

provisions of Article 9 (commencing with Section 11120) of Chapter 1 of Part 1 of Division 3 of Title 2 of the Government Code, or Article 1 (commencing with Section 6250) of Chapter 3.5 of Division 7 of Title 1 of the Government Code.

125281.10 Scientific and Medical Accountability Standards Working Group

(a) Membership

The Scientific and Medical Accountability Standards Working Group shall have 19 members as follows:

(1) Five ICOC members from the ten groups that focus on disease-specific areas described in section 125281.03 (a) (3), (a) (4) and (a) (5).

(2) Nine scientists and clinicians nationally recognized in the field of pluripotent and progenitor cell research.

(3) Four medical ethicists.

(4) The chairperson of the ICOC.

(b) Functions

The Scientific and Medical Accountability Standards Working Group shall have the following functions:

(1) To recommend to the ICOC scientific, medical and ethical standards.

(2) To recommend to the ICOC standards for all medical, socio-economic, and financial aspects of clinical trials and therapy delivery to patients, including, among others, standards for safe and ethical procedures for obtaining materials and cells for research and clinical efforts for the appropriate treatment of human subjects in medical research consistent with section 125281.06 (a) (2) herein, and to ensure compliance with patient privacy laws.

(3) To recommend to the ICOC modification of the standards described in subparagraphs (1) and (2) as needed.

(4) To make recommendations to the ICOC on the oversight of funded research to ensure compliance with the standards described in subparagraphs (1) and (2).

(5) To advise the ICOC, the Scientific and Medical Research Funding Working Group, and the Scientific and Medical Research Facilities Working Group on an on-going basis on relevant ethical and regulatory issues.

125281.11 Scientific and Medical Research Funding Working Group

(a) Membership

The Scientific and Medical Research Funding Working Group shall have 23 members as follows:

(1) Seven ICOC members from the 10 disease advocacy group members described in sections 125281.03 (a) (3), (a) (4), and (a) (5).

(2) 15 scientists nationally recognized in the field of stem cell research.

(3) The Chairperson of the ICOC.

(b) Functions

The Scientific and Medical Research Funding Working Group shall perform the following functions:

(1) Recommend to the ICOC interim and final criteria, standards and requirements for considering funding applications and for awarding research grants and loans.

(2) Recommend to the ICOC standards for the scientific and medical oversight of awards.

(3) Recommend to the ICOC any modifications of the criteria, standards and requirements described in subparagraphs (1) and (2) above as needed.

(4) Review grant and loan applications based on the criteria, requirements and standards adopted by the ICOC and make recommendations to the ICOC for the award of research, therapy development, and clinical trial grants and loans.

(5) Conduct peer-group progress oversight reviews of grantees to ensure compliance with the terms of the award, and report to the ICOC any recommendations for subsequent action.

(6) Recommend to the ICOC standards for the evaluation of grantees to ensure that they comply with all applicable requirements. Such standards shall mandate periodic reporting by grantees and shall authorize the Scientific and Medical Research Funding Working Group to audit a grantee and forward any recommendations for action to the ICOC.

(7) Recommend its first grant awards within 60 days of the issuance of the interim standards.

(e) Recommendations for Awards

Award recommendations shall be based upon a competitive evaluation as follows.

(1) Only the 15 scientist members of the Scientific and Medical Research Funding Working Group shall score grant and loan award applications for scientific merit. Such scoring shall be based on scientific merit in three separate classifications—research, therapy development and clinical trials, on criteria including the following:

(A) A demonstrated record of achievement in the areas of pluripotent stem cell and progenitor cell biology and medicine, unless the research is determined to be a Vital Research Opportunity.

(B) The quality of the research proposal, the potential for achieving significant research or clinical results, the timetable for realizing such significant results, the importance of the research objectives, and the innovativeness of the proposed research.

(C) In order to ensure that Institute funding does not duplicate or supplant existing funding, a high priority shall be placed on funding pluripotent stem cell and progenitor cell research that cannot, or is unlikely to, receive timely or sufficient federal funding, unencumbered by limitations that would impede the research. In this regard, other research categories funded by the National Institute of Health shall not be funded by the Institute.

(D) Notwithstanding subparagraph (C), other scientific and medical research and technologies and/or any stem cell research proposal not actually funded by the Institute under subparagraph (C) may be funded by the Institute if at least two-thirds of a

quorum of the members of the Scientific and Medical Research Funding Working Group recommend to the ICOC that such a research proposal is a Vital Research Opportunity.

125281.12 Scientific and Medical Facilities Working Group

(a) Membership

The Scientific and Medical Research Facilities Working Group shall have 11 members as follows:

(1) Six members of the Scientific and Medical Research Funding Working Group.

(2) Four real estate specialists. To be eligible to serve on the Scientific and Medical Research Facilities Working Group, a real estate specialist shall be a resident of California, shall be prohibited from receiving compensation from any construction or development entity providing specialized services for medical research facilities, and shall not provide real estate facilities brokerage services for any applicant for, or any funding by the Scientific and Medical Research Facilities Working Group and shall not receive compensation from any recipient of Institute funding grants.

(3) The Chairperson of the ICOC.

(b) Functions

The Scientific and Medical Research Facilities Working Group shall perform the following functions:

(1) Make recommendations to the ICOC on interim and final criteria, requirements and standards for applications for, and the awarding of, grants and loans for buildings, building leases, and capital equipment; those standards and requirements shall include, among others,

(A) facility milestones and timetables for achieving such milestones;

(B) priority for applications that provide for facilities that will be available for research no more than two years after the grant award;

(C) the requirement that all funded facilities and equipment be located solely within California;

(D) the requirement that grantees comply with reimbursable building cost standards, competitive building leasing standards, capital equipment cost standards, and reimbursement standards and terms recommended by the Scientific and Medical Facilities Funding Working Group, and adopted by the ICOC;

(E) the requirement that grantees shall pay all workers employed on construction or modification of the facility funded by facilities grants or loans of the Institute, the general prevailing rate of per-diem wages for work of a similar character in the locality in which work on the facility is performed, and not less than the general prevailing rate of per diem wages for holiday and overtime work fixed as provided in Division 2, Part 7, Chapter 1 of the Labor Code;

(F) the requirement that grantees be not-for-profit entities;

(G) the requirement that awards be made on a competitive basis, with the following minimum requirements: