# Facilities Working Group Meeting
# July 12, 2007

PURPOSE: Define the recommended criteria, standards and requirements—i.e. policies, rules & definitions—and the procedure for FWG review of the Large Facilities Grant RFA

# Objectives for Today

- Recommend Requirements, Standards and Criteria to the ICOC for Large Facilities RFA
- Recommend a review process to the ICOC for Large Facilities RFA

# Objectives for Large Facilities RFA

- Proposition 71 Requirements
- The Scientific Strategic Plan
  - $150M—Large Facilities Grants
  - $72M—Small Facilities Grants
- The ICOC's direction
  - Single RFA for Facilities
- Input from public meetings

# Context for Large Facilities RFA

Science to lead (Part 1)

Grants Working Group (GWG) to Evaluate Scientific Merit.

Key Facilities Considerations (Part 2)

- Criteria
- Requirements
- Standards

# Agenda
# Part Two Application Review

## Review Criteria

- Prop 71 standards & requirements
- Identify other standards & requirements
- Evaluation Criteria
- Weighting

## Review Process

- Present Options for Process Review
- Part One Discussion
- Part Two Discussion

# Requirements and Criteria

- **Requirements—**What are the requirements that the applicants must meet to be responsive to the RFA?
- **Evaluation Criteria—**What are the criteria that will be used by the Facilities WG to evaluate applications on a competitive basis?

# Prop 71 Requirements

Requirements of Applicant

- ☒ Must have milestones & timetables
- ☒ Must be located in California
- ☒ Must be not-for-profit entity
- ☒ Must provide 20 percent matching funds
- ☒ Must have goals for California suppliers
- ☒ Must pay prevailing wage

Requirements of CIRM

- ☒ Must be awarded on a competitive basis
- ☒ Priority for completion in 2 years

# Definitions--Prop 71 Requirements

- Milestones & Timetables—A definitive schedule that shows planned activities leading to completion of new facility

- Located in California
- Not-for-Profit Entity
- California Suppliers
- Prevailing Wage

Requirements defined consistent with current Grants Administration Policy (GAP)

# Definitions--Prop 71 Requirements (cont'd)

FWG needs to clarify the definition of:

Matching Fund and other forms of Institutional Commitment/Leverage

# Definition of Matching Funds

Applicant provides minimum 20 percent match for each CIRM dollar

# Clarification of Matching Funds

Match – Threshold needed to satisfy the minimum requirement specified in Prop 71. This amount would be provided as a cash contribution to the project.

Additional Matching Amount--Amounts provided by applicant in excess of the minimum matching amount for the project or other related objectives. Refer to this amount as "leverage" for clarity. (More on this later)

# Requirements and Criteria

- **Requirements—**What are the requirements that the applicants must meet to be responsive to the RFA?

- **Evaluation Criteria—**What are the criteria that will be used by the Facilities WG to evaluate applications on a competitive basis?

# Environmentally Responsive Design

- UC Green Building Policy
- US Green Building Council Certified Standard

# Summary of Requirements

## PROP 71

- ☒ Milestones & timetables
- ☒ Must be located in California
- ☒ Must be not-for-profit entity
- ☒ Prevailing wage
- ☒ California suppliers
- ☒ Awarded on a competitive basis

## FWG - Additional

- ☒ Clarifies 20% Matching Funds
- ☒ Adds Green Building Standard
- ☐ OTHER?

# Shared Labs Sample of Criteria

- Feasibility
- Cost
- Timeline and Milestones
- Institutional Commitment
- Historical Performance
- Responsiveness to RFA

# Criteria & Requirements from FWG Information Meetings

- Urgency
- Excellence
- Collaboration
- Innovation
- Accountability
- Leverage
- Functionality

# Proposed Evaluation Criteria

- Urgency
- Value (considering costs, quality, excellence of facilities and innovation)
- Leverage
- Functionality

# What we heard about Urgency

- Construction costs are escalating at about 1 percent a month
- Lack of space is becoming the limiting factor in expanding hESC programs
- Difficult for institutions to build new facilities within 2 years of grant award if just starting. Some have already begun project planning and can meet this.

# What we heard about Urgency (cont'd)

- Prioritize spaces that can be delivered quickly, with proven track record
- Priority for completion in two years needs to consider up front planning time and temporary notice of completion for occupancy. Start date of NGA (adding several months).

# What we heard about Excellence

- First and foremost is the scientific excellence
- Strong translational research
- A proven track record
- Teaching must be incorporated into CIRM technology centers
- Grantees must show evidence of preclinical and clinical translational research

# What we heard about Collaboration

- Facilities should work effectively between large and small institutions
- Allocate funds to institutions with a community of outstanding scientists from other disciplines & active industry collaborations that can be documented
- Provide other institutions and visiting scholars access to major facilities.

