D. An Awardee may negotiate a License Agreement for a CIRM- Funded Invention or CIRM-Funded Technology for commercialization of a Drug only if the licensee agrees in writing to abide by the provisions of sections VII and VIII of this policy. The License Agreement shall include language stating the following: "The California Institute for Regenerative Medicine and the State of California are intended beneficiaries of this agreement".

E. In licensing CIRM-Funded Inventions or CIRM-Funded Technology Exclusively or Non-Exclusively, Non-Profit Awardees 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 Awardee 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 Awardees for non-commercial purposes, upon request from a Non-Profit Awardee.

F.An Awardee 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 this policy of an Exclusive License in writing to CIRM.

VII. Access Requirements for Products Developed by Awardees

A. A Commercializing Entity must submit a plan to afford access to a Drug to Californians who have no other means to purchase the Drug. As used in this section, "no other means" means Californians who are not covered by a prescription drug benefit provided by any third-party payer (private or public) covering the particular Drug, and whose family incomes are below 300 percent of the federal poverty level. The access plan must be consistent with industry standards at the time of commercialization accounting for the size of the market for the Drug and the resources of the Commercializing Entity. Commercializing entities shall have the burden of establishing that the proposed access plan satisfies the requirements of this Section.

B. A Commercializing Entity must submit the access plan described above to CIRM within 10 business days following final approval of the Drug by the federal Food and Drug Administration, unless, within that timeframe, the Commercializing Entity seeks an extension from CIRM. If CIRM grants an extension, the access plan must be submitted no later than 30 business days following final approval of the Drug by the federal Food and Drug Administration.

C. The access plan shall be subject to the approval of CIRM after a public hearing conducted by CIRM that provides for receipt of public comment. CIRM may adopt appropriate procedures to protect proprietary information submitted by Commercializing Entities in connection with said public hearing. Approval shall not be unreasonably withheld. Overall, CIRM shall not require that proposed access plans exceed industry standards for such plans at the time of commercialization in California.

D. Access plans approved hereunder shall make a Commercializing Entity responsible only for providing the Drug itself. Nothing herein shall require the Commercializing Entity to be responsible for any costs of administering the Drug nor for any associate costs of medical procedures or protocols for the Drug therapy, nor for any costs for attendant care.

E. The Independent Citizens Oversight Committee ("ICOC") may waive the requirement to submit an access plan if the ICOC determines, after a public hearing, that in the absence of the waiver, development and broad delivery of the Drug will be unreasonably hindered or that the waiver will provide significant benefits that equal or exceed the benefits that would otherwise flow to the state pursuant to an access plan. To invoke this waiver provision, a Commercializing Entity must deliver a written request to the Chair of the ICOC within 10 business days following final approval of the Drug by the federal Food and Drug Administration, unless the Chair of the ICOC agrees to an extension. The request must be accompanied by materials describing how development and broad delivery of the Drug will be unreasonably hindered by compliance with this section, and/or how the waiver will provide significant benefits that equal or exceed the benefits that would otherwise flow to the state pursuant to an access plan. The request shall be posted on CIRM's website no fewer than ten (10) business days prior to the ICOC's consideration. The ICOC may meet in closed session to review confidential or proprietary material, or other material as allowed by Health and Safety Code section 125290.30, subdivision (d).

F. A Commercializing Entity must provide the Drug in accordance with any applicable statewide discount prescription drug program.

G. A Commercializing Entity must sell a Drug, which resulted in whole or in part from an Award and which is purchased in California with Public Funds at any benchmark price described in the California Discount Prescription Drug Program (commencing with California Health and Safety Code section 130500) or a successor statewide prescription drug discount program.

H. This policy is not intended, and this regulation shall not be construed, to preempt or prevent any other requirement under state or federal law or regulation, or agreement or contract, that would result in selling a Drug at a lower price than provided hereunder.

VIII. Revenue Sharing

A. A Commercializing Entity must share with the State of California for deposit in the State's General Fund a fraction of Net Commercial Revenue as follows:

(1) A royalty on Net Commercial Revenue at a rate of 0.1% per $1 million of CIRM Award(s) utilized for the earlier of ten (10) years from the date of First Commercial Sale of the applicable Drug, product or service, or until such payments equal nine times the amount of the Award(s). (By way of example, Awards totaling $15 million will result in royalty payments of 1.5% of Net Commercial Revenues.)

(2) In addition, upon satisfaction of the obligation in subsection (1) above, a 1% royalty shall be owed on Net Commercial Revenues in excess of $500 million per year until the last-to-expire patent covering a CIRM-Funded Invention, if any, that generates or plays a role in the generation of, in whole or in part, said Net Commercial Revenue; provided at least $5 million in CIRM Award or Awards were made in support of such CIRM-Funded Invention.