomedical Materials sharing, applies only to Awardees and Loan Recipients. On the other hand, in order to comply with CIRM’s regulations, Awardees (and Loan Recipients) must enter agreements compelling certain other identified entities to engage in specified conduct.

CIRM also regulates other entities by virtue of the fact that an Awardee or Loan Recipient will not be able to comply with CIRM’s regulations unless they require certain actions from others. For instance, section 100602(a) requires Awardees to enter into agreements with Collaborators and Awardee Personnel to ensure disclosure of CIRM Funded Inventions.

In addition, all intellectual property regulations in Chapter 6 apply to Loan Recipients (see Section 100801) except for the reporting obligations and revenue sharing obligations described above in Answer 1.

Finally, the regulations also require 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 regulations. For further discussion about the obligations of Collaborators and other partners, see questions {25} and {26} below.

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

Answer: CIRM’s IP regulations are triggered upon the *first CIRM dollar received*. However, certain provisions of the regulations apply only after given monetary thresholds or other conditions are satisfied. For instance, the licensing revenue sharing obligations of Section 100608 apply only after the Awardee receives \$500,000 in revenues from their license, after certain deductions (see Footnote 1 identifying deductions).

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 100605(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: Awardees, Collaborators (and their successors and assigns), and “Commercializing Entities.” A Commercializing Entity is a For-Profit Awardee, its Collaborator, or its licensee that sells, offers for sale or transfers a Drug, product(s) or service(s) resulting in whole or in part from CIRM-Funded Research.

[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 a number of factors with the main trigger being the status of the Awardee, whether a Non-Profit or a For-Profit.

The first question to consider is whether the entity is a non-profit organization or a for-profit organization? If the Awardee is a non-profit, the Awardee would be required to share either 15% or 25% of the licensing revenue (depending upon whether CIRM has funded 50% or more of the total costs of the project) it receives when it out-licenses a CIRM-funded invention or technology and the licensing revenue exceeds \$500,000.¹ For instance, if an awardee receives \$1 million in licensing revenue and CIRM has funded 50% of the total project costs, the State would receive \$125,000 (25% of \$500,000). Conversely, if CIRM has funded less than 50% of the total project costs, the State would receive \$75,000 (15% of \$500,000).

While a for-profit Awardee is also subject to the licensing revenue formula above, the sharing of licensing revenue will cease once a product is marketed in California. Once that happens, the Awardee will no longer have to share licensing revenue, and instead the company 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 reach \$72 million earlier).

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

Answer: It depends. If the Awardee is a Non-Profit, the answer is No. On the other hand, the Licensee of a For-Profit CIRM awardee will be subject to revenue sharing if it becomes a “Commercializing Entity” (see definition in answer 5, above).

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

Answer: CIRM has attempted to develop a revenue-sharing scheme which is easy to implement and fair to the taxpayers of California.

An Awardee or Collaborator must share 15% or 25% of the Awardee’s revenue from the license, depending on the level of CIRM’s contribution to the Project. If CIRM funds at least half the Project costs, then the State is entitled to 25% of the Awardee/Collaborator’s licensing revenue. If CIRM funds less than half the project costs, the State’s share is 15%.

¹ Licensing Revenue does *not* include additional grants, loans and other research funding. In the case of a For-Profit Awardee, it also does not include payments received for development milestones and upfront payments.

Finally, revenue sharing is not triggered until after the Awardee or Collaborator receives \$500,000 in licensing revenue.

Example #1: *Awardee accepts a \$5 million CIRM Grant and patents a discovery resulting from the CIRM-Funded Research. 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: After deducting the inventor’s share of \$100,000, CIRM receives 25% of the Awardee’s share in excess of \$500,000 (\$900,000 less \$500,000) regardless of whether the license was an Exclusive or Non-Exclusive License, which would be \$100,000 (.25 * 400k).

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.*

Result: The state receives 15% of the licensing revenue, or \$60,000 (.15 * 400k).

[9.] Does further grant funding from another source count as “Licensing Revenue” which the Awardee must share with the State?

Answer: No. See Footnote 1.

[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: If the original CIRM Awardee is a non-profit, it will be required to share Licensing Revenue it receives as outlined in Question [8].

While a for-profit awardee is also subject to the licensing revenue formula above, the sharing of licensing revenue will cease once a product is marketed in California. Instead the company marketing 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 reach \$72 million earlier).

Example: 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.

Under the 2014 Regulations:

Year	Revenue (millions of \$)	Royalty to CA	Blockbuster (1%)
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

Note that after Year 10, the royalty obligation has ceased but there is a separate blockbuster obligation that is defined further in Section 100608(b)(2).

Access and Pricing Requirements:

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

Answer: Awardees, Collaborators and their Exclusive Licensees 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 Awardee, Collaborator or Exclusive Licensee seeks an extension from CIRM. The plan is subject to approval by CIRM after a public hearing providing for receipt of public comment. This obligation does not apply to non-exclusive licensees.

