

2009

2010

REPORT ON OPERATIONS

Supplemental to the Strategic Plan Update



OPERATIONAL HISTORY/PROGRESS TOWARDS CIRM GOALS

This section provides a brief description of CIRM's genesis and administrative organization and outlines the Agency's achievements to date and recommendations for future improvements across the organization.

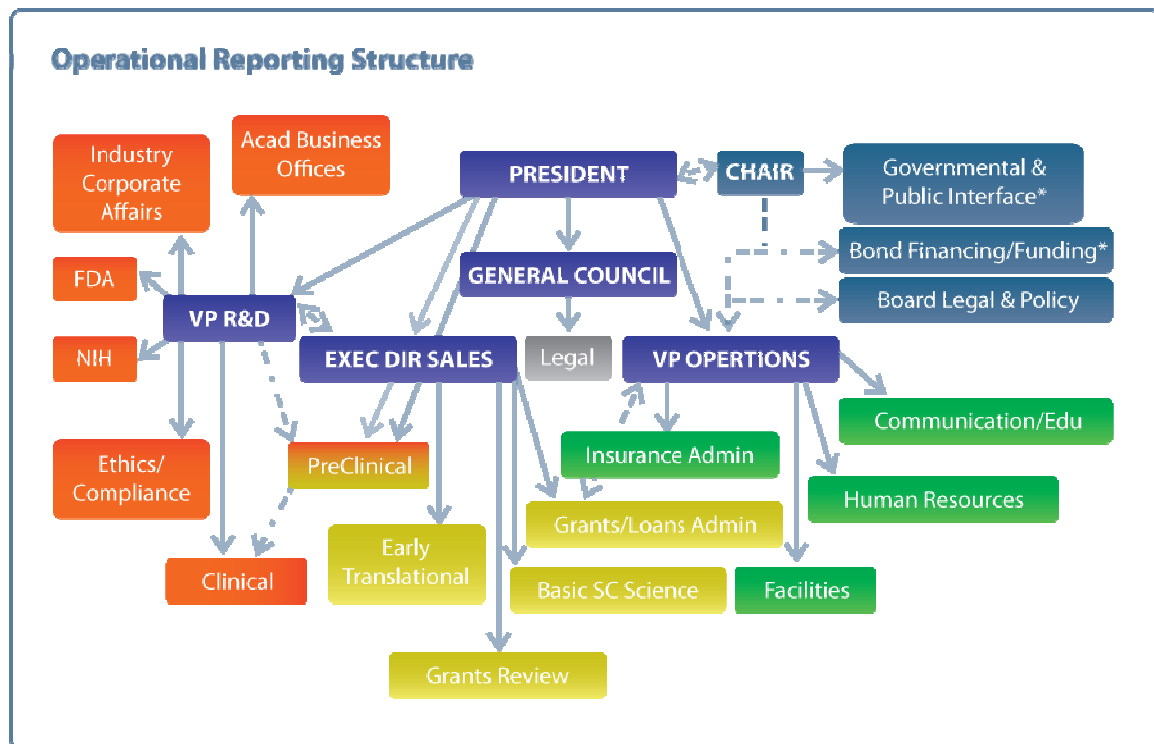
GENESIS

CIRM had an unusual and eventful beginning. Although Proposition 71 was approved in November 2004 by 59 percent of voters, legal maneuvers by stem cell opponents to declare the Act unconstitutional delayed CIRM's funding from reaching fully authorized levels for almost 30 months. Initial funding for CIRM operations occurred after 16 months, with limited Bond Anticipation Note (BAN) proceeds being made available by generous and visionary private citizens who purchased these BAN securities. In addition, in 2007 Governor Arnold Schwarzenegger authorized a \$150 million Pooled Money Investment Fund Loan from the state's General Fund to initiate CIRM-funded research.

Until the litigation resolved, CIRM was forced to operate with a skeleton crew, which did an outstanding job initiating the Agency's operations and programs. Indeed, CIRM's small staff multitasked in ways that knowledgeable observers of funding agencies have considered unprecedented.

On May 16, 2007, CIRM emerged victorious from its legal challenges when California's Supreme Court refused to reconsider lower court rulings affirming the constitutionality of Proposition 71. With the legal path cleared, the first tranche of state general obligation bonds was issued on October 4, 2007, allowing CIRM to repay the General Fund and the BAN holders and become fully operational. Given the severely limited resources for almost three years, the accomplishments of CIRM and the Governing Board are remarkable.