# What we heard about Collaboration (cont'd)

- Academic collaboration is much different than industry collaboration
- Collaborations among institutions seems to be the most important criteria and needs to include resourcing
- CIRM should encourage formal collaborations for hESC research
- CIRM facilities should be a venue for public learning

# What we heard about Innovation

- Green Building design should be a goal
- Creative, innovative small places should have some seed-ability (for facilities grants)

# Defining Leverage

"the use of a small initial investment, credit, or borrowed funds to gain a very high return in relation to one's investment, to control a much larger investment..."

# Two types of Leverage

- Project Leverage—Additional funding provided by the applicant in support of the specific project that is being funded with CIRM & matching funds

- Program Leverage—The additional resources that the applicant expects to devote to stem cell research as a result of the project that would include all types of resources—human & physical capital

# What we heard about Leverage

- Facilities should leverage regional initiatives and consortia beyond single institution
- Consider broad measures of institutional commitment (i.e. documented faculty, operating and program commitments) & new faculty
- Consider geographic proximity (of researchers)
- Evaluate relationship between high matching funds and high project costs

# What we heard about Leverage (cont'd.)

- Establish a concept of "net matching funds" and "net costs" that would focus on CIRM goals and not institutional goals (e.g. high architecture)
- CIRM facilities should be built where CIRM money has gone
- Consider track record and future faculty recruitment plans

# What we heard about Leverage (cont'd)

- Build where the leverage is greatest, including faculty commitments
- Build to serve populated areas
- CIRM can expect a higher return if awards given to institutions with comprehensive programs

# What we heard about Functionality

- Facilities to be “fire-walled” from federal funding
- Need core laboratories which are key resources for hESC programs—culture labs, imaging, viviaria, computational, biochemistry
- Success--people bumping into one another
- Important for CIRM to help at the beginning to get to Phase 1 trials

# What we heard about Functionality (cont'd)

- Ask Scientists what its like to work in a facility
- Must pay attention to IT
- Facilities should be flexible for all types of SC research and expandable
- Small facility proposals to be focused on specialty area of institution
- Consider measures of how CIRM funds will expand hESC research capacity (i.e. number of PIs)

# What we heard about Functionality (cont'd)

- CIRM facilities should create an interdisciplinary work environment for scientists working on basic SCR, translational SCR and bioengineering
- Should build capacity to attract new researchers from out-of-state
- Think of CIRM facilities as Technology Centers with varying capabilities

# What we heard about Functionality (cont'd)

- Demonstrated FDA compliant preclinical work
- Split RFA to include large and small institutions
- Key criteria will be having animal models for human stem cell therapies
- Consider funding programs that span multiple disciplines

# What we heard about Functionality (cont'd)

- Consider impacts on the region
- Consider infrastructure available to support stem cell research
- Locate space where the researchers are

# Requirements and Criteria

- **Requirements—**What are the requirements that the applicants must meet to be responsive to the RFA?

- **Evaluation Criteria—**What are the criteria that will be used by the Facilities WG to evaluate applications on a competitive basis?

# Scoring of Criteria

- Requirements —These do not have points. Are the Requirements met? Yes or No. If no—Not responsive and requires a curable deficiency.

- Criteria—Assign points based on a total of 100 points.

# Criteria from FWG Info Meetings

## CRITERIA

- Urgency
- Value
  - Excellence
  - Innovation
  - Costs
- Leverage
- Functionality

## WORKING GROUP ACTION

- Define Each
- Assign Points to Each

# Possible Definition of Urgency

- The applicant has placed a high priority on timely completion of the project

# Possible Definition of Value

- The project costs and quality represent a good return for the funds invested.

# Possible Definition of Leverage

- Project Leverage—Additional funding provided by the applicant above the minimum matching amount in support of the specific project that is being funded with CIRM & matching funds

- Program Leverage—Additional resources that the applicant expects to devote to stem cell research as a result of the project that would include all types of resources—human & physical capital

