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## M E M O R A N D U M

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**TO:** Intellectual Property and Industry Subcommittee

**FROM:** Elona Baum, Matt Plunkett, Scott Tocher

**SUBJECT:** Proposed Amendments to IP Regulations – Revenue Sharing and Definitions

**DATE:** May 31, 2012 – Revised June 19th, 2012

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### I. Background:

Attached are a set of proposed amendments to the Intellectual Property and Revenue Sharing Requirements for Non-Profit and For Profit Grantees Title 17, California Code of Regulations Sections 100601 (definitions) and 100608 (revenue sharing).

Under CIRM's regulations, there are two revenue sharing provisions. Section 100608(a) requires Grantees and Collaborators to share 25% of their licensing revenue in excess of 500,000. This rate is reduced in accordance with the proportional share of CIRM funding which contributed to the licensed invention and technology as compared to the total project costs incurred during the project period (the "Proportionality Reduction"). The other revenue sharing provision is set forth in section 100608(b). It provides that Grantees and Collaborators must share revenues resulting from CIRM Funded Research as follows: after revenues exceed \$500,000, three times the grant award, paid at a rate of 3% per year, plus upon earning \$250M in a single calendar year, a onetime payment of three times the award, plus upon earning revenues of \$500M in a single calendar year, an additional onetime payment of three times the award and finally in the instance where a patented CIRM Funded Invention or CIRM Funded Technology contributed to the creation of Net Commercial Revenue greater than \$500M in a single calendar year, and where CIRM awarded \$5 million or more, an additional 1% royalty on revenues in excess of \$500 million annually over the life of the patents.

The one time payments triggered at \$250 million and \$500 million in annual revenues, create an uneven payment obligation which is characterized as being "lumpy" and could be a disincentive for the engagement of industry. In addition, the Proportionality Reduction provided for in Section 100608(a) creates administrative challenges and uncertainty. The following proposed amendments seek to address these issues while at the same time ensuring a comparable economic return to California.

SB 1064, which was enacted by the Legislature in 2010 with CIRM's support, codified the revenue sharing formulas into law. In recognition of the relatively early stage of the research and need to partner with industry in order to commercialize CIRM-funded discoveries, SB 1064 authorized CIRM's Governing Board to modify the formulas if it determined that it was necessary to do so either to ensure that research and therapy development are not unreasonably hindered as a result of CIRM's regulations or to ensure that the State of California has an opportunity to share in the revenues derived from such research and therapy development. The proposed amendments re-strike the balance both to ensure that industry will partner with CIRM and to ensure that the State has the opportunity to benefit from successful therapy development.

<sup>1</sup>. Following posting of this Memorandum on May 31, 2012, non-substantive, technical edits were made to the last bullet of this Memorandum (p.2) as follows: (i) changed Net Commercial Sales to Net Commercial Revenue (the term used in the proposed amendment) and (ii) consistent with the proposed amendment, eliminated reference to "patented CIRM Funded Technologies" which appeared at the end of the bullet (note: from a practical perspective, patented CIRM Funded Technologies would fall within definition of CIRM Funded Inventions.)

## II. Objectives

The proposed amendments:

- Smooth out payment obligations in order to facilitate industry investment and engagement in CIRM programs which, in turn, will leverage CIRM's funding and provide access to industry know how
- Extend the revenue sharing obligations to commercializing entities to ensure the State realizes revenues from successful therapy development
- Simplify the proportionality calculation relating to CIRM's existing licensing revenue sharing regulation
- Maintain the existing revenue sharing scheme as it pertains to non-profit grantees (except with respect to the simplification of the licensing revenue sharing proportionality calculation)
- Maximize the amount of funding that companies can re-invest in product development, by exempting pre-commercial revenues from CIRM's revenue sharing
- Maintain the requirement that funds generated from CIRM's revenue sharing regulations are deposited in the California's General Fund