Proposition 71 established a new governance model to specifically address the scope and complexity of its mission. The leadership structure- a partnership between the Chairman of the Board and the President- has many precedents in the private sector. Each of these leadership positions demands highly specialized knowledge and expertise across several related fields. The limited size of the agency dictates a flat organizational structure with leaders who personally perform at an expert level in multiple disciplines. The Chairman's position requiring expertise in finance, law, and governmental affairs, and the President's position ideally combining extraordinary leadership in biomedical science, stem cell research, biotech, and governmental programs or policy. Each of these two individuals must be capable of independently leading and innovating in their sphere of responsibility, while collaboratively – as a team- forging a united execution strategy. For example, the critical path for science funding must be merged with the financing and legal constraints of the bond markets; California's competing capital requirements, schedules, and capacity; and state and federal law. This team leadership structure- lead by the partnership of the Chairman and the President- has permitted the board and the agency to move through innumerable obstacles- in science and funding- with remarkable speed, productivity, and intense accountability.



ORGANIZATIONAL STRUCTURE

Internally, CIRM is organized into four main administrative components: the Science Office (Vice President R&D and Executive Director of Scientific Affairs), the Office of Administration (Vice President Operations, Finance, Communications and Human Resources), Presidents Office (President and General Counsel) and the Chairman's Office (Chairman and Deputy Chairs), all of which are supported by staff who report directly or administratively to the President or Chairman. The Chairman's Office operationally reports to the Chairman and works on a daily basis with the Governing Board Chairman, Robert Klein, to carry out the statutory responsibilities of this office, as defined by Proposition 71.

SCIENCE OFFICE

Much of CIRM's success derives from the enormous talent and effort of the staff in its Science Office. Despite severe understaffing during the first three years of operations, the Office designed and launched CIRM's scientific programs and policies. Among their achievements, CIRM Science Office staff has:

- drafted the scientific concept plans that translate the scientific goals of the 2006 Strategic Plan into scientific and operational grant-award programs;
- developed Requests for Applications (RFAs) and application forms and instructions that initiated scientific competitions for research and training for California scientists and organizations;
- staffed the Grants Working Group to facilitate the highly effective peer review process for grant evaluations, which included managing the complex logistics of organizing meetings, recruiting reviewers for each competition, administering the conflict-of-interest disclosure and screening process, distributing grant applications, conducting meetings of the Grants Working Group and collating the data, writing public summaries of the reviews, and presenting the results of each review to the Governing Board and the public;

- created the initial software programs that allowed CIRM staff and the Grants Working Group to conduct many of the activities of review online, which facilitated the ranking and funding recommendations for applications to help the Governing Board make its funding decisions;
- developed policies, including grants administration and intellectual property policies, for both non-profit and for-profit organizations and procedures for reporting, monitoring, and assuring compliance with the requirements of these policies, including eligibility determinations and proper budgeting to ensure good stewardship of the state's money over the life of grants;
- established grant progress reporting assessment procedures to evaluate research productivity and advance against proposed timetables and milestones.

Scientific competitions. The work of the science team is best reflected in the scientific competitions initiated in response to Request for Applications (RFAs). The scientific adjudication and awarding of grants is a multi-step process that requires the coordination of all of CIRM's resources. Although the process, described below, has worked well, further fine-tuning is anticipated.

At the heart of the process is an effective peer review system established by the Science Office. The Grants Working Group is comprised of an extraordinary group of world-recognized, non-California scientists drawn from the United States and other countries, working alongside a committed group of Patient Advocates who play a critical role in communicating the Group's recommendations to the Governing Board. The Panel has established high standards of excellence, a collaborative working style, and an environment that fosters respectful discussion within a spirit of collegiality. Organized and guided by criteria set by CIRM staff, the scientific experts evaluate grant applications and score them based on the sole criterion of scientific excellence. In making final funding recommendations, the GWG, led by Vice-Chairs chosen from among patient advocate members of the Governing Board, considers the programmatic fit of a research proposal and the potential of the project to advance a particular therapeutic opportunity. The Patient Advocate Vice-Chair and the other patient advocate members of the GWG play an invaluable role leading discussions of the link between scientific excellence and programmatic priorities.

The Grants Working Group panels have also shown remarkable flexibility in providing expert opinions on numerous types of grant applications, from investigator-initiated basic research proposals to training grants and grants for new investigators, major facilities, and the generation of new cell lines. CIRM is grateful to the committed members of the Grants Working Group for the long hours they devote to evaluating large numbers of grant applications and for their dedication in traveling to California from distant locations to attend meetings.

IMPROVING PROCESSES TO ENHANCE SCIENTIFIC CAPACITY

CIRM's scientists have the primary responsibility for delivering CIRM's scientific and clinical mission. The team is comprised of highly qualified and experienced scientists, and as CIRM's research portfolio enlarges the team will expand from its current number of 14 to around 20 individuals. Scientists with experience in rapidly growing new areas such as tissue engineering and pharmacology, as well as physicians with clinical trial expertise will be particularly essential to CIRM's expanding support of translational research.

