SCARIFIER BETTER THAN HOPE

Overview of CIRM Policies and Procedures

March 23, 2021









1. Needs Assessment

The Team determines how much money CIRM will need in the ensuing six months to fund all anticipated programs and administrative expenses during that time period



2. Meeting with DOF

- Chair and Director of Finance meet semiannually with the Department of Finance in the Governor's office
- Present needs assessment and rationale
- DOF accepts or amends CIRM recommendations
- DOF informs the State Treasurer of its conclusions

+

3. State Treasurer Convenes Authorizing Committee

- The State Treasurer convenes the California Stem Cell Research and Cures Finance Committee Meeting (the "Committee")
- The Committee includes the State
 Treasurer, representatives from the DOF and State Controller's office plus the
 CIRM Chair, Vice Chair and additional
 CIRM Board member
- The Committee meets twice a year in advance of the State's semiannual issuance of bonds/CP on behalf of State Agencies
- The Committee authorizes the issuance of CIRM's bonds/CP in accordance with the DOF instructions

4. State Treasurer issues bonds/CP

- Following Committee authorization, the State Treasurer issues bonds/CP on behalf of CIRM
- Issuance is part of semiannual issuance on behalf of State agencies (spring and fall)
- Bond/CP proceeds are held in a segregated account by the State Controller



5. State Controller disburses funds

- CIRM money covers Big Bucket (projects) or Little Bucket (administrative) expenses
- CIRM notifies the State Controller each time it needs to disburse Big Bucket funds
- The State Controller disburses those Big Bucket funds directly to the specified recipient (e.g., grantee)
- The State Controller also disburses Small Bucket payments to pay vendors and to meet payroll for the CIRM Team.
 Funds are issued to vendors via a paper warrant upon receipt or a valid invoice or automatically under a prearranged disbursement schedule (such as direct deposit for monthly payroll)



SCASIFICACIONES ETTER THAN HOPE

ICOC Subcommittees

Maria Bonneville

VP Administration Executive Director to the Governing Board

March 23, 2021



ICOC Governing Board

35 Board Members

- Chair
- Vice-Chair
- 12 Patient Advocate Members
- 2 Nurses
- 15 Executive Officers from research institutions, medical schools and universities
- 4 California life-science commercial entity members





ICOC Meeting Schedule

- Full board meetings once a quarter
- Application Review Subcommittee (ARS) meetings once a month
- Remaining meetings for the year:

April – date TBD - ICOC

May 27th- ARS

June 28th - ICOC

July 20th - ARS

August 24th - ARS

September 23rd- ICOC

October 19th- ARS

November 23rd- ARS

December 14th - ICOC





ICOC Subcommittees

Today's Subcommittees

- Application Review Subcommittee
- Science Subcommittee
- Communication Subcommittee
- Legislative Subcommittee
- Governance Subcommittee
- Evaluation Subcommittee
- Transition Subcommittee
- Intellectual Property & Industry Engagement

Moving Forward

- Consolidate Evaluation and Governance
- Retire Legislative matters will be brought straight to the board
- Retire Transition no need for this any longer





Current Subcommittee Membership

Application Review Subcommittee	Communications Subcommittee	EvaluationSubcommittee	Finance Subcommittee	Governance Subcommittee
Dan Bernal	Ysabel Duron(Chair)	Stephen Juelsgaard (Co-Chair)	Stephen Juelsgaard (Chair)	Art Torres(Chair)
Anne-Marie Duliege	GeorgeBlumenthal	Judy Gasson(Co-Chair)	Judy Gasson	Al Rowlett
Ysabel Duron	MarkFischer-Colbrie	Jonathan Thomas	Al Rowlett	Oswald Steward
Elena Flowers	Lawrence Goldstein	ArtTorres	Suzanne Sandmeyer	Jonathan Thomas
DavidHiggins	Lauren Miller Rogen	Deborah Deas	Oswald Steward	Kristiina Vuori
Steve Juelsgaard	Oswald Steward	KristiinaVuori	Jonathan Thomas	
David Martin	Jonathan Thomas		ArtTorres	
Christine Miaskowski		_	KristiinaVuori	
Lauren MillerRogen				•
Joe Panetta				
AdrianaPadilla				
Al Rowlett				
OsSteward				
Jonathan Thomas				
ArtTorres	7			

Legislative Subcommittee	IP/Industry Subcommittee	Science Subcommittee	Transition Subcommittee
Art Torres(Chair)	Stephen Juelsgaard (Chair)	Oswald Steward (Chair)	Jonathan Thomas (Chair)
Linda Malkas	Anne-Marie Duliege	Deborah Deas	JudyGasson
Joe Panetta	Joe Panetta	Anne-Marie Duliege	Steve Juelsgaard
Al Rowlett	Oswald Steward	JudyGasson	Linda Malkas
Kristiina Vuori	Jonathan Thomas	Lawrence Goldstein	Sholomo Melmed
	·	DavidHiggins	Joe Panetta
		Steve Juelsgaard	Al Rowlett
		Shlomo Melmed	ArtTorres
		ArtTorres	KristiinaVuori
		Jonathan Thomas	DianeWinokur
		KristiinaVuori	

Karol Watson Diane Winokur





Process for Appointment

ICOC Bylaws

The ICOC shall appoint the chairperson of each subcommittee based upon the recommendations of the members of the ICOC. The chairperson of the subcommittee shall then appoint the other members of the subcommittee with the concurrence of the Chairperson of the ICOC.

Once subcommittees are set, we will work on updating the mission and scope of each.