# Possible Definition of Functionality

- The proposed project work corresponds to the program space needs

# Getting to Scoring

Criteria

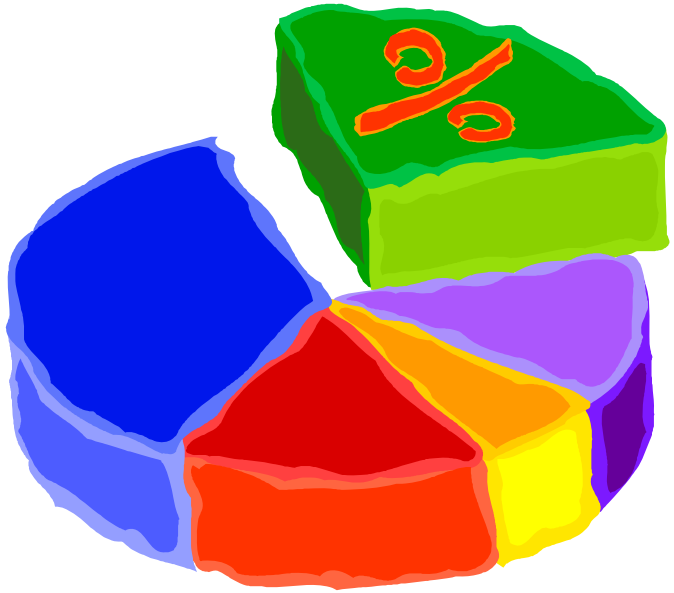
→ Definitions

→ Evaluation Standards

→ Scoring

# Scoring

How will you score each criteria based on the evaluation standards?



# Scoring Alternatives

- Equal points for each

  OR

- Emphasize key standards that are a high priority by giving higher scores:
  - For speed—Consider more Urgency points
  - For economy—Consider more Value points
  - For funding—Consider more Leverage points

# Options for Process Review

- Part 1–Science review
- Part 2—Technical review

# Scientific Review by GWG – Part 1

The GWG will evaluate each proposed facility as it relates to the overall stem cell research program at the applicant institution.

The GWG will review the program's:

- **Breadth** of stem cell research from basic to clinical elements; and
- **Depth** (i.e., quality, strength) of each scientific element in four areas (e.g., scientific program, formal partnerships, core services, capacity for growth).

# Breadth of Program

| Institution | Element X<br>Basic and discovery research | Element Y<br>Preclinical research | Element Z<br>Preclinical development and clinical research |
|---|---|---|---|
| A | ✓ | ✓ | ✓ |
| B | ✓ | ✓ | N/A |
| C | N/A | N/A | ✓ |

Applicant will select and compete in those scientific elements where they have strength.

# Depth of Scientific Program

For each key element, the GWG will assess the quality and strengths of:

- **Scientific and/or medical program** (e.g., scientific excellence, track record, interdisciplinary synergy)
- **Formal partnerships and research consortia** (i.e., institutional partnerships to conduct collaborative research with industry or non-profit entities)
- **Core services** (i.e., existing and planned core services that support or will support the program elements)
- **Capacity for growth** (e.g., commitment to programs, faculty recruitment/retention, use of space, expansion of programs)

# Examples of Criteria

- Scientific and/or medical program
  - Strength and integration of the research programs
  - Number and types of programs to be housed in the proposed facility
  - Track record of institution and participants
  - Number of CIRM-funded grants and relevant NIH grants per PI
  - Number of relevant publications & patent applications (e.g., in past 5 years)
  - Interdisciplinary synergy and collaboration
  - Development of therapies and conduct of clinical studies (especially in cell-based therapy)

# Examples of Criteria

- Formal partnerships and consortia
  - Number and types of partnerships (e.g., industry, non-profit organizations)
  - Evidence of productivity and effectiveness
  - Number and types of relevant shared resources
  - Number of relevant co-publications with partners
  - Length of time partnerships have existed

# Examples of Criteria

- Core services
  - Types and number of core services
  - Relevance of cores to the stem cell research program
  - Number of PIs actively using each core
  - Relevant projects that require core use
  - Number of relevant publications resulting from core use

# Examples of Criteria

- Capacity for growth
  - Plans for development, expansion, and continuity of programs
  - Amount of space for laboratory, cores, and program development
  - Number of faculty recruits with multi-year commitments
  - Institutional resources to handle technology transfer (# of FTEs)

# Possible GWG Recommendations

| Institution | Element X<br>Basic and discovery research | Element Y<br>Preclinical research | Element Z<br>Preclinical development and clinical research |
|---|---|---|---|
| A | Yes | Yes | Yes |
| B | Yes | Yes | No |
| C | Yes | No | No |
| D | Yes | N/A | N/A |
| E | No | No | N/A |

# Part 2--Process for FWG Review

## STRATEGIC PLAN

Two funding levels—

- Small grants $72MM ($5-10 million)
- Large grants $150 MM ($10's of millions)

## ICOC

- Single RFA for all facilities proposals, large and small
- Science leads
- Need to expedite as costs are escalating

# Options for Process Review

- One Step - Concurrent reviews by Grants WG and Facilities WG (like shared labs) (with funding targets)
- Sequential two-step review, with Grants WG recommendations to ICOC, then Facilities WG review
- Single RFA with no specific funding levels
- Combined Review Grants WG and Facilities WG in one meeting
- No Review by Grants WG (with FWG panel of scientific experts)

| GRANTS WORKING GROUP<br>Applicants Self-Select For CIRM<br>Science "Level" | | Grants WG Recom to ICOC |
|---|---|---|
| CIRM Institutes | Elements X, Y & Z*<br>Science Excellence<br>Collaboration | Recommends<br>Applicants<br>as INSTITUTES |
| CIRM Centers of Excellence | Two Elements<br>Science Excellence<br>Collaboration | Recommends Applicants as<br>CENTERS |
| CIRM Special Programs | One Element<br>Science Excellence<br>Collaboration | Recommends Applicants as<br>SPECIAL PRGM |
| Not Funded | Not Competitive | Not Recommended |