The CIRM scientists have a broad range of specific expertise, including neurosciences, neurodegenerative disorders, mitochondrial function and membrane biology, embryology and mouse genetics, immunology, surgery and immunosuppression, signal transduction, cancer biology, anesthesiology, critical care, stem cell microenvironments, visual systems, animal and human embryology, human embryonic stem cell biology, stem cell

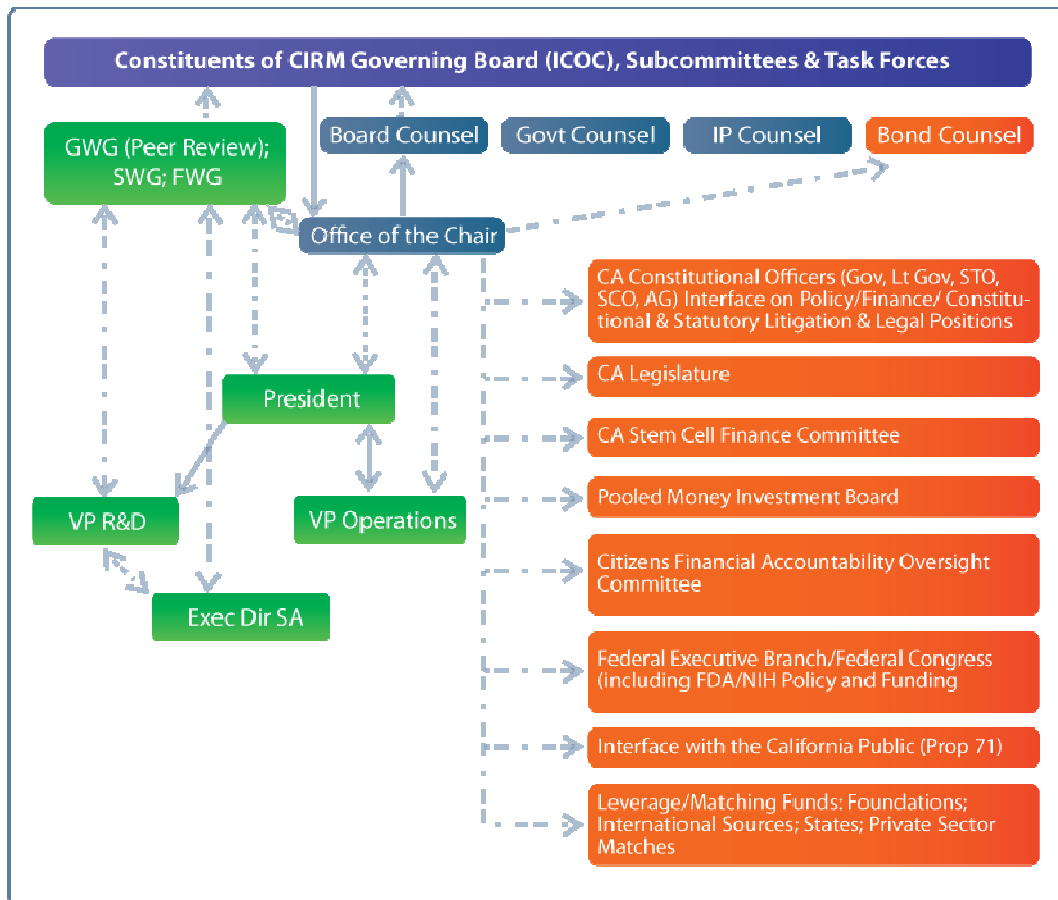
differentiation and transplanted, and product development. CIRM strongly encourages their continued specialization and supports their attendance at primary conferences of their discipline and their ongoing communication with scientists working in their area of specialization.

OFFICE OF ADMINISTRATION

Staff members in the Office of Administration are critical to CIRM’s smooth operations. During CIRM’s startup period, they put in place procedures regulating all Agency operations including financial, human resources, information technology, communications, and internal administration. Administrative personnel also worked with Governing Board members and external advisors, in particular in collaboration with the National Academy of Sciences, to establish ethical standards for CIRM investigators and to ensure compliance with state and federal laws and regulations.

New financial tracking and reporting systems have been established to monitor CIRM’s operations and research granting programs. These are now incorporated in the President’s Reports to the ICOC.

CIRM has begun implementing significant improvements in its administrative operations to accommodate an expanding number of programs and operational responsibilities and will continue these efforts going forward.



