Grantee Requirements

	Provision	Summary/Comments
Definition	• YES • 100601 (n)	• Entity that is legally responsible and accountable for the use of CIRM funds provided for performance of grant-supported project • The "600 Series" applies to both For-Profit and Non-Profit Grantees • See also "Grantee Personnel" definition at 100601(o)
Reporting	• YES • 100602(a-c) and (e)	• Grantee Personnel and Collaborators must have a contractual obligation to notify Grantee of any CFI. 100602(a) • Grantees must notify CIRM of CFI using a confidential Invention Disclosure Form. 100602(b) • During Project Period and for 15 years thereafter, Grantee must notify CIRM about patents, contributory funding, licensing and collaboration, revenue generated, and progress toward commercialization relating to a CFI. 100602(a to c) • Grantee must maintain records needed to establish compliance with IP regulations. 100602(e) • CIRM reserves right to audit Grantee and Collaborators. 100602(e)
Publication	• Yes • 100603	• Regulations do not require publication • If publication concerning CFT or CFI occurs, then Grantee must submit a Publication Disclosure Form within 60 days. 100603(a) • Written and oral publications for CFI and CFT must acknowledge CIRM funding. 100603(d)
Materials	• YES • 100604(a-g)	• Grantee must share Publication Related Biomedical Material for research purposes in California at not more than actual cost. 100604(a) • Alternatives and cessation of this requirement may be available under certain circumstances. 100604 (c) and (e) • No obligation to share 3rd party materials 100604 (g)
Patents/Ownership	• YES • 100605 (b and c)	• Grantees may retain or transfer their rights to any CFI, CFT or CFR and to any patent or patent applications relating thereto • Grantees shall costs associated with costs of patent prosecution regarding CFIs, but are not restricted in their right to seek to recover said costs through licensing or otherwise.
Licensing Rights	• YES • 100606(a-h)	• Grantees must make reasonable effort to bring CFT and CFI to practical application. It may do so through various means including self commercialization and licensing. 100606 (a and b) • If Grantee pursues licensing strategy, Non-Exclusive Licenses are preferred, however Exclusive Licenses may be granted under certain circumstances. 100606(b and c) • Exclusive Licenses must contain certain provisions including milestone driven development plan and agreement by Exclusive Licensee to abide by access and pricing requirements of Section 100607. (100606.c.2.A and 100602(d) • Grantees must enforce terms of Exclusive Licenses and must report material breaches of Exclusive License obligations to CIRM. 100606 (h) • Non-Profit Grantees must retain right to practice CFI and CFT despite terms of licenses and must also make CFT and CFI available to other CIRM Non-Profit Grantees for non-commercial purposes. 100606(f)

Access	• YES • 100607 (a-e)	• Grantees commercializing a Drug that resulted wholly or partly from CIRM-Funded research must have a plan allowing uninsured Californians access to the Drug. Plan requirements shall be consistent with industry standards and need not include costs of administering Drug or associated medical procedures. 100607 (a,c, and e).
Pricing	• YES • 100607 (f and g)	• Grantees commercializing a Drug that resulted wholly or partly from CIRM–Funded Research must provide that Drug at a prices as provided in the California Discount Prescription Drug Program. 100607 (f) • Grantees commercializing a Drug that resulted wholly or partly from CIRM–Funded Research which is purchased in California with Public Funds must provide that Drug at a benchmark price described in the California Discount Prescription Drug Program. 100607(g)
Revenue Sharing	• YES • 100608(a-b)	• Grantees must share 25% of Licensing Revenue for CFI, CFT or CFR with State after the first $500,000. 100608 (a). Share of Licensing Revenue due to State will be reduced where funding from other sources directly contributed to development of the CFI or CFT. See calculation at 100608(a)(2). • Grantees who receive Net Commercial Revenue from self-commercializing product which resulted from CIRM-Funded Research must pay royalties to the State as follows: 1) 3X amount of CIRM Grant (payable at 3% of annual Net Commercial Product Revenue; plus if NCR from commercialized product exceeds $250 million, 3X total Grant award; plus if such NCR exceeds $500 million, 3X total Grant award; plus if Grant exceeded $5 million and CFI or CFT is involved in achievement of NCR of $500 million or more in any year, then 1% of NCR above $500 million for life of patent or for 20 years post grant if no patent. 100608 (b)
Press Release	• YES • 100609	• Notify CIRM one day before issuing press release referring to CFR. 100609
March In Rights	• YES • 100610	• CIRM may request Grantees to enter license for CFT or CFI. 100610(a). If Grantee refuses request, CIRM has right to enter license on behalf of Grantee under certain limited circumstances including failure to make reasonable efforts to achieve practical application and failure to provide or comply with an access plan. 100610(b) • Grantee has a one year cure opportunity (100610.e) and may also appeal March-In Notice to ICOC. 100610(f)