## III. Proposed Changes

### Licensing Revenue Sharing (Section 100608(a)):

- The amendments to section 100608(a) simplify the calculation of the Proportionality Reduction. Instead of tracking dollar for dollar other funding sources to determine the proportionality of CIRM funding for a given invention, the amendments provide that in the event that CIRM funds 50% or more of a CIRM Funded Project then the State of California will receive 25% of the Grantee's licensing revenue which rises from the licensing of CIRM Funded Technology (e.g. data) or CIRM Funded Inventions resulting in whole or in part from the CIRM Funded Project. In the alternative, if CIRM funded less than 50% of the Project, the State will receive 15% of the Grantee's licensing revenues.
- By virtue of an amendment to the definition of Licensing Revenue, For-Profit Grantees will not be required to share pre-commercial revenues such as upfront payments and development milestone payments. This is consistent with recent amendments to the Loan Administration Policy which recognize that pre-commercial revenue is akin to a payment in arrears for prior investments.
- For-Profit Grantees and Collaborators will be required to share licensing revenues with California which, for example, arise from the licensing of methods, but in order to avoid double payments arising from the same income stream, For-Profits will not have an obligation to share with CIRM any royalty income they receive if CIRM is receiving a royalty on the same revenue stream from a Commercializing Entity pursuant to section 100608(b).

### Royalty on Net Commercial Sales (Section 100608(b)):

The "self-commercialized" revenue provisions of the current regulatory scheme are revised to smooth out the payment obligation and to extend the obligation to commercializing entities. This provision will apply to commercial sales revenues (not licensing revenues) received by a "Commercializing Entity" to the extent the CIRM funded Drugs, products or services resulted in whole or in part from CIRM grants to a For-Profit Grantee. It amends the revenue sharing formula as follows:

- Sets the rate of payout owed to California to one-tenth of one percent (0.1%) per one million dollars (\$1Million) in Grants provided to For-Profit Grantee(s) for the lesser of (i) 10 years or (ii) nine times (9x) the Grant; and

- Includes a follow on 1% royalty where Net Commercial Revenue exceed \$500 million per year and where CIRM grant(s) aggregate more than \$5 million and involve a patented CIRM- Funded Invention.

1 Amend 17 Cal. Code of Regs. section 100601 to read:

2 **§ 100601. Intellectual Property Regulations - Definitions.**

3 The following definitions apply to the regulations in this chapter:

4 (a) Authorized Organizational Official. The individual, named by the applicant  
5 organization, who is authorized to act for the applicant organization and to assume the  
6 obligations imposed by the laws, regulations, requirements, and conditions that apply to  
7 applications and awards.

8 (b) Budget Period. The intervals of time (usually 12 months) into which a Project Period  
9 is divided for budgetary funding and reporting purposes as specified in the relevant NGA.

10 (c) CIRM-Funded Invention. An Invention, whether patentable or not, which arises from  
11 CIRM-Funded Research and is either:

12 (1) reduced to practice by a Grantee, Grantee Personnel and/or its Collaborator(s) during  
13 a CIRM-Funded Project or Activity; or

14 (2) conceived during a CIRM-Funded Project or Activity and reduced to practice by a  
15 Grantee, Grantee Personnel and/or its Collaborator(s) during a CIRM-Funded Project or Activity  
16 or within 12 months of the close of the Grant.

17 (d) CIRM-Funded Project or Activity. Those activities specified or described in an  
18 Application that are approved by the ICOC for funding and for which CIRM has issued an NGA,  
19 regardless of whether CIRM funding constitutes all or only a portion of the financial support  
20 necessary to carry them out.

21 (e) CIRM-Funded Research. All aspects of work conducted on a CIRM-Funded Project  
22 or Activity that is paid for, in whole or in part, with CIRM funds.

1 (f) CIRM-Funded Technology. Data, materials, research results or know-how whether  
2 patentable or not, that is (1) generated or conceived in the Project Period of a Grant, and is paid  
3 for in whole or in part with CIRM-funds.

4 (g) Collaborator. Any person or entity other than a Grantee and Grantee Personnel who  
5 (1) receives directly or indirectly CIRM funding for work performed under a Grant, and (2) who  
6 obtains any ownership rights to a CIRM-Funded Invention or CIRM-Funded Technology during  
7 the Project Period.

8 (h) Commercializing Entity. A For-Profit Grantee and its Collaborator or Licensee that  
9 sells, offers for sale or transfers a Drug, product(s) or services resulting in whole or in part from  
10 CIRM-Funded Research.