SCARIFICA BETTER THAN HOPE

CIRM Grants Working Group

Gil Sambrano

Vice President Portfolio Development and Review

March 23, 2021

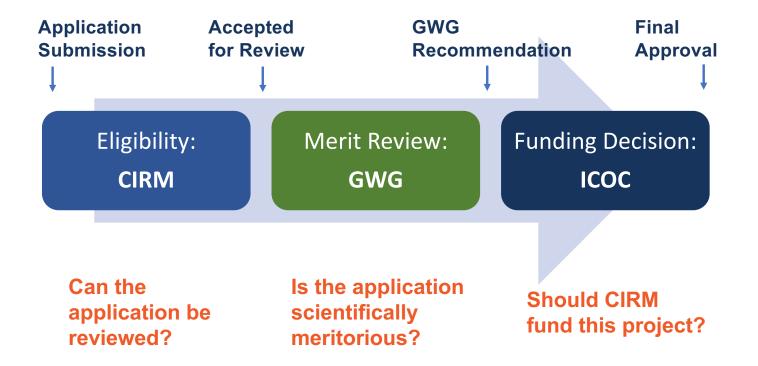


What is the GWG?

- The CIRM Grants Working Group (GWG) is responsible for evaluating the scientific merit of all applications submitted to CIRM and to provide funding recommendations to the ICOC.
- The GWG is composed of:
 - 15 scientific members (not in California)
 - 7 patient advocate members of the ICOC
 - Chair of the ICOC, ex officio
- GWG panels are assembled and tailored with experts to evaluate proposals from specific funding opportunities such CLIN, TRAN, DISC.



Application Review Process





Merit Review: **GWG**

Is the project scientifically meritorious?

- ✓ Does the project hold the necessary significance and potential for impact?
- ✓ Is the rationale sound?
- ✓ Is the project well planned and designed?
- ✓ Is the project feasible?
- ✓ Does the project address the needs of the underserved?



Merit Review: **GWG**

GWG May Use a Two-Stage Review

- When the total number of applications exceeds the capacity of the GWG to review in a single session.
- In the first stage, GWG members including patient advocates conduct a prereview of applications and select which ones to advance to a full review.
- The CIRM President and CIRM will examine non-selected applications to determine if any merit a full review. The remainder are not considered further.
- In the second stage, the GWG members review the selected applications in the usual manner, score, and make their funding recommendations to the ICOC.



GWG Scientific Scoring





Funding Decision: ICOC

Should CIRM fund the project?

- Application Review Subcommittee
- Occur monthly, mostly by teleconference
- Presentation of GWG recommendations
- Includes scores and summary of key strengths/weakness.
- Conducts Programmatic Review
- Vote to fund or not to fund





Funding Decision: ICOC

Programmatic Review Considerations

- Scientific score and overall ranking of applications
- Alignment with CIRM mission and objectives of opportunity
- Potential impact of project to patients
- CIRM portfolio of projects
- DEI score
- Availability of funds





SCARIFICA BETTER THAN HOPE

Review of CIRM Standards Working Group

Geoffrey Lomax, DrPH
Senior Science Officer

March 23, 2021



Scientific and Medical Standards Working Group (SWG)

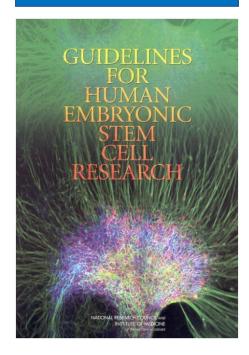
- Recommend to the ICOC standards for:
 - Medical, socioeconomic, and financial aspects of clinical trials and therapy delivery to patients
 - Safe and ethical procedures for obtaining research materials (cells and tissue) & research consent
 - The oversight of funded research
- Composition:
 - ICOC chairperson and five patient advocates
 - Nine scientists and clinicians recognized in stem cell research
 - Four medical ethicists





SWG History: Phase 1 Oversight Framework for CIRM

2005 → **2007**



Adopt National Academies Framework for Human Embryonic Stem Cell Research

- NAS Guidelines were adopted as state regulations covering all CIRM-funded research
- Fundamental Aim: Address "gaps" in federal regulations
- Major Impacts:
 - Creation of Stem Cell Research Oversight Committees
 - Robust informed consent for gamete and embryo research
 - Expanded hESC lines available to researchers



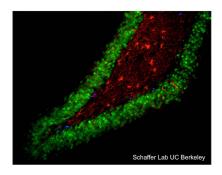


SWG History: Phase 2 Framework Validation

$2008 \to 2010$



Advancing the Effective Research Oversight: 2010 Regional Workshops on Regulatory Compliance



Workshop Summary May 2010

Develop Good Practices Statewide for Stem Cell Research Oversight

- Facilitate grantees adoption of good oversight practices consistent with CIRM's policies
- Workshops attended by CIRM awardees
 - Shared implementation strategies
 - How Stem Cell Oversight Committees interact with IRBs
 - Recommendations to CIRM for enhancing effectiveness





SWG History: Phase 3 iPSC Derivation and Banking

$2011 \rightarrow 2015$

Ethical and Policy Considerations for A Pluripotent Stem Cell Resource Center 2011 Update



Summary of the April 29, 2011 Annual meeting of the CIRM Medical Accountability Standards Working Group

Los Angeles, California

June 28, 2011

www.CIRM.ca.gov

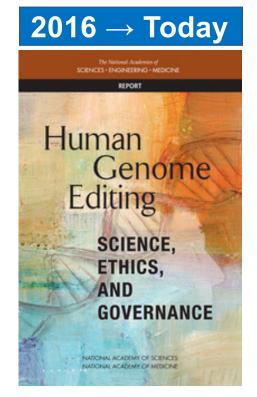
Establish Robust Education, Consent and Donation Protocol for CIRM's iPSC Bank

- Multiple CIRM SWG meeting to gather input from
 - Patients and families
 - Researchers and bio-bank administrators
 - Health / research communication experts
- CIRM Projects Outputs
 - Model informed consent for CIRM's iPSC Banking Imitative
 - Educational materials for prospective donors
 - Verification procedures to support use of iPSC lines





SWG History: Current & Future Considerations Examples



Genome Editing and Advance Treatments

- Endorsed NAS Statement on Genome Editing
- SWG 2016 Informed Consent Considerations for Embryo Genome Editing Studies

Potential Future Considerations

- Consent for clinical trials
- Embryo research
- Maintain vigilance on genetics research policy
- Permitted reimbursement





SCARIFICA BETTER THAN HOPE

Review of CIRM Scientific and Medical Facilities Working Group

James Harrison

March 23, 2021



Scientific and Medical Facilities Working Group (FWG)

- Composition 11 Members:
 - ICOC chairperson and six members of the GWG
 - Four California real estate specialists
- Functions Recommend to the ICOC standards for:
 - Applications and awards for facilities funding for nonprofits institutions in California
 - Oversight of facilities awards
 - Review and recommend applications for facilities awards (Prop. 71 earmarked up to \$286.5 million for facilities)





- Established in 2005
- Developed standards for application, award, and oversight of facilities funding to California nonprofit institutions
- Reviewed and recommended applications for Shared Labs Awards in 2007, with scientific merit of applications reviewed by GWG
 - Criteria included feasibility, cost, timeline, and institutional commitment
 - Funded 17 awards





- Reviewed and recommended applications for Major Facilities Awards in 2007-2008, with scientific merit of applications reviewed by GWG
 - Criteria included urgency, value (excellence, innovation and costs), functionality, shared resources, and leverage
 - Levels of funding varied based on combination of uses
 - Institutes (discovery, translational, and clinical)
 - Centers of Excellence (two of three elements of research)
 - Special Programs (one element of research)





- Funded 12 new research facilities in California at cost of \$271M (included facilities and research equipment)
 - CIRM Institutes
 - Sanford Consortium for Regenerative Medicine (Sanford Burnham, Salk, Scripps, and UCSD)
 - Stanford Lorry Lokey Stem Cell Research Building
 - UCSF Dolby Center for Regeneration Medicine Building
 - UCI Gross Stem Cell Research Center
 - USC Board CIRM Center for Regenerative Medicine and Stem Cell Research
 - UC Davis Institute for Regenerative Medicine





- CIRM Institutes
 - UCLA Broad Center for Regenerative Medicine and Stem Cell Research
- CIRM Centers of Excellence
 - Buck Institute for Age Research
 - UC Berkeley Stem Cell Center
- CIRM Special Programs
 - UC Santa Cruz CIRM Institute for Biology of Stem Cells
 - UC Merced Stem Cell Instrumentation Foundry
 - UC Santa Barbara Center for Stem Cell Research and Engineering





 Generated \$ 543M in matching funds, 13,000 job years, and \$100M in state tax revenues







FWG Future

- FWG has not met since 2010; needs to be reconstituted
- Functions Recommend to the ICOC standards for:
 - Review and recommend applications for facilities awards programs established by Prop. 14
 - Shared Labs (up to \$26M)
 - Community Care Centers of Excellence (up to \$78M)





SCARIFICA BETTER THAN HOPE

Board Policies

James Harrison

Counsel

March 23, 2021



CIRM Conflict of Interest Policies





CIRM Board Members Appointed Based on Expertise

- CIRM benefits from diverse expertise and experience of Board members
- Members are appointed to represent the interests of all Californians





Board Members are public officials for purposes of California conflict of interest laws

- Political Reform Act
- Form 700 and Attorney General Ethics Course
- Government Code Section 1090
- Common law conflicts of interest.





CIRM Conflict Rules Go Further than State Law

- Members are precluded from participating in, or attempting to influence, a decision regarding an application submitted by their employer
- Members are precluded from applying for CIRM funding, acting as a PI on a CIRM application, or receiving salary support through a CIRM award
- Members are precluded from accepting a gift from any person or entity that does or seeks to do business with CIRM if gift is intended to influence or reward member for official action





CIRM Policies to Protect Against Appearance of Conflicts

- GWG scientific members are appointed from out-of-state
- Members are required to complete conflict verification before participating in consideration of applications
- CIRM team supplements conflict verification with review of Form 700s
- Programmatic review of applications conducted on blind basis
- Application Review Subcommittee makes all final funding decisions





Board Bylaws

- Define functions of Board
- Govern conduct of Board meetings
- Establish standing subcommittees and provide for establishment of additional subcommittees





Code of Conduct

- Establishes expectation that members regularly attend and actively participate in Board meetings and meetings of subcommittees of which they are members
- Requires Board members to protect the confidentiality of information provided to them as members of the Board, including in their capacity as members working groups or subcommittees
- Requires that requests for CIRM team to perform specific tasks be coordinated through Chair and President





Internal Governance Policy

- Defines responsibilities of Chair, Vice Chair, and President
- Provides for administrative and organizational structure of CIRM





SCASIFICACIONES ETTER THAN HOPE

Intellectual Property Regulations Summary

Benjamin Huang
Associate General Counsel

March 23, 2021



Proposition 71 Language (2004)

Section 125290.30 Public and Financial Accountability Standards

(h) Patent Royalties and License Revenues Paid to the State of California

The ICOC shall establish standards that require that all grants and loan awards be subject to intellectual property agreements that balance the opportunity of the State of California to benefit from the patents, royalties, and licenses that result from basic research, therapy development, and clinical trials with the need to assure that essential medical research is not unreasonably hindered by the intellectual property agreements. All revenues received through the intellectual property agreements established pursuant to this subdivision shall be deposited into the General Fund.





IP Regulations coverage

- Invention and Licensing Reporting to CIRM
- Publication Requirements
- Patent ownership
- Licensing and Assignment of CIRM-Funded Inventions and Technology
- Access Requirements for Products
- Revenue Sharing
- March-In Rights





Versions of the IP Regulations-(revenue sharing focus)

Initial 2006 version

- licensing revenue from patents for non-profits/for-profits
- royalty from for-profit self-commercialization

2009 version

-added CIRM-funded Technology licensing obligation (e.g. clinical data) as Disease Team program funding clinical research was launched

2014 version

- -revised revenue sharing formula for non-profits
- -changed the for-profit royalty formula

2018 version (current)

-changed the non-profit licensing formula into a royalty formula so all grantees are treated the same





Current revenue-sharing language

In Section 100650 Section VIII.(A), a royalty is calculated for the eventual Commercializing Entity to share with the State of California for deposit in the State's General Fund.

The first calculation is a royalty on Net Commercial Revenue at a rate of **0.1% per \$1 million** of CIRM Award for the earlier of 10 years from date of first sale or 9x of the grant amount. (For example, an Award totaling \$15 million will result in royalty payments of 1.5% of Net Commercial Revenues lasting until the earlier of 10 years after first sale or \$135 million deposited in the General Fund.)

In the event there is a CIRM-Funded Invention involved, the royalty requirements above are fulfilled, and the CIRM awards amounted to \$5 million or over, there is an additional 1% royalty on revenue in excess of \$500 million per year until the last-to-expire patent covering a CIRM-Funded Invention.





Proposition 14 Language (2020)

Section 125290.30 Public and Financial Accountability Standards

(j) Patent Royalties and License Revenues Paid to the State of California

(1)The ICOC shall establish standards that require that all grants and loan awards be subject to intellectual property agreements that balance the opportunity of the State of California to benefit from the patents, royalties, and licenses that result from basic research, therapy development, and clinical trials with the need to assure that essential medical research is not unreasonably hindered by the intellectual property agreements. All royalty revenues received through the intellectual property agreements established pursuant to this subdivision shall be deposited into an interest-bearing account in the General Fund, and to the extent permitted by law, the amount so deposited and interest thereon shall be appropriated for the purpose of offsetting the costs of providing treatments and cures arising from institute-funded research to California patients who have insufficient means to purchase such treatment or cure, including the reimbursement of patient-qualified costs for research participants.





SCARIFICA BETTER THAN HOPE

Board Self-Evaluation

James Harrison
Counsel

March 23, 2021



Background

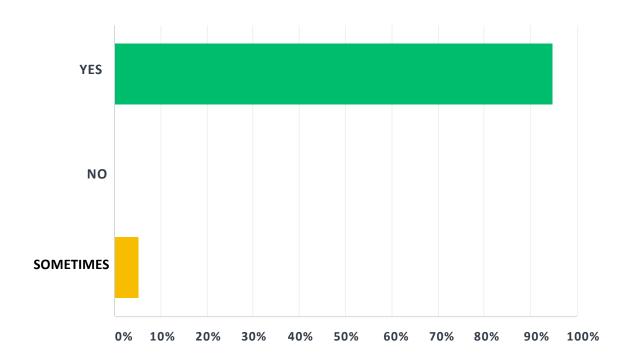
- Survey sent to all Board members and alternates
- Last survey conducted in 2011
- Given board turnover and the expansion of the size of the Board, anticipated fewer responses than in 2011
- Survey results suggest interest in reinvigorating role of subcommittees, providing more input into development of Board agenda, and receiving more robust information regarding matters presented to the Board





Q1 CIRM Lives Up to Its Mission





ANSWER CHOICES	RESPONSES	
YES	94.74%	18
NO	0.00%	0
SOMETIMES	5.26%	1
TOTAL		19

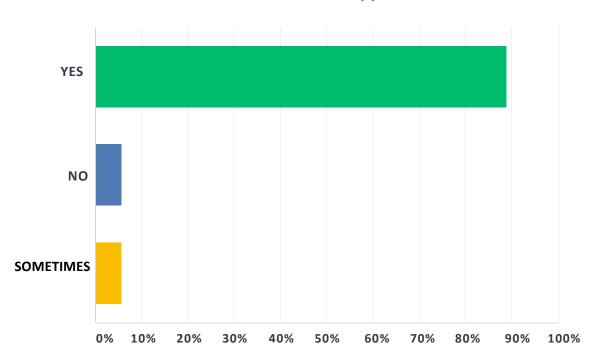




Q2 Board Focuses on the Appropriate Strategic, Fiduciary, and Oversight Issues that Guide the Work of CIRM





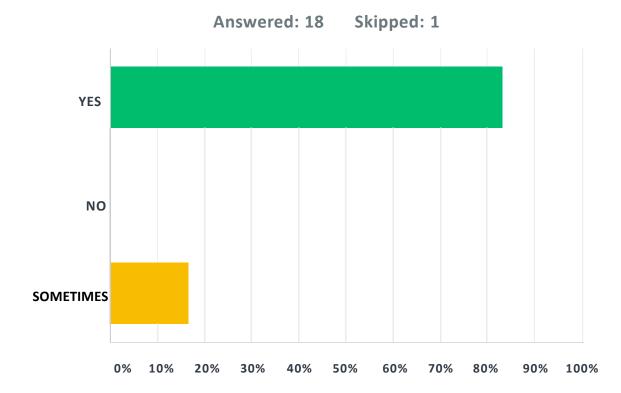


ANSWER CHOICES	RESPONSES	
YES	88.99%	16
NO	5.56%	1
SOMETIMES	5.56%	1
TOTAL		18





Q3 Board Attends to Policy-Related Activities that Guide the Work of Management Staff

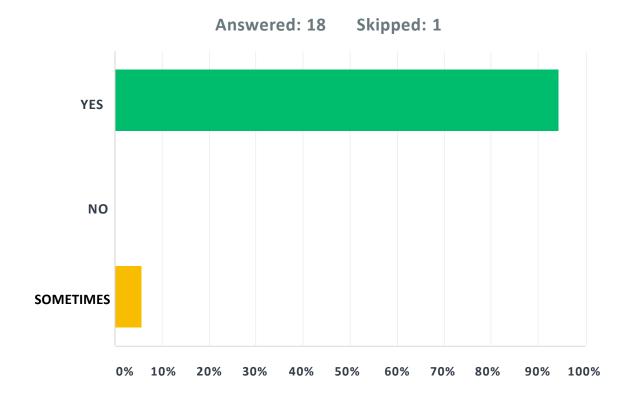


ANSWER CHOICES	RESPONSES	
YES	83.33%	15
NO	0.00%	0
SOMETIMES	16.67%	3
TOTAL		18





Q4 Board Avoids Getting into Excessive Administrative/Management Details

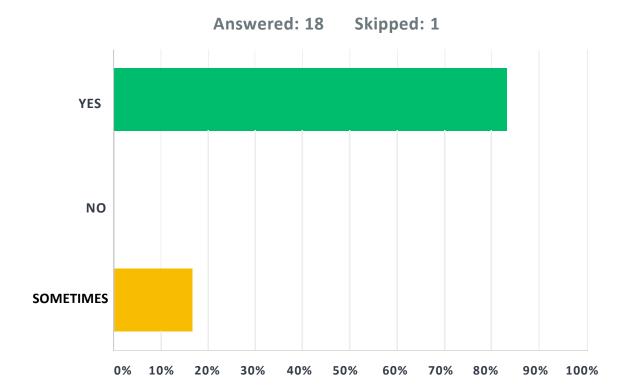


ANSWER CHOICES	RESPONSES	
YES	94.44%	17
NO	0.00%	0
SOMETIMES	5.56%	1
TOTAL		18





Q5 Board Engages in Appropriate Level of Oversight of CIRM Staff

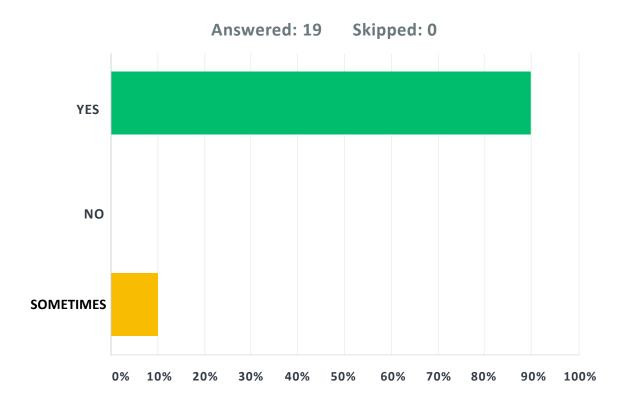


ANSWER CHOICES	RESPONSES	
YES	83.33%	15
NO	0.00%	0
SOMETIMES	16.67%	3
TOTAL		18





Q6 Board is Independent-Minded and Asks the Penetrating Questions Required to Uncover Issues



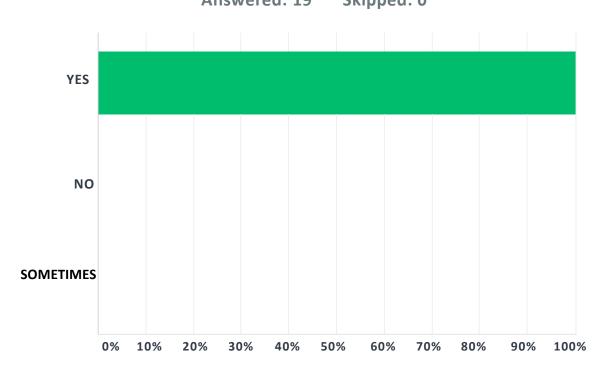
ANSWER CHOICES	RESPONSES	
YES	89.47%	17
NO	0.00%	0
SOMETIMES	10.53%	2
TOTAL		19





Q7 Board Members Offer a Diversity of Opinions and Address Issues in a Respectful Manner



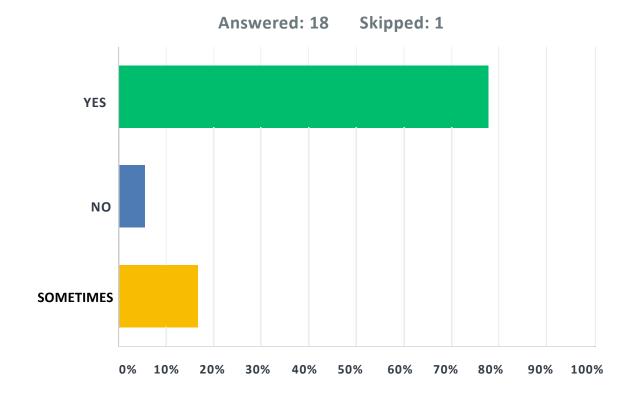


ANSWER CHOICES	RESPONSES	
YES	100.00%	19
NO	0.00%	0
SOMETIMES	0.00%	0
TOTAL		19





Q8 Board's Level of Reliance on the Views of the President and/or Other Management Staff is Appropriate

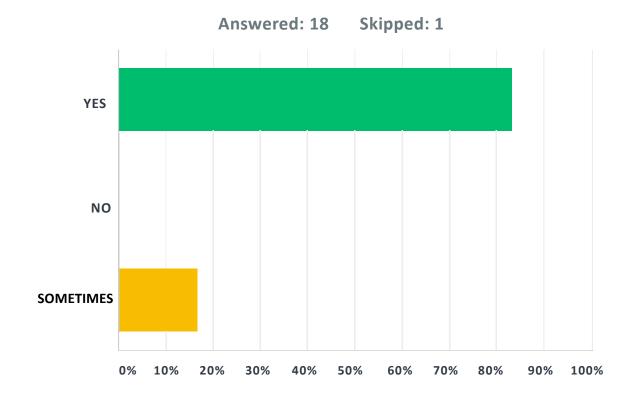


ANSWER CHOICES	RESPONSES	
YES	77.78%	14
NO	5.56%	1
SOMETIMES	16.67%	3
TOTAL	3	18





Q9 Board Plays an Appropriate Role in CIRM's Finances



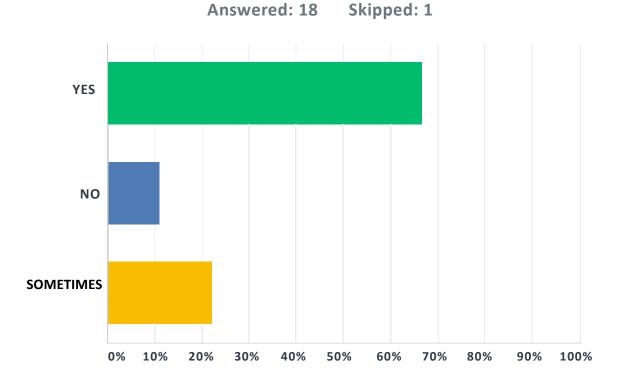
ANSWER CHOICES	RESPONSES	
YES	83.33%	15
NO	0.00%	0
SOMETIMES	16.67%	3
TOTAL		18





Q10 Board Makes Appropriate Use of Subcommittees to Provide Input/Recommendations





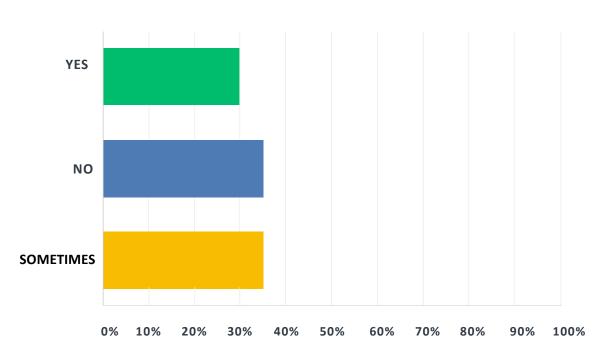
ANSWER CHOICES	RESPONSES	
YES	66.67%	12
NO	11.11%	2
SOMETIMES	22.22%	4
TOTAL		18





Q11 Board Members Have Appropriate Input into the Preparation of the Agendas



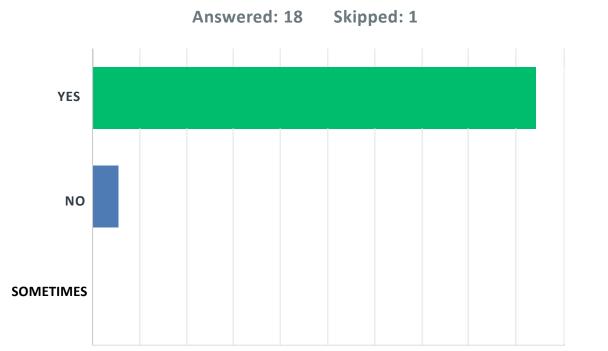


ANSWER CHOICES	RESPONSES	
YES	29.41%	5
NO	35.29%	5
SOMETIMES	35.29%	5
TOTAL	17	7





Q12 Board Meets with Appropriate Frequency and Timing to Carry Out its Mission



ICOC Survey

ANSWER CHOICES	RESPONSES	
YES	94.44%	17
NO	5.56%	1
SOMETIMES	0.00%	0
TOTAL		18



10%

20%

30%

40%

50%

60%

70%

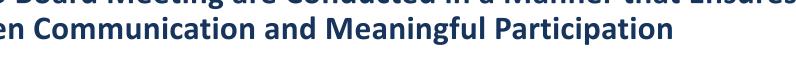
80%

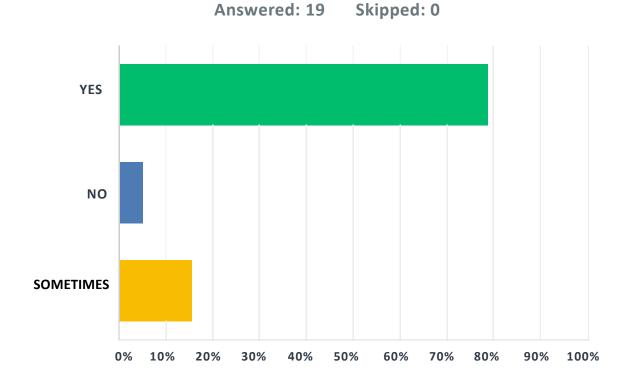
90%

100%



Q13 Board Meeting are Conducted in a Manner that Ensures **Open Communication and Meaningful Participation**





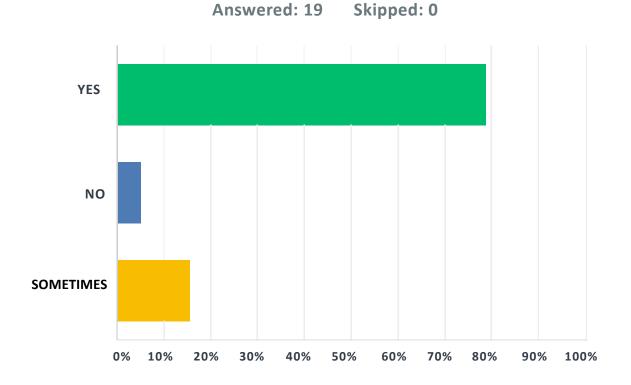
ANSWER CHOICES	RESPONSES	
YES	78.95%	15
NO	5.26%	1
SOMETIMES	15.79%	3
TOTAL		19





Q14 Board Grasps and Deliberates the Important Issues and **Brings Decision Topics to Closure in a Timely Manner**



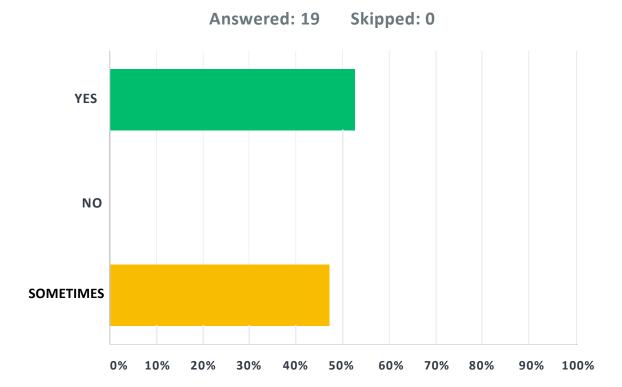


ANSWER CHOICES	RESPONSES	
YES	78.95%	15
NO	5.26%	1
SOMETIMES	15.79%	3
TOTAL		19





Q15 Board Receives Adequate Information to Understand the Issues Presented and to Make Good Decisions



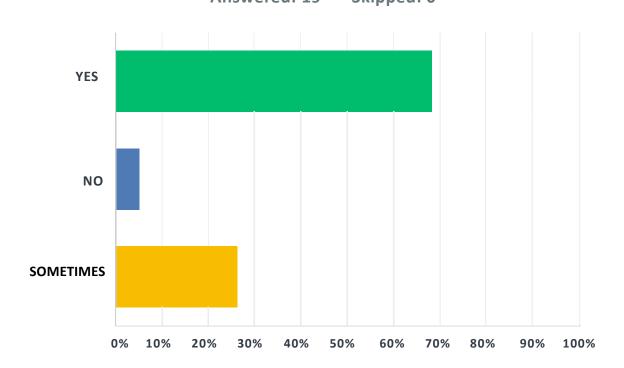
ANSWER CHOICES	RESPONSES	
YES	52.63%	10
NO	0.00%	0
SOMETIMES	47.37%	9
TOTAL		19





Q16 The Information Received Prior to and During the Meetings is Clear and Concise and is Delivered in a Timely Fashion





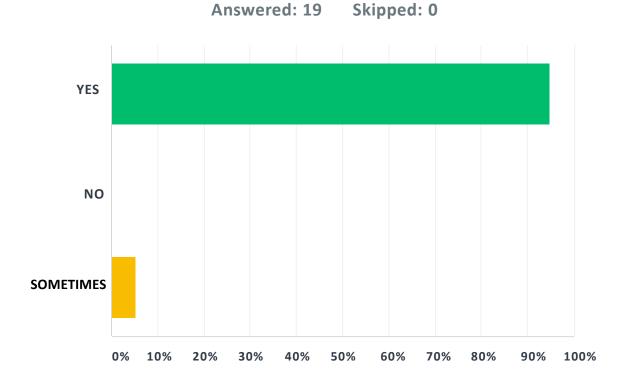
ANSWER CHOICES	RESPONSES	
YES	68.42%	13
NO	5.26%	1
SOMETIMES	26.32%	5
TOTAL		19





Q17 Functionally, the Board has an Effective, Cooperative, and



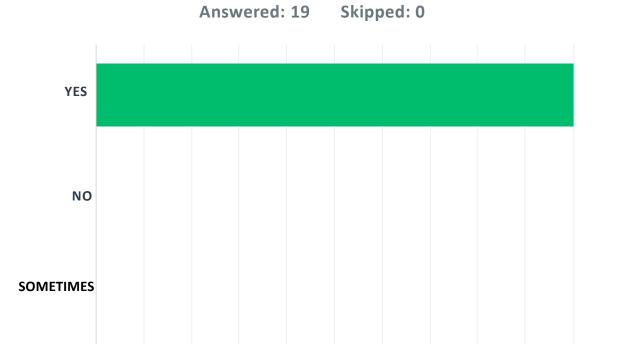


ANSWER CHOICES	RESPONSES	
YES	94.74%	18
NO	0.00%	0
SOMETIMES	5.26%	1
TOTAL		19





Q18 I Understand and Support CIRM's Mission



ICOC Survey

ANSWER CHOICES	RESPONSES	
YES	100.00%	19
NO	0.00%	0
SOMETIMES	0.00%	0
TOTAL		19



10%

20%

30%

40%

50%

60%

70%

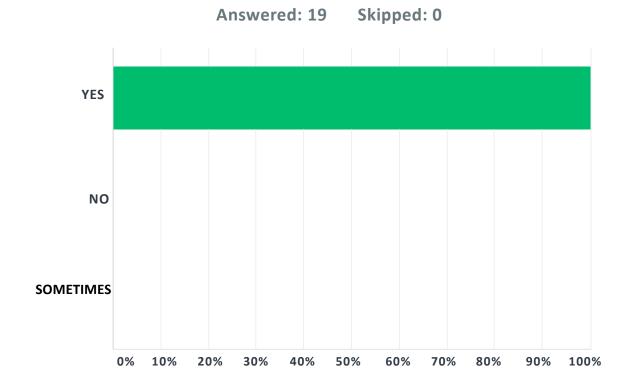
80%

90%

100%



Q19 I Understand My Responsibilities as a Board Member

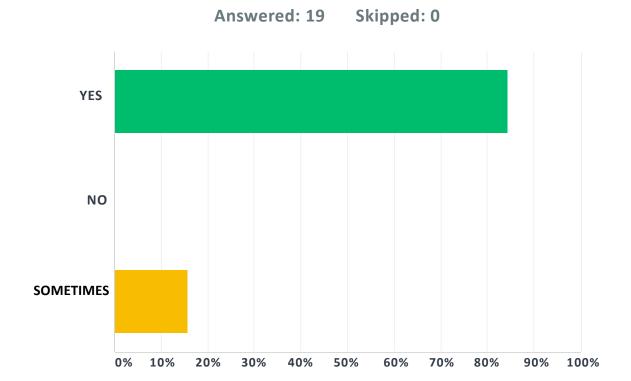


ANSWER CHOICES	RESPONSES	
YES	100.00%	19
NO	0.00%	0
SOMETIMES	0.00%	0
TOTAL		19





Q20 I Come to the Board Meetings Fully Prepared to Participate



ANSWER CHOICES	RESPONSES	
YES	84.21%	16
NO	0.00%	0
SOMETIMES	15.79%	3
TOTAL		19

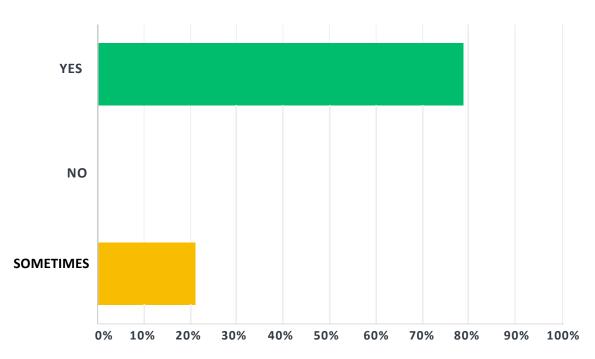




Q21 At Board Meetings, I feel Comfortable Raising and Discussing Dissenting or Contrary Opinions







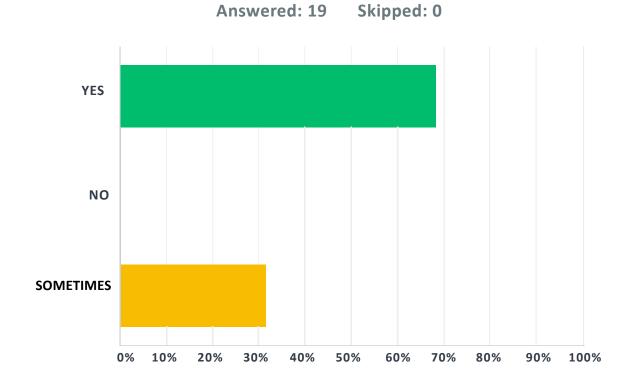
ANSWER CHOICES	RESPONSES	
YES	78.95%	15
NO	0.00%	0
SOMETIMES	21.05%	4
TOTAL		19





Q22 I Think About the Work of CIRM Between Board Calls and Meetings



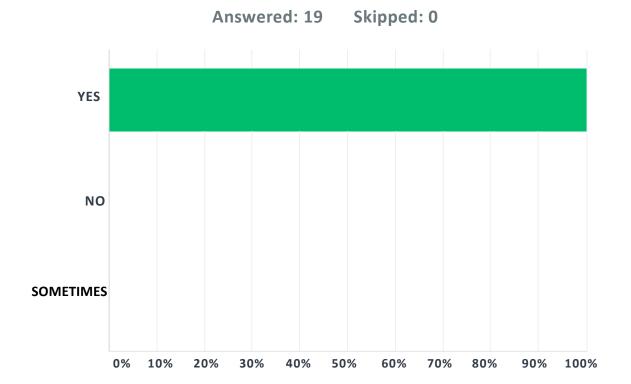


ANSWER CHOICES	RESPONSES	
YES	68.42%	13
NO	0.00%	0
SOMETIMES	31.58%	6
TOTAL		19





Q23 I Understand the Issue of Conflict of Interest



ANSWER CHOICES	RESPONSES	
YES	100.00%	19
NO	0.00%	0
SOMETIMES	0.00%	0
TOTAL		19





Q24 I Receive Personal Satisfaction from my Role as a Board Member



ICOC Survey

ANSWER CHOICES	RESPONSES	
YES	100.00%	19
NO	0.00%	0
SOMETIMES	0.00%	0
TOTAL		19



10%

20%

30%

40%

50%

60%

70%

80%

90%

100%