[12.] 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 Awardee/Collaborator/Exclusive Licensee. In addition, the Awardee/Collaborator/Exclusive Licensee 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.

[13.] Do CIRM’s regulations seek to ensure Californians pay a fair price for drugs they helped create?

Answer: Yes. Awardees, Collaborators and Exclusive Licensees, and their successors and assigns, must participate in the CalRx program and provide a Drug, the development of which was in whole or in part the result of CIRM-Funded Research, to those eligible at the CalRx prices. Awardees/Collaborators/Exclusive Licensees must also provide Drugs to publicly-funded purchasers at one of the benchmarks described in CalRx. The 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.

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

Answer: No. The pricing requirements above apply only if the product is self-commercialized by the Awardee/Collaborator or Exclusive Licensee, and their successors and assigns. Also, the pricing requirements do not apply to products sold outside of California and only apply to certain Californians who are uninsured or underinsured.

[15.] Does a Non-Exclusive Licensee have to abide by the access and pricing provisions of section 100607?

Answer: No. The access and pricing provisions of section 100607 apply *only* to Awardees, Collaborators and Exclusive Licensees (and their successors and assigns). See above for further discussion of the important elements of the access and pricing provisions.

March In Rights:

[16.] 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 (including failure of the Awardee/Collaborator/Exclusive Licensee to cure) CIRM may intercede in certain circumstances on behalf of the State and grant exclusive or nonexclusive licenses if the Awardee/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**.

[17.] 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

[18.] 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 CIRM's IP regulations (Chapter 6) to the creation of pre-clinical data, Chemistry and Manufacturing Controls work, and clinical data.

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

Answer: No. While CIRM's regulations require an Awardee to take reasonable steps to develop, commercialize or otherwise bring to practical application CIRM-Funded Technologies and Inventions, the regulations neither grant CIRM an ownership interest in these discoveries nor require 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.

[20.] 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 Research 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 Research 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 it would put the Awardee at a disadvantage with a competitor or if necessary to provide economic incentive to commercialize invention. (Section 100606(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.

[21.] 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 100602, subdivision (c)(4), states an Awardee “must report to CIRM the execution of all Exclusive License Agreements, Non-Exclusive License Agreements, Material Transfer Agreements or Collaborative Agreements conveying rights in CIRM-Funded Inventions or CIRM-Funded Technology.” 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 Regulations.

[22.] In determining whether to license CIRM-Funded Technologies and intellectual property 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 100606(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

[23.]: Awardees who elect to enter Exclusive Licenses for a CIRM-Funded Invention or CIRM-Funded Technology are required under Section 100606(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 IP regulations do 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.

[24.] If an invention arises during the CIRM-Funded Research, do CIRM’s regulations attach to that invention?

Answer: In addition to CIRM-Funded Technology (in Question 18 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, CIRM’s regulations attach to “CIRM-

Funded Inventions.” That term is defined to reach inventions arising from CIRM-Funded Research 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:

[25.] I will be partnering with other scientists from different institutions in my CIRM-Funded Research. Do CIRM’s regulations apply to their research that is conducted as part of the CIRM-Funded Research, as well?

Answer: As stated in Question 2, obligations arise both directly and indirectly under CIRM’s regulations. Regulations relating to access plans and pricing (100607) specifically apply to Awardees, Collaborators

and Exclusive Licensees. Other regulations directly apply only to CIRM Awardees (100604); 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 CIRM's regulations 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 100601.

As stated in Question 2, if the partnering scientist licenses any CIRM Funded Technology or CIRM Funded Inventions after the close of the Grant, the scientist may have the obligations set forth above in Question 2, except the revenue sharing requirements of section 100608, which apply only to Awardees and Collaborators. (See Answer to Question 26, below.)

[26.] Do Collaborators and non-exclusive licensees have obligations to CIRM?

Answer: A Collaborator is subject to the revenue sharing and access 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). Non-Exclusive Licensees are not subject to revenue sharing (§ 100608) or the access and pricing requirements (§ 100607).

Mergers and Acquisitions:

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

Answer: The obligations of these regulations will follow to the new entity.

Publication-Related Biomedical Materials Requirements:

[28.] What is required of a researcher when the results of CIRM-Funded Research 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 Q30)

[29.] 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 regulations are 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.

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

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.

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

Answer: No. The term "Publication-Related Biomedical Materials" is defined in Section 100601, subdivision (ff). 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:

[32.] If I wish to publicize the results of CIRM-Funded Research, 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 Research. 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.

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

Answer:

The IP regulations do 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 100606(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 (see Section 100606(b)) and thereby discharging the obligation to negotiate Non-Exclusive Licenses for third party development of the invention or technology. (This is in contrast to the expectation to license in some circumstances, as described above in Question 20.)