11 (i) Data. Scientific, clinical or technical recorded information derived during the  
12 Project Period of a Grant, regardless of form or the media on which it may be recorded, but not  
13 any of the following: financial, administrative, management data, other information incidental to  
14 contract administration, preliminary analyses, drafts of scientific papers, plans for future  
15 research, peer reviews, or communications with colleagues. “Data” excludes physical objects  
16 (e.g., laboratory samples).

17 (j) Drug. (1) An article recognized in the official United States Pharmacopoeia,  
18 Homoeopathic Pharmacopoeia of the United States, or National Formulary, or any supplement to  
19 any of them; (2) an article intended for use in the diagnosis, cure, mitigation, treatment, or  
20 prevention of disease in humans or animals; or, (3) an article intended for use as a component of  
21 any article specified in subdivision (1) or (2). This term includes therapeutic products such as  
22 blood, blood products and cells, but excludes medical procedures and services relating thereto.

1 |           (k) Exclusive License. A License Agreement that conveys to the licensee the sole right  
2 | to make, use, sell, offer for sale and/or import in one or more fields of use or territories, as to a  
3 | CIRM-Funded Invention or CIRM-Funded Technology, that is not available to be licensed to  
4 | other entities or persons.

5 |           (l) Exclusive Licensee. Any individual or entity receiving by license all rights to make,  
6 | use, sell, offer for sale and/or import in one or more fields of use or territories a CIRM-Funded  
7 | Technology or a CIRM-Funded Invention.

8 |           (m) First Commercial Sale. The date upon which revenue is derived from the sale or  
9 | transfer, but not the licensing or assignment, of a Drug, product or service in the United States or  
10 | member country of the European Union.

11 |           (n) For-Profit Organization. A sole-proprietorship, partnership, limited liability  
12 | company, corporation, or other legal entity that is organized or operated for the profit or financial  
13 | benefit of its shareholders or other owners.

14 |           (o) Grant. A funding mechanism, other than a loan, providing money and/or property  
15 | to an eligible entity to assist the recipient in carrying out all or any portion of a CIRM-Funded  
16 | Project or Activity.

17 |           (p) Grantee. The Non-Profit Organization or For-Profit Organization awarded a Grant  
18 | by CIRM that is legally responsible and accountable for the use of the CIRM funds provided for  
19 | the performance of the grant-supported project or activity. The Grantee is the entire legal entity,  
20 | including Affiliates, even if only a particular division is designated in the Notice of Grant Award  
21 | (“NGA”). An entity is an Affiliate of a Grantee if both entities share substantial common  
22 | direction or control (either directly or indirectly), or if either entity owns (directly or through one

1 or more entities) at least a 25% capital or profits interest in the other. All University of  
2 California Grantee campuses shall be considered as separate and individual Grantees.

3 ~~(q)~~ Grantee Personnel. Grantee's Principal Investigator(s) and Grantee's employees,  
4 students and contractors working under the direct or indirect supervision of the Principal  
5 Investigator or a Co-Principal Investigator under the Grant.

6 ~~(r)~~ Invention. A discovery that is conceived and/or reduced to practice, whether  
7 patentable or not.

8 ~~(s)~~ Inventor. A person who is an inventor under the patent law of the relevant governing  
9 jurisdiction.

10 ~~(t)~~ License Agreement. An agreement by which an owner of a CIRM-Funded Invention  
11 or CIRM-Funded Technology conveys the right to make, use, develop, sell, offer to sell, and/or  
12 import a CIRM-Funded Invention or CIRM-Funded Technology in exchange for consideration.

13 ~~(u)~~ Licensing Activities. Efforts of an owner or Collaborator of a CIRM-Funded  
14 Invention or CIRM-Funded Technology to negotiate, execute or enforce a License Agreement.

15 ~~(v)~~ Licensing Revenue. The consideration received from the license of a CIRM-Funded  
16 Invention or CIRM-Funded Technology (provided however that with respect to a For-Profit  
17 Grantee or For-Profit Collaborator, Licensing Revenue does not include pre-commercial  
18 revenues such as development milestones and upfront payments). Licensing revenue excludes  
19 any additional grants, loans and other forms of research funding obtained to support the Project.