Grantee Personnel

	Provision	Summary
Definition	• YES • 100601	• Includes Grantee's Principal Investigator(s) and Grantee's employees, students and contractors working under supervision of the PI. 100601(o)
Reporting	• YES	• Grantee Personnel must have written agreement with Grantee requiring disclosure of any CFI and disclosure of information required in Grantee's reports to CIRM. 100602(a) and (c)(7)
Publication	• NO	• But note that under 100603(d), reporting on CIRM-Funded Inventions or Technology must acknowledge CIRM funding
Materials Sharing	• NO	
Patents/Ownership	• NO	
Licensing Rights	• NO	
Access	• NO	
Pricing	• NO	
Revenue Sharing	• NO	
Press Release	• NO	
March In Rights	• NO	

Collaborator

	Provision	Summary
Definition	• YES • 100601 (g)	• Person or entity that both i) directly or indirectly receives CIRM funding for work on a Grant and ii) obtains any ownership rights to CFI or CFT during the Project Period but excluding Grantee and Grantee Personnel. 100601(g)
Reporting	• YES •	• Written agreement to promptly disclose any CFI to Grantee is required. 100602(a). Written agreement to provide Grantee with information needed for Grantee to comply with its reporting obligations is also required. 100602 (c)(7)
Publication	• NO	• But note that under 100603(d), reporting on CIRM-Funded Inventions and Technology must acknowledge CIRM funding
Materials	• NO	
Patents/Ownership		
Licensing Rights	• NO	
Access	• YES • 100607(a-e)	• Same as Grantee • Collaborator commercializing a Drug that resulted wholly or partly from CIRM-Funded research must have a plan allowing uninsured Californians access to the Drug. Plan requirements shall be consistent with industry standards and need not include costs of administering Drug or associated medical procedures. 100607 (a,c, and e).
Pricing	• YES • 100607 (f and g)	• Same as Grantee • Collaborator commercializing a Drug that resulted wholly or partly from CIRM–Funded Research must provide that Drug at a prices as provided in the California Discount Prescription Drug Program. 100607 (f) • Collaborator commercializing a Drug that resulted wholly or partly from CIRM–Funded Research which is purchased in California with Public Funds must provide that Drug at a benchmark price described in the California Discount Prescription Drug Program. 100607(g)
Revenue Sharing	• YES • 100608(a-b)	• Same as Grantee • Collaborators must share 25% of Licensing Revenue for CFI, CFT or CFR with State after the first $500,000. 100608 (a). Share of Licensing Revenue due to State will be reduced where funding from other sources directly contributed to development of the CFI or CFT. See calculation at 100608(a)(2). • Collaborators who receive Net Commercial Revenue from self-commercializing product which resulted from CIRM-Funded Research must pay royalties to the State as follows: 1) 3X amount of CIRM Grant (payable at 3% of annual Net Commercial Product Revenue; plus if NCR from commercialized product exceeds $250 million, 3X total Grant award; plus if such NCR exceeds $500 million, 3X total Grant award; plus if Grant exceeded $5 million and CFI or CFT is involved in achievement of NCR of $500 million or more in any year, then 1% of NCR above $500 million for life of patent or for 20 years post grant if no patent. 100608 (b)

