

1 Adopt 17 Cal. Code of Regs. section 100406 to read:

2 **§ 100406. Licensing CIRM-Funded Patented Inventions.**

3 (a) A Grantee bears responsibility for Licensing Activities including identification of
4 potential licensees, negotiation of license agreements, and documentation of the progress and
5 execution of development under a License Agreement of a CIRM-funded Patented Invention. A
6 Grantee must submit an annual report of these Licensing Activities as described in Title 17,
7 California Code of Regulations, section 100402.

8 (b) If a Grantee elects not to develop a CIRM-funded Patented Invention itself, then it
9 shall make commercially reasonable efforts to negotiate non-exclusive licenses for third party
10 development of such inventions, unless doing so would put the Grantee at a competitive
11 disadvantage with a competitor.

12 (c) A Grantee may negotiate an Exclusive License if exclusivity is reasonably believed
13 by Grantee to be an economic incentive necessary to achieve commercial development and
14 availability of the invention.

15 (1) A Grantee must document the development and commercialization
16 capabilities of any intended exclusive licensee prior to entering into an Exclusive
17 License.

18 (2) A Grantee must include in any Exclusive License terms addressing all
19 reasonably anticipated therapeutic and diagnostic uses for the invention.

20 (3) A Grantee must include in any Exclusive License terms including:

21 (A) a commercial development plan to bring the invention to practical
22 application, including milestones and benchmarks, so that the progress of development
23 can be assessed and monitored;

1 (B) explicit remedies for failure to develop, including modification or termination
2 of an Exclusive License in the event that a licensee is unable to fully develop the rights
3 granted; and

4 (C) explicit grounds for modification or termination, such as failure to use
5 commercially reasonable efforts to meet agreed-upon milestones or benchmarks, failure
6 to negotiate in good faith alternative milestones or benchmarks, and failure to provide
7 access as provided in subdivision (c)(5).

8 (4) A Grantee may negotiate an Exclusive License for a CIRM-funded Patented
9 Invention that is required for commercialization of a Drug, as defined in Title 17, California
10 Code of Regulations, section 100401, subdivision (e), only if the licensee agrees to abide by the
11 provisions of Title 17, California Code of Regulations, section 100407.

12 (5) A Grantee must monitor and annually report to CIRM the performance of an
13 exclusive licensee to ensure that the licensee develops the invention according to the milestones
14 and benchmarks of the commercial development plan.

15 (6) A Grantee must take commercially reasonable action to enforce the terms of an
16 Exclusive License and must promptly report any material breach of an Exclusive License to the
17 CIRM scientific program officer.

18 Note: Authority cited: Article XXXV, California Constitution; Section 125290.40(j), Health and
19 Safety Code.

20 Reference: Section 125290.30, Health and Safety Code.