Adopt 17 Cal. Code of Regs. section 100401 to read:

§ 100401. Intellectual Property Regulations - Definitions.

The following definitions apply to the regulations in this chapter:

(a) Authorized Organizational Official. The individual, named by the applicant organization, who is authorized to execute agreements that legally bind the applicant institution to assume the obligations imposed by the laws, regulations, requirements, and conditions that apply to Grant applications or Grant awards.

(b) CIRM-funded Patented Invention. An invention that has been patented under Title 35 of the United States Code, and that resulted wholly or in part from CIRM-funded Research, except in the event the patent has expired, been abandoned or found to be invalid or otherwise unenforceable (unless noted otherwise in these regulations).

(c) CIRM-funded Research. Research that has been funded in whole or in part by a CIRM Grant.

(d) Currently Active Grant. A Grant that is still in the Project Period, or that is outside the Project Period but CIRM funds are still being spent on the project, or the repayment of CIRM grant funds remains unsatisfied.

(e) Drug. (1) An article recognized in the official United States Pharmacopoeia, Homoeopathic Pharmacopoeia of the United States, or National Formulary, or any supplement to any of them; (2) an article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; or, (3) an article intended for use as a component of any article specified in subdivision (1) or (2). This term includes therapeutic products such as blood, blood products, cells, and cell therapies.

(f) Exclusive License. A License Agreement for a CIRM-funded Patented Invention that authorizes the licensee to the exclusive exercise of one or more of the rights (or a portion of the rights) belonging to the patent holder under the patent.

(g) For-Profit Organization. A legal entity that is organized for the profit or benefit of its shareholders or owners.

(h) Grant. CIRM funding in the form of a payment to conduct research.

(i) Grantee. A For-Profit Organization that receives a Grant and that is legally accountable for the funds and for the performance of CIRM-funded Research.

(j) License Agreement. An agreement by which the owner of a CIRM-funded Patented Invention allows a licensee to commercially use or develop the CIRM-funded Patented Invention in exchange for financial or other consideration.

(k) Licensing Activities. Efforts of a Grantee to execute or enforce a License Agreement.

(l) Material Transfer Agreement ("MTA"). An agreement that governs the transfer of tangible research material between organizations and defines the rights of the providor and the recipient with respect to the materials and any derivatives.

(m) Net Licensing Revenue. Gross revenue derived from a License Agreement minus the direct costs incurred in the prosecution and protection of a CIRM-funded Patented Invention.

(n) Net Commercial Revenue. Income from commercial sales of a product(s) resulting from CIRM-funded Research. Net Commercial Revenue excludes the following (as they pertain to the making, using or selling of products resulting from CIRM-funded Research):

(1) import, export, excise and sales taxes, and customs duties;

(2) costs of insurance, packing, and transportation from the place of manufacture to the customer's premises;

(3) credit for returns, allowances or trades; and

(4) pre-commercial revenues received in connection with research and development and/or clinical activities.

(o) Principal Investigator. The Principal Investigator ("PI") is an individual designated by the Grantee to direct CIRM-funded Research and who is accountable to the Grantee and to CIRM for the proper conduct of that research.

(p) Project Period. The amount of time over which CIRM funds research through a Grant.

(q) Public Funds. Funds belonging to the State of California or of any county, city, city and county, or other municipal corporation or subdivision thereof, or any public agency therein.

(r) Publication-related Biomedical Materials. Tangible research material of biomedical relevance first produced by a Grantee in CIRM-funded Research including but not limited to unique research resources (such as synthetic compounds, organisms, cell lines, viruses, cell products, cloned DNA, as well as DNA sequences, mapping information, crystallographic coordinates, and spectroscopic data), as described in a published scientific paper as provided by Title 17, California Code of Regulations, section 100403. Specific examples include specialized and/or genetically defined cells, including normal and diseased human cells, monoclonal antibodies, hybridoma cell lines, microbial cells and products, viruses and viral products, recombinant nucleic acid molecules, DNA probes, nucleic acid and protein sequences, certain types of animals including transgenic mice and other property such as computer programs. This term does not include therapeutic products or diagnostic products.

Note: Authority cited: Article XXXV, California Constitution; Section 125290.40(j), Health and Safety Code. Reference: Section 125290.30, Health and Safety Code.