Press Release	• YES • 100609	• Same as Grantee • Notify CIRM one day before issuing press release referring to CFR. 100609
March In Rights	• YES • 100610(a-e)	• Same as Grantee[1] • CIRM may request Grantees to enter license for CFT or CFI. 100610(a). If Grantee refuses request, CIRM has right to enter license on behalf of Grantee under certain limited circumstances including failure to make reasonable efforts to achieve practical application and failure to provide or comply with an access plan. 100610(b) • Grantee has a one year cure opportunity (100610.e) and may also appeal March-In Notice to ICOC. 100610(f)

[1] Note that in 100610(f), only a Grantee may appeal CIRM decision to issue a March-In Notice to the ICOC. This is the only section of the March-In Rights provision that treats Grantees different than Collaborators. I am not certain that this distinction was deliberate.

Licensee

	Provision	Summary
Definition	• NO	• But see 100601(r) which defines License Agreement as an agreement by which the owner of a CFI or CFT conveys the right to make, use, develop, sell, offer to sell and/or import the CFI or CFT in exchange for consideration.
Reporting	• YES • See 100602(c)(7)	• Written agreement to for licensee provide Grantee with information needed for Grantee to comply with its reporting obligations is required. 100602 (c)(7). Information concerning patents, funding from 3rd party sources, licenses, revenue generated, progress toward commercialization should be included. 100602 (c)(7) • Licensees must maintain records needed to by Grantee to establish compliance with IP regulations. 100602(e)
Publication	• NO	
Materials Sharing	• NO	
Patents/Ownership	• NO	
Licensing Rights	• NO	
Access	• NO	
Pricing	• NO	
Revenue Sharing	• NO	
Press Release	• NO	
March In Rights	• NO	

Exclusive Licensee

	Provision	Summary
Definition	• YES • 100601(k)	• Any individual or entity receiving by license all rights to make, use, sell, offer for sale and/or import in one or more fields of use or territories a CFT or CFT. 100601(k)
Reporting	• YES • 100602(c)(7)	• Written agreement to for licensee provide Grantee with information needed for Grantee to comply with its reporting obligations is required. 100602 (c)(7). Information concerning patents, funding from 3rd party sources, licenses, revenue generated, progress toward commercialization, inter alia, should be included. 100602 (c)(7) • Licensees must maintain records needed to by Grantee to establish compliance with IP regulations. 100602(e)
Publication	• NO	
Materials Sharing	• NO	
Patents/Ownership	• NO	
Licensing Rights	• YES	• Non-Exclusive Licenses are preferred, but Exclusive Licenses for CFI or CFT may be entered by Grantee if exclusivity is reasonably believed by Grantee to be an economic incentive necessary to achieve commercial development and availability. 100606(c) • Exclusive Licenses for a CFI or CFT must contain certain provisions including i) terms addressing all reasonably anticipated therapeutic and diagnostic uses for the CFT or CFI that the licensee is prepared to develop; ii) milestone driven commercial development plan; iii) remedies for failure to develop including modification or termination; and iv) specific grounds for modification or termination. 100606 (c). • Exclusive Licensee must agree to abide by access and pricing requirements of Section 100607. 100602(d) • Non-Profit Grantees must retain right to practice CFI and CFT despite terms of licenses and must also make CFT and CFI available to other CIRM Non-Profit Grantees for non-commercial purposes. 100606(f) • Grantees must enforce terms of Exclusive Licenses and must report material breaches of Exclusive License obligations to CIRM. 100606 (h)
Access	• YES • 100607(a-e)	• Same as Grantee • Exclusive Licensees commercializing a Drug that resulted wholly or partly from CIRM-Funded research must have a plan allowing uninsured Californians access to the Drug. Plan requirements shall be consistent with industry standards and need not include costs of administering Drug or associated medical procedures. 100607 (a,c, and e).