20 Calculation: Revenue is calculated by subtracting a proportion of expenses reasonably  
21 incurred in prosecuting, defending and enforcing related patent rights equal to CIRM's  
22 percentage of support for development of such CIRM-Funded Invention and/or CIRM-Funded

1 Technology from total consideration rendered, except to the extent that such expenses are  
2 recoverable from a third party as provided in Section 100605(c) or otherwise. In the case of non-  
3 profit Grantees and non-profit Collaborators Licensing Revenue is calculated by subtracting  
4 amounts due to the Inventor pursuant to existing institutional policies from total consideration  
5 rendered.

6 ~~rendered to an owner or Collaborator of a CIRM-Funded Invention or CIRM-Funded~~  
7 ~~Technology pursuant to a License Agreement, but excludes subsequent research funding. In the~~  
8 ~~case of Non-Profit Grantees only, Licensing Revenue is calculated by subtracting amounts due to~~  
9 ~~the Inventor pursuant to existing institutional policies from total consideration rendered. For all~~  
10 ~~owners of a CIRM-Funded Invention or CIRM-Funded Technology, Licensing Revenue is~~  
11 ~~calculated by subtracting a proportion of expenses reasonably incurred in prosecuting, defending~~  
12 ~~and enforcing related patent rights equal to CIRM's percentage of support for development of~~  
13 ~~such Invention and Technology from total consideration rendered except to the extent that such~~  
14 ~~expenses are recoverable from a third party as provided in Section 100605(c) or otherwise.~~

15 (w) Material Transfer Agreement (“MTA”). An agreement that governs the transfer of  
16 tangible research material between a Grantee and/or its Collaborator and an individual or entity  
17 (“Recipient”) and defines the rights of the Grantee and the rights and limitations of the Recipient  
18 with respect to the materials and any derivatives therefrom.

19 (x) Net Commercial Revenue. Income from the sale in any country or transfer (; but not  
20 licensing or assignment); of a Drug, ~~or~~ product(s) or services resulting in whole or in part from  
21 CIRM-Funded Research. Net Commercial Revenue excludes the following (as they pertain to  
22 the making, using or selling of products resulting from CIRM-Funded Research):



1 (1) import, export, excise and sales taxes, and customs duties;

2 (2) costs of insurance, packing, and transportation from the place of manufacture to the  
3 customer's premises;

4 (3) credit for returns, allowances or trades; and

5 (4) pre-commercial revenues received in connection with research and development

6 and/or clinical activities, [such as upfront and milestone payments](#).

7 (~~yw~~) Non-Exclusive License. A License Agreement under which the rights transferred or  
8 conveyed in a CIRM-Funded Technology or a CIRM-Funded Invention to the licensee remain  
9 available to be licensed to one or more entities.

10 (~~zx~~) Non-Exclusive Licensee. Any individual or entity that obtains the right to make,  
11 use, sell, offer for sale and/or import in a specific field of use or territory, CIRM-Funded  
12 Technology or a CIRM-Funded Invention, through a Non-Exclusive License.

13 (~~aa~~) Non-Profit Organization. A university or other institution of higher education or  
14 another organization of the type described in 501(c)(3) of the Internal Revenue Code of 1986, as  
15 amended (26 U.S.C. 501 (c)(3)) and is exempt from taxation under 501 (a) of the Internal  
16 Revenue Code (26 U.S.C. 501 (a)) and California Revenue and Taxation Code section 23701d.

17 (~~bb~~) Notice of Grant Award (“NGA”). The document that notifies the Grantee and  
18 others that an award has been made, contains or references all terms and conditions of the award  
19 as well as the Grantee’s and Principal Investigator’s agreement to those terms and conditions,  
20 and documents the commitment of CIRM funds.

21 (~~cc~~) Principal Investigator. The Principal Investigator (“PI”) is an individual  
22 designated by the Grantee to direct CIRM-Funded Research. He or she is responsible and

1 accountable to the Grantee and CIRM for the proper conduct of the project or activity.

2 References herein to “Principal Investigator” include Co-Principal Investigators as well.

3 | (~~dd~~~~bb~~) Project Period. The amount of time over which CIRM funds a a specific Grant.

4 | (~~eee~~) Public Funds. Funds belonging to the State of California or of any county, city,

5 city and county, or other municipal corporation or subdivision thereof, or any public agency

6 therein.