CHAIRMAN'S OFFICE

The Office of the Chair under Chairman Robert Klein has its primary responsibilities described in the Initiative as follows:

The chairperson's primary responsibilities are to manage the ICOC, the governing board, agenda and work flow including all evaluations and approvals of scientific and medical working group grants, loans, facilities and standards evaluations, and to oversee the CIRM annual report and public accountability requirements; to manage and optimize the institute's bond financing plans and funding cash flow plan; to interface with the California Legislature, the United States Congress, the California health care system, and the California public; to optimize all financial leverage opportunities for the institute; and to lead negotiations for intellectual property agreements, policies, and contract terms. The Chair also serves on all three of the Agencies working groups.

OFFICE OF THE PRESIDENT

The President, aided by the General Counsel and other legal officers, and supported by his Executive Assistant, is responsible for setting the direction, breadth of activities, and pace of CIRM's implementation program; its relationships with other institutions; and the scientific vision guiding the Agency's delivery of its mission. Doing so requires continuous knowledge of CIRM's primary activities and involves close communications with the Chair of the Governing Board, Vice President of Operations, Vice President of Research and Development, and other executive staff. The President aims to direct CIRM by drawing the best from all members of staff. Simply put, the Agency operates as an integrated, ambitious program, committed to supporting the relationships required to achieve its mission. The president acts to leverage California's scientific and medical assets by creating a national and international network of the world's leading stem cell research scientists and clinicians, working together to advance the medical and scientific mission of proposition 71.

COMMUNICATION AND EDUCATION

CIRM'S RESPONSIBILITY TO THE PUBLIC

California's public and financial support comes with a responsibility to keep the entire community informed about CIRM's activities and accomplishments. This requires more than a passive posting of grants awarded. To be well informed about CIRM's scientific mission and how funds are being invested to improve human health, the public must first understand some basic information about stem cell research and why broad and sustained funding is critical to advancing this research from the laboratory to patient care. Armed with sufficient background information and realistic reports of progress, citizens can put into perspective the research results achieved through CIRM funding and recognize the true hope they represent.

To this end, CIRM has launched a broad-based communication and public education effort. The aim is to address the general public and several niche audiences, including the media, patient advocacy organizations, researchers, legislators, and business leaders. CIRM plans to reach each audience through multiple channels: face-to-face communication, print media, and especially the Web. Many members of the Science Office, as well as CIRM grantees, are being called upon to increase opportunities for face-to-face education and outreach.

Since March 2008, CIRM has been enhancing the content on its Website to include more information about stem cell research in general and CIRM-funded research in particular, with links to related content on many of the CIRM-funded institutions' Websites. In May 2009, CIRM brought online an entirely new Website that represented

the first phase in building a mini stem cell university on the Web. CIRM hopes to engage enough outside resources and new, in-house-produced content to make its Website a definitive resource for anyone who wants to learn where new research results have taken the field and to put those results into perspective. Because many people have become accustomed to learning by video, the CIRM Website now also includes information in this format from leaders in the field on a wide range of topics and issues within stem cell science.

REACHING OUR AUDIENCES

For patient advocates. CIRM expects the new “For the Public” landing page off the Website to become a valued resource. Much of its content is searchable by disease, and individual stories will maximize Web learning by providing links to researchers’ home pages and related video, images, research papers, and press releases. CIRM plans to collate materials related to specific diseases and use them as a basis for in-person meetings with advocate leaders, to enlist them in further disseminating CIRM content and to create links back to CIRM and its Facebook page. The eAlerts list serve system and a new Really Simple Syndication (RSS) feed system will play key roles in this effort.

For business leaders. CIRM is reviewing the knowledge about and attitudes toward the Agency among business leaders to help direct communication activities within this niche. Two information-exchange sessions for industry held in September 2007 were rated as valuable as were two sessions associated with reviewing this plan in February 2009. CIRM’s leadership frequently accepts and seeks opportunities to speak to business groups in California. For the biotech community, CIRM expects the “For Researchers” landing page on the new Website to be a useful tool for tracking RFAs and grant awards.

For State Executive Officers: The office of the Chair and the Director of Communications will organize briefings for the constitutional officers and their staff, many of whom will be encouraged to sign-up for the RSS feed to stay apprised of CIRM activities. In-person meetings will continue on a frequent basis with CIRM’s government relations representative, and periodically with CIRM senior executives.

For the legislative community. CIRM plans to conduct advocacy workshops on pending federal and state legislation to assemble information on the potential influence of these legislative measures on stem cell therapies and the ability to access patients. CIRM will organize briefings for legislators and their staff, many of who will be encouraged to sign-up for the RSS feed to stay apprised of CIRM activities. In-person meetings will continue on a frequent basis with CIRM’s government relations representative, and periodically with CIRM senior leadership and board members. CIRM is building a rapid response team to answer legislative requests and to effectively assimilate legislative input.

For the media. CIRM has begun augmenting its traditional press releases, and those produced by grantee institutions, with video segments. These clips will feature certain faculty describing science at a lay level and employ compelling visual images suitable for TV to convey the excitement that stem cell science holds for the future of medicine.

