

# **Proposed Amendments to Extraordinary Petition Policy and Adoption of Additional Analysis Option**

## **Agenda Item 16**

# Adopted Policies

- Board had adopted several policies to address information provided by applicants after the submission of their applications:
  - Supplemental Information Process
  - Extraordinary Petition Policy
  - Additional Analysis Option
- Purpose of proposal today is to ensure that these policies are integrated and effective



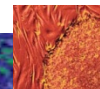
# Supplemental Information Process

- Supplemental Information Process provides two mechanisms to obtain additional information from clinical research and Disease Team applicants before the GWG makes a funding recommendation
- CIRM scientific staff and GWG identify questions before the review and obtain answers from applicants
- If questions arise during review, CIRM scientific staff obtain real time response from applicants; if questions require submission of supplemental information, GWG may defer recommendation until it has had time to assess information



# Extraordinary Petition Policy

- Provides parameters for written communications by applicants to Board:
  - Three-page limit
  - Five business day submission deadline
- President and scientific staff review timely-filed petitions and prepare recommendation which they provide upon request
- Extraordinary petitions are discussed **only** upon request by a Board member
- Extraordinary petitions are distinct from appeals



# Extraordinary Petition Policy (Continued)

## Proposed modification:

- **Written comments submitted by applicants after deadline will be labeled “other correspondence”**
- **Applicants should refrain from orally presenting information to the Board if it is not contained in an extraordinary petition**

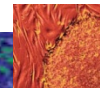


# Additional Analysis Option

- Former policy provided an option for additional analysis of factual dispute that could not be resolved at Board meeting; policy expired in March.
- Board relied on its inherent authority to refer five Disease Team II applications for additional analysis
- Proposed policy is intended to offer guidance to applicants and Board

## Proposed policy:

- **Additional analysis should be limited to material dispute of fact and material new information**



# Additional Analysis Option (Continued)

- Material Dispute of Fact:
  - Applicant disputes accuracy of statement in review summary
  - Disputed fact significant in GWG scoring or recommendation
  - Dispute relates to objectively verifiable fact rather than scientific opinion
  - Discrepancy not resolved through Supplemental Information Process
  - Resolution of dispute affects Board funding decision



# Additional Analysis Option (Continued)

- Material New Information:
  - Verifiable through external sources
  - Arisen since GWG consideration
  - Responds to criticism(s) and/or question(s) from GWG review
  - Included in extraordinary petition submission (before 5 business-day deadline)





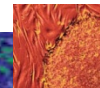
# Additional Analysis Option (Continued)

- Examples of externally verifiable information include:
  - approval by the Food and Drug Administration to initiate a clinical trial;
  - a documented, enforceable agreement between the applicant and a commercial partner;
  - a final court decision or administrative action; and
  - documentation confirming that a manuscript has been accepted for publication in final form



# Additional Analysis Option (Continued)

- Information submitted as part of the Supplemental Information Process will not be considered “new information”
- New scientific data will not be considered “new information” unless it has been peer reviewed and published

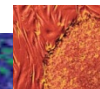


# Process for Additional Analysis

- Conducted by GWG Review Chair, Patient Advocate, and Scientific Member of GWG review panel
- Limited to analysis of material dispute of fact or material new information identified by Board
- Charge is to recommend whether resolution of factual dispute or consideration of new information warrants change in GWG funding recommendation

## **Recommended Action:**

**Motion to approve proposed modifications to the Extraordinary Petition Policy and Adoption of Additional Analysis Option.**



## Supplemental Information Process

### Before Grants Working Group Meeting

- GWG members and CIRM scientific officers identify and communicate questions to applicants.
- Applicants respond with supplemental information before GWG meeting.

### At Grants Working Group Meeting

- If questions arise during meeting, CIRM's scientific officers may contact applicant to obtain response.
- If questions require submission of new supplemental information, GWG may defer recommendation on application until information is provided and GWG considers it.

Complimentary to, but separate from

## Extraordinary Petition Policy

### Written Comments

**Format:** 3 pages or less, Arial typeface, 11-pt. font, 1" margins on all sides; indicates information to be redacted

#### Before 5 business-day deadline

#### "Extraordinary Petition"

- Directed to ICOC Chairman and President, distributed to ICOC, and posted on website.
- CIRM may redact proprietary or confidential information.
- President, in consultation with scientific staff, prepares recommendation.
- If ICOC member requests discussion, staff provides analysis and recommendation to Board.

#### After 5 business-day deadline

#### "Other Correspondence"

- Limited review of written comments by CIRM President and Scientific Officers

## ICOC Board Meeting

- Extraordinary petitions and other correspondence provided to Board.
- Board discusses extraordinary petitions / other correspondence *only* upon request of Board member.
- President and CIRM scientific officers provide input upon request.
- If new information is included, President and CIRM scientific officers advise Board whether new information meets criteria for "material new information" and warrants additional analysis.
- Board members may make motions to fund, deny funding, or refer for additional analysis.

Board member moves to refer material factual dispute or material new information for additional analysis

## Additional Analysis Option

### Material Dispute of Fact

1. Applicant disputes accuracy of statement in review summary
2. Disputed fact significant in GWG scoring or recommendation
3. Dispute of objectively verifiable fact
4. Discrepancy not resolved through Supplemental Information Process
5. Resolution of dispute affects Board funding decision

### Material New Information

1. Verifiable through external sources
2. Arises since GWG consideration
3. Responds to criticism(s) and/or question(s) from GWG review
4. Included in extraordinary petition submission (before 5 business-day deadline)

### Additional Analysis

Additional analysis is conducted by the Co-Vice Chair, the Review Chair, and a scientific member of the GWG, supported by the President and other scientific staff. When Co-Vice Chair is conflicted, a patient advocate will review. When the Review Chair is conflicted, another scientific member of the GWG will review.