Resolution on U.S. Clinical Trials:

CIRM is committed to the development of safe and effective cell-based therapies under the highest medical and ethical standards to relieve disease and injury. By this Resolution, the CIRM Scientific and Medical Accountability Standards Working Group (the "Standards Working Group") recommends standards for clinical trials and therapy delivery to patients in the United States as follows:

WHEREAS, the Standards Working Group recognizes that clinical trials conducted in the United States pursuant to a United States Food and Drug Administration (FDA) Investigational New Drug (IND) application are subject to robust federal, state and CIRM requirements and processes, including:

- Federal statutes and regulations requiring oversight by Institutional Review Boards (IRBs) ;
- California state requirements including the licensing of manufacturing facilities
- CIRM policies and practices in addition to regulations providing for robust oversight including reporting to CIRM of significant adverse events; and patient enrollment and upon request providing CIRM with data safety monitoring plans

Product Safety Requirements for Cell-Based Therapies

WHEREAS, FDA's regulations include a comprehensive framework for ensuring adherence to the principles intended to protect recipients of investigational cell-based products including compliance with:

(i) The requirement to have an Investigational New Drug (IND) issued before commencement of clinical trials in the United States (except in limited circumstances);
(ii) Good Clinical Practices;
(iii) Current Good Manufacturing Practices;
(iv) Good Laboratory Practice, and
(v) Current Good Tissue Practice for establishments that manufacture human cell, tissue, and cellular and tissue-based products (HCT/Ps).

The FDA includes donor screening and donor testing requirements and, CIRM supports activities designed to enhance current good tissue practice intended to support the safety of HCT/Ps.

Institutional Review and Oversight and Informed Consent

WHEREAS, existing CIRM regulations require all human subjects research to be conducted in accordance with the Title 45 Code of Federal Regulations, Part 46 (Protection of Human Subjects) and Title 21, Parts 50 (Protection of Human Subjects) and 56 (Institutional Review Boards). These regulations adopted by the Department of Health and Human Services establish a common framework for the review and oversight of research; require the informed consent of human participants in research, as well as approval and ongoing monitoring of the study by an Institutional Review Board (IRB).

WHEREAS, CIRM practices require clinical trials to be registered on ClinicalTrials.gov and the IRB(s) overseeing the trial and providing review to be registered with the federal Office for Human Research Protection. In addition, the Food and Drug Administration has established standards governing the composition, operation, and responsibility of institutional review boards (IRBs).

Monitoring Plans

WHEREAS, CIRM requires Investigators to have available a data and safety monitoring plan. Further, the regulations define IND holder and investigators responsibilities to provide trial oversight, such as monitoring for all clinical trials. Such plans for monitoring must be included as part of the protocol and submitted to the IRB and reviewed and approved before the trial begins.

Active CIRM Oversight

WHEREAS, CIRM exercises robust oversight over all its funded projects and has established processes requiring timely notice of clinical trial progress, CIRM requires IND holders to report to CIRM significant adverse events at the same time they disclose such events to their IRB.

Reporting of Results

WHEREAS, CIRM's Grants Administration Policy requires reporting of scientific progress and activities in annual progress reports, including the reporting of cumulative subject accrual and progress in conducting analyses for sex/gender and race/ethnicity differences in clinical trials and in practice CIRM requires that awardees must share the results of their studies for the benefit of the field. Within a reasonable timeframe after the completion of a study the grantee will be expected to submit the study results for peer-reviewed publication.

Access Requirements

WHEREAS, the California Health and Safety Code provide that CIRM grantees and the exclusive licensees of CIRM grantees "submit a plan to CIRM to afford access to any drug that is, in whole or in part, the result of research funded by CIRM to Californians who have no other means to purchase the drug" and as CIRM funded research gets closer to market approval, CIRM will create process to assist in implementation of this requirement.

Advancing the Field

WHEREAS, the CIRM Medical and Ethical Standards Working Group has recommended policies to enhance the responsible conduct of CIRM-sponsored research. For research in clinical settings, CIRM is committed, thorough its active oversight efforts, to working with trial sponsors to evaluate and advance effective approaches for supporting participant safety and autonomy.

Resolution

Based On The Forgoing, IT IS HEREBY RESOLVED by the CIRM Scientific and Medical Accountability Standards Working Group that: existing federal and California statutory and regulatory requirements for clinical trials conducted in the United States combined with CIRM's active oversight, procedures and practices including requiring prompt notice of significant adverse events provide the robust oversight for clinical trials that meet the high standards required by the CIRM Scientific and Medical Accountability Standards Working Group.