The media are a significant conduit of information to the general public, and journalists need to understand a broader perspective of the field than that afforded by daily news coverage. Thus, an important component of CIRM’s mission is to offer the media educational opportunities. More than 30 journalists attended CIRM’s first writer’s seminar on September 17, 2008, where 9 guest speakers presented on a wide variety of topics in stem

cell research. Beyond educational seminars designed specifically for media, we will also consider implementing mini-fellowship programs offering hands-on lab experience.

For the science and medical community: CIRM communicates with grantees and partners through a grantee conference and by posting critical information online. CIRM encourages the involvement of scientists in education programs for elementary, high school, and undergraduate students, postgraduates, and the general community and plans to include early-stage career scientists in a wide range of communication and education activities. CIRM will be developing a Web 2.0 portal during 2009 to serve as an on-line community for CIRM grantees to exchange information.

For the Governing Board: Continuing education of the Board is an important component of CIRM's communications strategy. Efforts include regular "Spotlight on Disease" sessions in which clinical and basic scientists, alongside patients, discuss current progress in the research and treatment of specific diseases and injuries. In addition, snapshots of research advances in stem cell science are provided regularly at Board meetings by the President, with summaries of the presentations posted on the Website. The CIRM scientists and other members of CIRM staff also provide updates on new discoveries, clinical developments, IP, and other important developments in the field as they occur.

For the general public: The CIRM Website will serve as the primary communication tool between the Agency and general public. In addition, CIRM is creating opportunities for leaders and researchers in the field to speak before live audiences. For example, in March-April 2009, CIRM held three Town Forums – one in San Francisco, one in San Diego and one in Los Angeles that drew approximately 600 attendees. CIRM's goal is to hold at least one town forum each year in three regions of the state.

To promote interactive learning, CIRM is considering issuing an RFP to develop a portable, multimedia display on stem cell research that can be used prior to and after future Town Forums, at grantee institutions, and in CIRM's lobby.

CIRM will work directly with the educational community, and in particular with high school science teachers, to create educational modules that can be used broadly in the schools at multiple levels. A Request for Proposals to develop these materials may be issued in 2009 pending analysis by staff and review by the board.

To reach international audiences, CIRM's Chief Communications Officer serves on the International Society for Stem Cell Research's (ISSCR) public education committee. The committee fosters the dissemination of teacher materials and the development of Web educational content and also organizes a public symposium at the annual ISSCR meeting.

MAKING COMMUNICATIONS HAPPEN

CIRM has hired a communications staff, bringing to the Agency significant experience in science communication, media relations, Web content development, and video storytelling. An additional communication expert on contract handles special projects, and a public relations agency enhances targeted media placement. For some audiences, in particular government ones, this communications team provides message development support for the government relations' team in the Office of the Chair who manage the relationships.

In addition, CIRM's communication team has significantly extended the reach and impact of its communications efforts by enlisting the public information officers of grantee institutions, thereby creating a virtual statewide public education effort focused on stem cell communications. Press releases are cross-posted on both CIRM's and these institutions' Websites and collaboration across institutions makes most of the video products possible. Liaisons extend to national and international scientific organizations and patient advocacy organizations with which CIRM coordinates communication and key messaging.

ETHICS AND COMPLIANCE

ETHICAL STANDARDS AND PROCESSES FOR REVISION

Before CIRM developed its own policies, the Governing Board adopted the National Academies' Guidelines for Human Embryonic Stem Cell Research as interim regulations for its grants. The Academies' guidelines were considered the gold standard for the ethical conduct of hESC research when they were announced in April 2005. When CIRM's Governing Board adopted these guidelines in May 2005, California became the first state to employ them as interim regulations.

In just over a year, the Standards Working group held eight public meetings to develop its final recommendations for CIRM's own guidelines. They represent the first comprehensive set of state regulations to implement and build on the Academies' guidelines.

CIRM's Medical and Ethical Standards (MES), which took effect in October 2006, provide comprehensive regulation of CIRM-funded research. Proposition 71 requires CIRM's Medical and Ethical Standards Working Group (SWG) to meet at least four times per year to consider the need for new standards and to periodically re-evaluate existing standards in light of developments in stem cell science and in national standards for research ethics.

The SWG has recommended a number of revisions to CIRM regulations that have enhanced CIRM-funded researchers' ability to use tissues, cells, cell lines, and blastocysts. For example, in 2008 the Group recommended amendments to make CIRM's regulations more consistent with the Guidelines of the National Academy of Sciences regarding access to human embryonic stem cells (hESC) lines, embryos, and somatic cells.

