

**§ 100606. Licensing and Assignment of CIRM-Funded Inventions and Technology.**

(a) Subject to the provisions of Title 17, California Code of Regulations, section 100610, a Grantee shall make reasonable efforts to develop, commercialize or otherwise bring to practical application CIRM-Funded Technology or CIRM-Funded Inventions.

(b) If a Grantee elects not to develop, commercialize or otherwise bring to practical application a CIRM-Funded Invention or CIRM-Funded Technology itself, then it shall make reasonable efforts to negotiate Non-Exclusive Licenses for third party development of such CIRM-Funded Inventions or CIRM-Funded Technology, unless (1) doing so would put the Grantee at a competitive disadvantage with a competitor, or (2) the Grantee through reasonable means shares or otherwise makes publicly available the CIRM-Funded Inventions or Technology.

(c) A Grantee may negotiate an Exclusive License for a CIRM-Funded Invention or CIRM-Funded Technology if exclusivity is reasonably believed by the Grantee to be an economic incentive necessary to achieve commercial development and availability of the invention.

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

(2) A Grantee must include in any Exclusive License terms addressing all reasonably anticipated therapeutic and diagnostic uses for the CIRM Funded Invention or CIRM-Funded Technology that the licensee is prepared to diligently develop and commercialize. Such terms shall include the following:

(A) a commercial development plan to bring the invention to practical application, including milestones and benchmarks, so that the Exclusive Licensee's progress of development can be assessed and monitored;

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

(C) explicit grounds for modification or termination, such as failure to use commercially reasonable efforts to meet agreed-upon milestones or benchmarks, failure to negotiate in good faith alternative milestones or benchmarks, and failure to abide by subdivision (f) of this regulation.

(d) A Grantee may negotiate an Exclusive License for a CIRM- Funded Invention or CIRM-Funded Technology that is required for commercialization of a Drug, as defined in Title 17, California Code of Regulations, section 100601, subdivision (i), only if the licensee agrees in writing to abide by the provisions of Title 17, California Code of Regulations, section 100607.

(e) Subject to the provisions of Title 17, California Code of Regulations, section 100610, a Grantee bears responsibility for Licensing Activities including identification of potential licensees, negotiation of License Agreements, and documentation of the progress and execution of development under a License Agreement for all CIRM-Funded Inventions or CIRM-Funded Technology. A Grantee must submit an annual Invention Utilization Report describing, among other things, these licensing and/or assignment activities as described in Title 17, California Code of Regulations, section 100602.

(f) In licensing CIRM-Funded Inventions or CIRM-Funded Technology Exclusively or Non-Exclusively, Non-Profit Grantees shall retain the right to practice the use of its CIRM-Funded Inventions or CIRM-Funded Technology and to utilize the same for its non-commercial purposes. A Non-Profit Grantee agrees to make its CIRM-Funded Inventions or CIRM-Funded Technology readily accessible on reasonable terms, directly or through a licensee or licensees or other suitable means, to other Non-Profit Grantees for non-commercial purposes, upon request from a Non-Profit Grantee.

(g) A Grantee must monitor and annually report to CIRM in its Invention Utilization Report the performance of an Exclusive Licensee to ensure that said Licensee performs according to the milestones and benchmarks as described in section 100602, subdivision (c).

(h) A Grantee must take reasonable action to enforce the terms of an Exclusive License and must promptly report any material breach affecting any of the obligations under these regulations of an Exclusive License in writing to CIRM.

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

Reference: Section 125290.30, Health and Safety Code.