Adopt 17 Cal. Code of Regs. section 100306 to read:

§ 100306. Licensing CIRM-Funded Patented Inventions.

(a) A Grantee Organization shall assume responsibility for licensing activities including identification of potential licensees, negotiation of license agreements and documentation of development progress for licenses relating to CIRM-funded patented inventions. In licensing CIRM-funded patented inventions, a Grantee Organizations agrees that it shall retain the right to practice the use of its CIRM-funded patented inventions for its non-commercial purposes. A Grantee Organization agrees to make its CIRM-funded patented inventions readily accessible on reasonable terms, directly or through a licensee or licensees, to other Grantee Organizations for non-commercial purposes, upon request from a Grantee Organization. Grantee organizations are required to submit an Invention Utilization Report relevant to CIRM-funded patented inventions on an annual basis.

(b) Grantee organizations shall negotiate non-exclusive licenses of CIRM-funded inventions whenever possible. Nevertheless, grantee organizations may negotiate and award exclusive licenses for CIRM-funded inventions if such licenses are necessary to provide economic incentives required to enable commercial development and availability of the inventions. In due diligence relating to such exclusive licenses, grantee organizations shall document development and commercialization capabilities of the intended licensee, and include terms in the license agreement addressing all relevant therapeutic and diagnostic uses for which the invention is applicable and the licensee agrees to diligently develop.

(c) In exclusive license agreements, grantee organizations shall include terms for commercial development plans to bring the invention to practical application. Such provisions

shall include commercial development milestones and benchmarks so that development can be assessed and monitored.

(d) Grantee organizations shall grant exclusive licenses involving CIRM-funded patented inventions relevant to therapies and diagnostics only to persons that agree to have a plan in place at the time of commercialization to provide access to resultant therapies and diagnostics for uninsured California patients. In addition, such licensees will agree to provide drugs at prices negotiated pursuant to the California Discount Prescription Drug Program (commencing with California Health and Safety Code section 130500, et seq.) to eligible Californians under that program. This regulation is not intended, and this regulation shall not be construed, to preempt any other requirement under state or federal law or regulation that would otherwise require provision of drugs at a lower price than provided hereunder. ~~provide to patients whose therapies and diagnostics will be purchased in California with California funds or fund of any political subdivision of the state the therapies and diagnostics at a cost equal to that resulting from the provisions of Title 42, United States Code section 1396r-8, subdivisions (c)(1)(A) (B) and subdivision (c)(2).~~ The CIRM may make access plans available for review by the ICOC on an annual basis.

(e) Grantee organizations shall monitor the performance of exclusive licensees of CIRM-funded patented inventions to ensure that the licensed invention is developed in a timely fashion. Remedies for failure to develop may include modification or termination of a license by the grantee in the event that a licensee is unable to fully develop the rights granted.

(f) Grantee organizations shall negotiate relevant and specific grounds for modification or termination of the license. Examples would include failure to meet agreed-upon commercialization benchmarks, failure to keep the licensed invention reasonably accessible to

the public for research purposes, and failure to reasonably meet the agreed-upon plan for access to resultant therapies as described in subdivision (d) of this regulation.

(g) Grantee organizations shall monitor the commercial development activities of the licensees to determine compliance with the terms of the license agreement and include reports of monitoring activities annually to the CIRM.

(h) Grantee organizations shall take administrative action to modify or terminate license rights where necessary and report such action to the CIRM.

Note: Authority cited: California Constitution, article XXXV; Section 125290.40, subd.(j), Health and Safety Code.

Reference: Section 125290.30, Health and Safety Code.