In July 2009, the NIH issued final Guidelines for Human Stem Cell Research. These Guidelines will likely serve as a foundation for stem cell research regulation nationally. A guiding principle behind CIRM's MES regulations is they should serve to support exchange and collaboration among researchers. Given the profound role NIH funding plays in the broader research environment, it is essential that CIRM policy be as consistent as possible with the new Guidelines.

Since the release of the NIH Guidelines, CIRM has initiated a formal evaluation of opportunities to further enhance regulatory consistency. In July 2009, CIRM sponsored a regulatory workshop. The workshop report details a number of recommendations for enhancing consistency with the NIH Guidelines. These recommendations focus on issues relating to access to cells and tissue.

IMPROVING ACCESS TO CELLS AND TISSUES

Based on information gained from workshops, interactions with grantee institutions and participation in national meetings, CIRM has identified a number of opportunities for improving access to cells and tissues. These opportunities include:

- developing procedures for identifying cell lines that comply with CIRM regulations and make this information available to grantees;
- further aligning CIRM regulations with NAS and NIH policy;
- supporting the registration of hESC lines in national and international registries.

CIRM anticipates working with the SWG to develop a series of recommendations to improve access to cells and tissue. These recommendations would be incorporated into CIRM's MES regulations.

CLINICAL TRIALS

As CIRM moves towards clinical application of cell therapies, the SWG will increasingly focus on medical and ethical considerations related to early clinical trials. Doing so will require ongoing consultation with a range of stakeholders, including the U.S. Food and Drug Administration, the Office of Human Research Subjects Protection in the U.S. Department of Health and Human Services, and patient advocacy organizations.

CIRM will continue to work to foster collaboration and exchange between national and international organizations regarding ethical, human subject, and clinical trials issues. The SWG will provide a forum for considering how oversight mechanisms for current stem cell research might be applied to the conduct of clinical trials.

During its 2009 annual meeting the Standards Working Group took the first step by holding a clinical trials workshop. The purpose of the workshop was to identify priorities for future policy and planning. The meeting's findings are summarized in the workshop report.

PARTICIPATION IN CLINICAL TRIALS AND BASIC RESEARCH

The Governing Board will actively engage the patient advocacy community to consider how to enhance their participation in research and clinical trials. The Board will examine how basic research and trial development can dovetail with the needs and expectations of potential participants. A primary goal will be to identify mechanisms that engender both participation and participant empowerment in CIRM-funded research.

COMPLIANCE WITH CIRM REGULATIONS AND CONTRACTS

CIRM has emphasized compliance with its grants administration policy to its grantees; individual members of the Science Office have made numerous visits to grantee institutions as part of an ongoing process to communicate, support, and underscore the need for compliance.

In 2008, CIRM expanded its program to evaluate grantee compliance with CIRM regulations and policies. The program entails an internal review of grantee records as well as site visits to evaluate compliance with the requirements of CIRM's Medical and Ethical Standards regulations and the Grants Administration Policy. Site visits include the review of CIRM grantees' stem cell research oversight programs and of specific grant applications for compliance with MES regulations and the Grants Administration Policy. CIRM's evaluation will help recipient organizations correct any shortcomings. Conversely, compliance visits to institutions and companies will provide CIRM with opportunities to receive valuable input from grantees and their administrators so as to further improve the Agency's procedures and regulations.

In 2009-10, CIRM anticipates completing site visits to all institutions receiving funding in excess of \$5 million. CIRM may also evaluate any specific application or institution on an as-needed basis to ensure compliance. CIRM

will also continue to refine broader programmatic approaches to ensure compliance with all regulations and policies, including the development of materials designed to provide guidance to grantees, sponsorship of workshops and training, and ongoing technical assistance to grantee intuitions.

RECOGNIZING OUR ROLE IN SETTING NATIONAL AND INTERNATIONAL STANDARDS

CIRM is actively involved in the development of national and international standards through its participation in state, national, and international organizations oriented towards research ethics and policy development. Specific affiliations include:

- membership in the International Stem Cell Forum's Ethics Working Party;
- membership in the Interstate Alliance for Stem Cell Research;
- partnership with the International Society for Stem Cell Research Registry Initiative; and
- participation in an international network to establish interoperable stem cell registries.

Through these organizational affiliations, CIRM will pursue a number of activities intended to improve international exchange and access to research materials. Specific activities will include:

- working within the Interstate Alliance for Stem Cell Research to identify opportunities for enhancing regulatory compatibility and harmonization across states and with the National Academies Guidelines and NIH Guidelines;
- working with the NIH and the Interstate Alliance for Stem Cell Research to develop consensus approaches for documentation of research oversight;
- collaborating with the International Society for Stem Cell Research to identify hESC lines and other research materials that conform to state, national, and international standards;
- develop a continuous dialogue with FDA on the matters of preclinical data and clinical trial requirements for stem cell and associated therapies;
- creating interactions between CIRM's organizational affiliates and the SWG to consider best practices for research ethics.

CIRM intends for these activities to maximize the diversity of research materials and paths available to CIRM grantees, while at the same time creating a timely and efficient system to assure utmost compliance with all relevant ethical standards.

LEGAL OVERSIGHT OF SCIENTIFIC OPERATIONAL FUNCTIONS

CIRM's General Counsel (GC) has the role of shaping the Agency's legal strategies relative to operations, relationships with business, and new initiatives to ensure compliance, working with Board Counsel, with state and federal laws and, where appropriate, with state, national and international regulations. To be an effective instrument for delivering new discoveries to the clinic, CIRM needs to remain an innovative agency able to capitalize on changes in science and in governmental policies and regulations. In this fast-moving area of research, evolving opportunities need a swift response by CIRM that remains both legal and within the margins of community support. The GC, Board Counsel, and other legal officers of CIRM are integral to keeping CIRM an effective instrument of the community's desire to embrace stem cells in regenerative medicine.

The primary responsibility of CIRM's legal team is to be seamlessly integrated into operations so that it readily identifies potential problems and puts processes in place to avoid them before they arise. The legal staff strives to ensure that all legal concerns that may be raised by operations are handled as part of an efficient, integrated

effort. The legal team acts as a check-and-balance resource for other departments, documenting the processes that support the innovative practices described throughout this Strategic Plan. The team's specific internal strategy include:

- handling legal complexities that may arise from the national and international alliances in which CIRM participates;
- furthering the understanding of CIRM's intellectual property policies as CIRM grantees move towards translational work and begins to make grants and loans to for-profit entities;
- assuring that accounting and funding practices are continuously reconciled legally to bond funding requirements;
- integrating operations with the internal Controller to ensure that appropriate contracting controls are enforced and that documentation of transactions is appropriately maintained per CIRM's policy;
- providing guidance to the Compliance team in reviewing CIRM Grantees for compliance with CIRM's regulations and policies;
- clarifying and improving CIRM's regulations in a responsive manner,
- sustaining CIRM's compliance with relevant state and federal laws and regulations;
- managing and advising on the numerous audits of CIRM's operational, financial, governance, and conflict-of-interest matters.

In the process of CIRM's daily operations, CIRM's General Counsel advises the president and the president directs all scientific compliance activities of the legal office.

STAFF PROFILE

CIRM's Governing Board, the Independent Citizen's Oversight Committee (ICOC) holds final decision-making authority on all research funded by CIRM, and as such has ultimate responsibility for the mission of Proposition 71 and for driving CIRM's scientific and administrative programs. For these reasons the President and staff of CIRM need to have a seamless, mutually supportive working relationship with the Chairman and other members of the Board.

At the same time, the Chairman, his staff, and Board members carry out responsibilities that are independent of the President's Office but central to CIRM's mission, including, for example, working closely with all the state's constitutional officers, State legislators, the Federal Executive Branch, the US Congress; overseeing CIRM's participation in the bond financing that provides funds for CIRM's research and administrative programs; and serving as CIRM ambassadors in the multiple communities vested in CIRM's mission.

The vision and aspirations of Proposition 71 are being realized through the dedicated efforts of CIRM's professional staff. Integral to CIRM's success has been choosing the right people to work in the Agency and giving them the tools they need to succeed.

To ensure that most of CIRM's funds flow towards research, Proposition 71 mandates that CIRM employ no more than 50 staff employees, plus the chair and the vice chair(s) of the board. This cap requires high performance by all CIRM employees, and for that reason CIRM seeks to hire and develop staff members who are not only expert in their field, but also flexible, motivated, and capable of transferring skills in ways that support CIRM's operating goals.

As of May 1, 2009, CIRM had 39 employees. The Agency's hiring practices have worked well: a strong team has been forged, comprised of individuals who are talented, committed, knowledgeable, and sufficiently flexible to execute the Agency's goals. To retain these talented individuals, CIRM strives to provide a professionally challenging work environment, policies that recognize and support work/life needs, a culture of professional collegiality, and a competitive compensation and benefits package. CIRM is also eager to provide staff with professional development opportunities, including but not limited to conference attendance, classes, and professional networking. Two percent of the overall fiscal-year salary budget is set aside for professional development.

Over the next several years, CIRM will need to hire additional employees to carry out its scientific and administrative functions. The anticipated staffing need at steady state is 30-32 science officers, grants administrators, and support staff. Since CIRM's aggressive science programs will result in approximately 400-500 grants and loans being managed and monitored at any one time, sufficient staffing of the Science Office will be essential to ensure quality control and appropriate investing of CIRM funds in the best science. Hiring additional science staff will also increase the workload on administrative staff in all departments.