Pricing	• YES • 100607 (f and g)	• Same as Grantee • Exclusive Licensees commercializing a Drug that resulted wholly or partly from CIRM–Funded Research must provide that Drug at a prices as provided in the California Discount Prescription Drug Program. 100607 (f) • Exclusive Licensees commercializing a Drug that resulted wholly or partly from CIRM–Funded Research which is purchased in California with Public Funds must provide that Drug at a benchmark price described in the California Discount Prescription Drug Program. 100607(g)
Revenue Sharing	• NO	
Press Release	• NO	
March In Rights	• YES • 100610(a-e)	• Same as Grantee (but see footnote 1) • CIRM may request Exclusive Licensee to enter license for CFT or CFI. 100610(a). If Exclusive Licensee refuses request, CIRM has right to enter license on behalf of Exclusive Licensee under certain limited circumstances including failure to make reasonable efforts to achieve practical application and failure to provide or comply with an access plan. 100610(b) • Exclusive Licensee has a one year cure opportunity (100610.e) and may also appeal March-In Notice to ICOC. 100610(f)

Successors

	Provision	Summary
Definition	• NO; but see Section 100611	• Under Sec. 100611: Any party that becomes a successor in interest by merger, purchase, assignment or any other means, of a Grantee, Collaborator or Exclusive Licensee regarding a CFT, CFI or CFR assumes all obligations of its predecessor in interest.
Reporting	• Yes, 100602 and 100611	• Under 100611, any party that becomes a successor in interest by merger, purchase, assignment or any other means, of a Grantee, Collaborator or Exclusive Licensee regarding a CFT, CFI or CFR assumes all reporting obligations of its predecessor in interest
Publication	• Yes, 100603 and 100611	• Under 100611, any party that becomes a successor in interest by merger, purchase, assignment or any other means, of a Grantee, Collaborator or Exclusive Licensee regarding a CFT, CFI or CFR assumes all publication obligations of its predecessor in interest
Materials	• Yes, 100604 and 100611	• Under 100611, any party that becomes a successor in interest by merger, purchase, assignment or any other means, of a Grantee, Collaborator or Exclusive Licensee regarding a CFT, CFI or CFR assumes all materials sharing obligations of its predecessor in interest
Patents/Ownership	• Yes, 100605 and 100611	• Under 100611, any party that becomes a successor in interest by merger, purchase, assignment or any other means, of a Grantee, Collaborator or Exclusive Licensee regarding a CFT, CFI or CFR assumes all rights and obligations of its predecessor in interest
Licensing Rights	• Yes, 100606 and 100611	• Under 100611, any party that becomes a successor in interest by merger, purchase, assignment or any other means, of a Grantee, Collaborator or Exclusive Licensee regarding a CFT, CFI or CFR assumes all licensing obligations of its predecessor in interest
Access	• Yes,100607 and 100611	• Under 100611, any party that becomes a successor in interest by merger, purchase, assignment or any other means, of a Grantee, Collaborator or Exclusive Licensee regarding a CFT, CFI or CFR assumes all access obligations of its predecessor in interest
Pricing	• Yes,100607 and 100611	• Under 100611, any party that becomes a successor in interest by merger, purchase, assignment or any other means, of a Grantee, Collaborator or Exclusive Licensee regarding a CFT, CFI or CFR assumes all pricing obligations of its predecessor in interest
Revenue Sharing	• Yes,100608 and 100611	• Under 100611, any party that becomes a successor in interest by merger, purchase, assignment or any other means, of a Grantee, Collaborator or Exclusive Licensee regarding a CFT, CFI or CFR assumes all revenue sharing obligations of its predecessor in interest
Press Release	• Yes, 100609 and 100611	• Under 100611, any party that becomes a successor in interest by merger, purchase, assignment or any other means, of a Grantee, Collaborator or Exclusive Licensee regarding a CFT, CFI or CFR assumes all press release obligations of its predecessor in interest
March In Rights	• Yes, 100610 and 100611	• Under 100611, any party that becomes a successor in interest by merger, purchase, assignment or any other means, of a Grantee, Collaborator or Exclusive Licensee regarding a CFT, CFI or CFR assumes all march-in related rights and obligations of its predecessor in interest