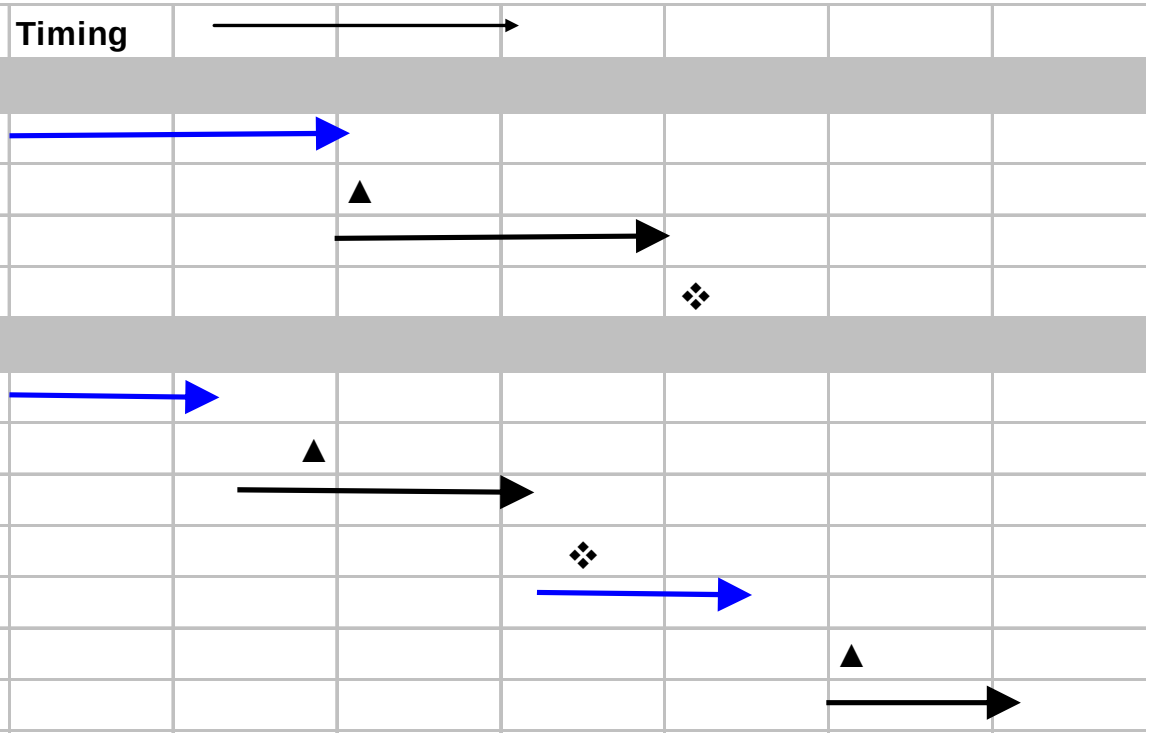
* X = Basic and discovery research
Y = Preclinical research
Z = Preclinical development and clinical research

## FACILITIES WORKING GROUP

| Scientific Level | In each level, Evaluates Applicants & Establishes a High or a Low Award based on technical and financial review | Possible Funding Level |
|---|---|---|
| CIRM Institutes | Consortium Award Amount | $$$$$$$ |
| | High award amount | $$$$$$ |
| | Lower award amount | $$$$$ |
| CIRM Centers of Excellence | High award amount | $$$$ |
| | Lower award amount | $$$ |
| CIRM Special Programs | High award amount | $$ |
| | Lower award amount | $ |

# One-step & Two-step review

| Review Process Options | Timing |
|---|---|
| **One Step, concurrent WG reviews** | |
| Application Preparation;Part 1&2 | |
| Part 1 & Part 2 Applications received | |
| WG preparation and review | |
| ICOC action | |
| **Two Step, sequential WG reviews** | |
| Part 1 Application Preparation | |
| Part 1 Applications received | |
| Grants WG preparation and review | |
| ICOC action | |
| Part 2 Applications preparation | |
| Part 2 Applications received | |
| Facilities WG preparation and review | |



# Next Steps

- Interested parties meeting to review criteria and scoring recommendation (July 25th)
- Facilities WG telephone conference call to (1) recommend a review process to the ICOC and (2) confirm criteria, standards, and scoring
- August 8th ICOC Meeting in San Francisco