New employees must be chosen carefully. In addition to talent, expertise, and commitment, CIRM employees must have the flexibility and the capacity to work in a constantly changing environment. Job descriptions for CIRM employees go beyond the standard, benchmarked job descriptors found within larger, established institutions.

ADMINISTRATIVE OPERATIONAL PROGRAM

In addition to its internal staff, CIRM affords opportunities for external collaboration, both to augment the Agency's intellectual resources and to develop partnerships. CIRM also provides volunteer opportunities, internships, fellowships and speaking engagements to promote information sharing with CIRM staff. CIRM cannot work in a vacuum and must allow for new perspectives and insight from others in the field.

In order to remain within the prescribed cap on full-time positions, CIRM is constantly judging whether work should be carried out internally or through the use of outside experts. In some cases, outsourcing is less expensive and more efficient. A good example of this is payroll administration, which is currently handled by a partner state agency with expert staff members dedicated to this function.

HUMAN RESOURCES

CIRM's human resources (HR) practices and policies have been designed and implemented by the Chief Human Resources Officer. Policies have been implemented to ensure the compensation program is consistent with the guidelines stipulated in Proposition 71. With the ongoing staffing challenges and unique nature of work being accomplished, HR has worked diligently to address these needs and recruit and retain excellent staff. With the cap of 50 staff, ongoing effort will be made to creatively manage resources to maximize staff expertise and retain talent. HR policies are developed and implemented to address the changing needs of the organization and support the unique culture. Towards that end, HR intends to:

- provide ongoing development of the President's Remuneration Committee to address all recruiting and retention issues;
- consult with managers on performance management and implementation of the annual review process;
- request relevant labor market data bi-annually or as needed to ensure CIRM's compensation program is competitive against the targeted market;
- ensure smooth running of office procedures including outsourced payroll function.

ADMINISTRATIVE FINANCES AND BUDGETING

CIRM's operational financial services are managed by CIRM's Finance Officer who works as an internal controller and manages a contract with the Department of General Services. The state's Contracted Fiscal Services Unit provides ongoing disbursement and accounting services, including recordkeeping and reporting vehicles.

CIRM operations are based on an annual budget that is capped at six percent, excluding legal fees. The Governing Board and its Finance Committee are ultimately responsible for monitoring and approving the budget, which covers costs for the Office of the President, Science Office, Office of Administration, and Office of the Chair.

During its startup phase CIRM has functioned well within its approved budgets, and significantly below its statutory budget caps, but more needs to be done to ensure that the Agency's budget and expenditures are transparent to CIRM and to the public. Towards that end, CIRM intends to:

- develop a cash-flow methodology to ensure sufficient funding for both administrative needs and grant/loan awards;
- enhance budgeting tools to ensure timely and accurate forecasting;

- facilitate timely financial reporting to all cost centers;
- be a repository of key state agency contacts; and
- maintain the documentation and updating of all financial processes.

GRANTS MANAGEMENT SERVICES

Quality control in CIRM's grants administration function is essential to keeping CIRM's mission on track and to ensuring that funds are being spent efficiently and according to expectations. The Grants Management (GM) Team, which is responsible for this function, strives for accuracy, consistency, and efficiency. Towards that end, the GM team has set five key goals:

- develop and implement a fully functional Web-based grants management system;
- create and provide standardized, regular reporting vehicles that are available to all CIRM constituents;
- keep CIRM turnaround time to a minimum;
- achieve 100% grantee compliance with CIRM policies and regulations;
- become a leader in innovative grants management practices.

To accomplish these goals, CIRM will implement electronic internal reviews and approvals for award payments and create an interface that provides a secure electronic route for transferring award payment data from the grants' management system to CalStars. The plan is to move to a paperless Grants Management office by establishing electronic fund transfers of award payments to recipients. Only the Notice of Grants Awards [NGAs] will require paper documentation. The GM team is working with the Science Office to ensure consistent data capture, tracking, and reporting, and to establish a methodology for the annual assessment of projecting and budgeting awards.

In short, the GM Team is committed to establishing clear, consistent processes for grantees in order to minimize the administrative burden and maximize the time spent on research. Within CIRM, the team will work to strengthen the identity of the grants management office as a resource for grantees and staff.

INTERNAL PROCESSES AND REVIEWS

As a California State Agency, CIRM recognizes the need for frequent audits of internal and external financial procedures. Accordingly, CIRM has:

- established internal processes and timetables designed to facilitate financial and procedural reviews;
- established a reporting calendar for financial activities;
- established systems to assure that all state procedures for contracting are followed;
- arranged a single repository for all information, subject to review;
- developed an operational recovery plan designed to keep to a minimum any disruption to the functioning of CIRM's offices and computer equipment resulting from a natural or manmade disaster.