7 | (~~ff~~~~dd~~) Publication-Related Biomedical Materials. Tangible research material of

8 biomedical relevance first produced in the course of CIRM-Funded Research including but not

9 limited to unique research resources (such as synthetic compounds, organisms, cell lines, viruses,

10 cell products, cloned DNA, as well as DNA sequences, mapping information, crystallographic

11 coordinates, and spectroscopic data), as described in a published scientific paper as provided by

12 Title 17, California Code of Regulations, section 100603. Specific examples include specialized

13 and/or genetically defined cells, including normal and diseased human cells, monoclonal

14 antibodies, hybridoma cell lines, microbial cells and products, viruses and viral products,

15 recombinant nucleic acid molecules, DNA probes, nucleic acid and protein sequences, certain

16 types of animals including transgenic mice and other property such as computer programs. This

17 term does not include tangible research material of biomedical relevance that is made

18 commercially available by a Grantee, Grantee Personnel, Licensee or a Collaborator, as

19 determined by CIRM pursuant to Title 17, California Code of Regulations section 100604,

20 subdivision (e).

21 Note: Authority cited: Article XXXV, California Constitution; Section 125290.40(j), Health and

22 Safety Code. Reference: Section 125290.30, Health and Safety Code.

1 Amend 17 Cal. Code of Regs. section 100608 to read:

2 **§ 100608. Revenue Sharing.**

3  
4 ~~(a) Licensing Revenue.~~ (a) A Grantee and Collaborator must share with the State of  
5 California a fraction of Licensing Revenue received under a License Agreement for a CIRM-  
6 Funded Invention, CIRM-Funded Technology, or results of CIRM-Funded Research, as follows:

7 (1) ~~InSubject to subdivision (a)(2) of this regulation and to adjustments made in~~  
8 ~~accordance with the event that CIRM funds at least one half of the total cost of the CIRM-~~  
9 ~~Funded Project resulting in the licensed or transferred CIRM-Funded Invention, CIRM-Funded~~  
10 ~~Technology or results of CIRM-Funded Research, then provisions hereof,~~ the amount owed is  
11 25 percent of Licensing Revenue received in excess of \$500,000 and shall be payable to the State  
12 of California for deposit into the State's General Fund (such payments to be used by the State of  
13 California in a manner consistent with Title 35 United States Code, Section 202, subdivision  
14 (c)(7)). The threshold amount of \$500,000 (in the aggregate) shall be adjusted annually by a  
15 multiple of a fraction, the denominator of which is the Consumer Price Index, All Urban  
16 Consumers, All Items (San Francisco-Oakland-San Jose; 1982-84=100) as prepared by the  
17 Bureau of Labor Statistics of the United States Department of Labor and published for the month  
18 of October 2009, and the numerator of which is such Index published for the month in which the  
19 Grantee accepts the Grant. In the event that CIRM funds less than one half of the total cost of the  
20 CIRM-Funded Project resulting in the licensed or transferred CIRM Funded Invention, CIRM  
21 Funded Technology or results of CIRM-Funded Research then the amount owed is 15 percent of  
22 Licensing Revenue in excess of the threshold amount described above.

1           (2) Notwithstanding the forgoing, in the event that a Commercializing Entity is making  
2 royalty payments pursuant to subsection (c) below, For-Profit Grantees and For-Profit  
3 Collaborators will have no obligation to share with the State of California, any Licensing  
4 Revenues they derive as a result of the same commercial revenue stream.

5           ~~(b) Net Commercial Revenue. (2) If any funding sources other than CIRM (including~~  
6 ~~those of the Grantee or Collaborator, as the case may be) directly contributed to the development~~  
7 ~~of said CIRM-Funded Invention or CIRM-Funded Technology, then the return to the State of~~  
8 ~~California on Licensing Revenue in excess of the threshold amount described in subdivision~~  
9 ~~(a)(1) of this regulation shall be proportionate to the support provided by CIRM, as follows: The~~  
10 ~~amount of CIRM funding of the CIRM-Funded Invention or CIRM-Funded Technology shall be~~  
11 ~~divided by the total of funding provided by all sources, and that fraction shall be multiplied by~~  
12 ~~25. That numeral is the percentage due to the State of California of Licensing Revenue.~~