Material Suppliers

	Provision	Summary
Definition	• NO	• But See 100601(u) which defines a Material Transfer Agreement
Reporting	• NO	
Publication	• NO	
Materials Sharing	• NO	• Note that under 100604(g), Grantees have no obligation to share third party materials described in publications of CFR, CFT or CFI. Nor are Grantees required to share Publication-related Biomedical Material covered by 3rd party intellectual property rights.
Patents/Ownership	• NO	
Licensing Rights	• NO	
Access	• NO	
Pricing	• NO	
Revenue Sharing	• NO	
Press Release	• NO	
March In Rights	• NO	

Consultants

	Provision	Summary
Definition	• Maybe	• See 100601(g and o) • Depending on the terms of the governing agreement, a consultant may fall within other defined terms including Grantee Personnel or Collaborator
Reporting	• Maybe	• If terms of the consultancy place the consultant within the definition of a defined class under the Regulations, then see the requirements for that class.
Publication	• NO	
Materials	• NO	
Patents/Ownership	• NO	
Licensing Rights	• NO	
Access	• NO	
Pricing	• NO	
Revenue Sharing	• NO	
Press Release	• NO	
March In Rights	• NO	

Loan Recipients

	Provision	Summary
Definition	• Yes	• Section 100801(a) of the CIRM Loan Administration Regulations identifies certain IP and Revenue Sharing Requirements which apply to Loan Recipients. The Definitions under Section 100601 are relevant to Loan Recipients.
Reporting	• Yes, except for subsections (c)(3) or (c)(5) of Regulation 100602.	Section 100801(a) of the CIRM Loan Administration Regulations identifies certain IP and Revenue Sharing Requirements which apply to Loan Recipients. In essence, Loan Recipients must comply with all such Requirements as if they were the Grantee of a Grant EXCEPT that Loan Recipients are NOT required to comply with Regulations 100602(c)(3) and (c) (5) or with Regulation 100608.
Publication	• Yes	• Section 100801(a) of the CIRM Loan Administration Regulations identifies certain IP and Revenue Sharing Requirements which apply to Loan Recipients. Publication requirements under Section 100603 are imposed on Loan Recipients.
Materials	• Yes	• Section 100801(a) of the CIRM Loan Administration Regulations identifies certain IP and Revenue Sharing Requirements which apply to Loan Recipients. Biomedical material sharing requirements under Section 100604 are imposed on Loan Recipients.
Patents/Ownership	• Yes	• Section 100801(a) of the CIRM Loan Administration Regulations identifies certain IP and Revenue Sharing Requirements which apply to Loan Recipients. The Patent/Ownership rights and requirements under Section 100605 apply to Loan Recipients.
Licensing Rights	• Yes	• Section 100801(a) of the CIRM Loan Administration Regulations identifies certain IP and Revenue Sharing Requirements which apply to Loan Recipients. Licensing rights and obligations requirements under Section 100606 apply to Loan Recipients.
Access	• Yes	• Section 100801(a) of the CIRM Loan Administration Regulations identifies certain IP and Revenue Sharing Requirements which apply to Loan Recipients. Access obligation requirements under Section 100607 apply to Loan Recipients.
Pricing	• Yes	• Section 100801(a) of the CIRM Loan Administration Regulations identifies certain IP and Revenue Sharing Requirements which apply to Loan Recipients. Pricing obligation requirements under Section 100607 apply to Loan Recipients.
Revenue Sharing	• No	
Press Release	• Yes	• Section 100801(a) of the CIRM Loan Administration Regulations identifies certain IP and Revenue Sharing Requirements which apply to Loan Recipients. Press release requirements under Section 100609 apply to Loan Recipients.
March In Rights	• Yes	• Section 100801(a) of the CIRM Loan Administration Regulations identifies certain IP and Revenue Sharing Requirements which apply to Loan Recipients. March-In rights and obligations under Section 100610 apply to Loan Recipients.