13           ~~(b) A Commercializing Entity Grantee and Collaborator~~ must share with the State of  
14 California for deposit in the State's General Fund a fraction of ~~any~~ Net Commercial Revenue  
15 that results in whole or in part it receives from ~~a self-commercialized product it commercializes~~  
16 ~~itself and which resulted from its~~ CIRM-Funded Research (regardless of whether a CIRM-  
17 Funded Invention or CIRM-Funded Technology is involved) as follows:

18           (1) ~~A royalty Grantees and Collaborators must pay royalties to the State of California for~~  
19 ~~deposit into the State's General Fund~~ on Net Commercial Revenue ~~exceeding the threshold~~  
20 ~~amount described in subdivision (a)(1) of this regulation. Total payments under this subdivision~~  
21 ~~(b)(1) shall equal and not exceed three times the total amount of the CIRM Grant or Grants that~~  
22 ~~led to the product. The rate of payback of the royalty shall be at a rate of 0.1% per \$1 million of~~

1 ~~CIRM Grant(s) for the earlier of Ten (10) years~~~~three (3) percent of the annual Net Commercial~~  
2 ~~Revenue from the date of First Commercial Sale; or nine times the product.~~

3 ~~(2) In addition, if Net Commercial Revenue from a product commercialized by the~~  
4 ~~Grantee, or Collaborators and which resulted from its CIRM Funded Research exceeds the~~  
5 ~~milestone of \$250 million in any calendar year, a one-time payment of three times the total~~  
6 ~~amount of the Grant(s); (By way of example, Grants totaling \$15 million) awarded shall be paid~~  
7 ~~to the State of California. In addition, if Net Commercial Revenue exceeds the milestone of~~  
8 ~~\$500 million in any calendar year, an additional one-time payment of three times the total~~  
9 ~~amount of the Grant(s) awarded shall be paid to the State of California.~~

10 ~~(3) In addition to any amounts due under any other provision of this regulation,~~  
11 ~~where a patented CIRM Funded Invention(s) or patented CIRM Funded Technology is~~  
12 ~~involved in the achievement of Net Commercial Revenue realized by a Grantee or~~  
13 ~~Collaborator equivalent to or greater than \$500 million in any year, and where a CIRM~~  
14 ~~Grant or Grants amounting to more than \$5 million (in the aggregate) were made in~~  
15 ~~support of CIRM Funded Research that contributed to the creation of Net Commercial~~  
16 ~~Revenue, the Grantee or Collaborator will result in royalty payments of 1.5% of Net~~  
17 ~~Commercial Revenues.) pay the State of California one percent annually of Net~~  
18 ~~Commercial Revenue in excess of \$500 million for the life of any patent covering such~~  
19 ~~patented CIRM Funded Invention or patented CIRM Funded Technology.~~

20 ~~(2) In addition, upon satisfaction of the obligation in subsection (b)(1) above, a~~  
21 ~~1% royalty shall be owed on Net Commercial Revenues in excess of \$500 million per~~  
22 ~~year, until the last to expire patent covering a CIRM Funded Invention, if any, that~~  
23 ~~generates, or plays a role in the generation of, in whole or in part said Net Commercial~~

1 Revenue; provided at least \$5 million in CIRM Grant or Grants were made in support of  
2 such CIRM-Funded Research, CIRM Funded Technology or CIRM Funded Inventions

3 (3) For purposes of subdivision (c) of this section, the royalty rate calculation  
4 shall apply only to Grants made to For-Profit Grantees and which were awarded  
5 subsequent to the effective date of this section, as amended.

6 (4) Royalty payments owed pursuant to this section shall be paid 60 days  
7 following the end of each calendar quarter.

8 (c) Grantees and Collaborators shall include provisions within any license of a CIRM-  
9 Funded Technology or CIRM-Funded Invention ensuring that a Commercializing Entity,  
10 whether a licensee or sub-licensee, directly owes payments to the State pursuant to subdivision  
11 (b) of this Section, where applicable.

12 (d) Revenues due the State according to this Section shall be paid to the California State  
13 Treasurer's Office, Division of Cash Management.

14  
15 Note: Authority cited: Article XXXV, California Constitution; and Section 125290.40(j), Health  
16 and Safety Code. Reference: Section 125290.30, Health and Safety Code.