Consideration of the Concept Plan for Request for Application (RFA) 07-03
CIRM Major Facilities Grant Program

BACKGROUND

The Scientific Strategic Plan indicates that CIRM will allocate funds to provide capital grants in several phases for new space or improved space in support of stem cell research. The ICOC approved the first phase at its June 2007 meeting, when it approved awards under RFA 07-01 for building renovations, equipment and operating funds to support shared research laboratories and stem cell techniques courses throughout the state.

At the April 2007 ICOC meeting, the President presented process options for the second phase of facilities grants, the Major Facilities Grant Program (RFA 07-03). There was a consensus of the members that the Major Facilities RFA 07-03 should be issued as a single grant initiative rather than as two or more initiatives as contemplated in the Scientific Strategic Plan. There was also a consensus that RFA 07-03 should be issued quickly because space constraints relative to NIH-free space requirements continue to be a limiting factor in the development of some areas of stem cell research, and because construction costs in California continue to rise at a significant rate.

Later in April, the Facilities Working Group (FWG) unanimously proposed that CIRM hold a series of meetings to seek input from the public in the development of the RFA. The ICOC approved the concept of public meetings at its May 2, 2007 meeting. CIRM staff worked with the Chair and Vice Chair of the FWG regarding the process for the public meetings. These meeting were held in four different locations around the state during May and June. The FWG reviewed the input from these public meetings at its July 12, 2007 meeting and also approved the Criteria, Definitions and Scoring for FWG Technical Review (Part 2) of RFA 07-03. CIRM also held an "interested persons" meeting to discuss and clarify any outstanding issues regarding the FWG proposal. On July 30, 2007, the FWG held a meeting for final review of the Criteria, Definitions, Evaluation Standards and Scoring for Part 2 and the process for review. The recommendations of the FWG and CIRM staff are presented in recommendations 1 and 2 of this item, Consideration of the Concept Plan for RFA 07-03. CIRM staff recommendations on Grants Working Group (GWG) criteria and funding are presented in recommendations 3 and 4 of this item.

RECOMMENDATION

The Facilities Working Group and the Acting President recommend to the Independent Citizens Oversight Committee the following actions for approval:

1. A two-step process for the Grants Working Group and Facilities Working Group review of RFA 07-03 with action by the ICOC on the Grants Working Group recommendations to be considered at a January 2008 ICOC meeting and final action

on the Facilities Working Group recommendations and approval of grant awards to be considered at the April 2008 ICOC meeting; and

2. Criteria, Definitions, Evaluation Standards and Scoring of Part 2, FWG Technical Review of RFA 07-03;

CIRM staff recommends to the Independent Citizens Oversight Committee the following actions for approval:

3. Evaluation Criteria for Part 1, Scientific Review of RFA 07-03, and

4. Allocation of $227 million in bond funding for RFA 07-03. When the ICOC acts on the Grants Working Group's recommendations on Part 1 of the RFA, the ICOC will set total funding targets for each of three distinct categories of capital grants based on the Grants Working Group review as follows:

    a. CIRM Institutes--funding for capital project proposals that support the most comprehensive stem cell research programs, with individual grants ranging from $25 to $40 million,
    b. CIRM Centers of Excellence--funding for capital project proposals with broad but somewhat less comprehensive stem cell research programs, with individual grants ranging from $10 to $20 million, and
    c. CIRM Special Programs—funding for capital project proposal that support specialized stem cell research programs, with individual grants ranging from $5 to $10 million.

DESCRIPTION

1. A two-step process for the Grants Working Group and Facilities Working Group review of RFA 07-03 (Attachment 1)

The FWG recommends the following procedure for review of the RFA. The ICOC will review grant applications in two steps. In Part 1 of the application and review, applicants will self-select one of three categories of funding in which they will compete: CIRM Institutes, CIRM Centers of Excellence, or CIRM Special Programs. In the event that the GWG and ICOC determine that an applicant is not competitive in its chosen category, but recommends that applicant for funding in a different category, the two-step process permits the applicant to revise its capital funding proposal for Part 2 review by the FWG to bring it into step with the program elements approved by the GWG. To permit this adjustment and provide predictability for applicants, the ICOC must take action on the recommendations of the GWG before the FWG evaluates the Part 2 capital funding component of the applications. In the second step, the ICOC will consider the FWG recommendations and make final decisions on approving grant awards at a subsequent meeting.

The two-step review procedure presents the additional challenge of requiring more time for applicants to prepare material and more time for the working groups to perform their reviews than would be required if the working group reviews were concurrent. However, an expedited schedule by the ICOC would allow consideration of the GWG recommendations in January 2008 with consideration of the FWG recommendations and final approval at the April 2008 meeting.

The milestones and tentative schedule for the recommended two-step review of the Major Facilities applications are included in **Attachment 1**.

2. Criteria, Definitions, Evaluation Standards and Scoring for Part 2 Technical Review of RFA 07-03 (Attachment 2)

The FWG held a series of public meetings in various parts of the state to hear testimony on the need for capital funding for stem cell research within California. A total of five meetings were held in San Francisco, Sacramento, Los Angeles, San Diego and Burlingame. Based on the input from these meetings, the FWG adopted Criteria, Definitions and Evaluation Standards for use in developing and reviewing the Major Facilities Grant RFA.

The recommended criteria include value, leverage, urgency, shared resources and functionality with points distributed among these categories on a 100 point scale. The criteria, definitions and evaluation standards are included as **Attachment 2** and are recommended by the CIRM staff and FWG for approval at this time.

3. Evaluation Criteria for Part 1 Scientific Review of RFA 07-03 (Attachment 3)

Testimony at the FWG public meetings also revealed a strong sentiment that in developing the Major Facilities Grant Program, CIRM should consider scientific merit as the most important consideration in the competition for funding under this program. In response to these comments, and similar comments expressed at the April 2007 ICOC meeting, CIRM staff has developed special criteria to be used by the Grants Working Group in its scientific evaluation of proposals submitted under the RFA. After considerable deliberation, CIRM staff settled on the recommended method of evaluation. This method will evaluate the depth and breadth of each application with respect to three distinct elements of the proposed research program. The three elements are:

> **Element X**: **Basic and discovery research**. This element includes research focused on understanding the fundamental biology of stem cells, pluripotency and differentiation.
>
> **Element Y**: **Preclinical research**. This element covers investigations directed toward the development of treatments including the application of basic discoveries and technologies to model systems (such as in vitro assays and in vivo animal models) and drug discovery.

Element Z: **Preclinical development and clinical research**. This element refers to programs in preclinical product development, and those to test outcomes of the use of diagnostics, therapeutics or procedures.

The RFA would ask each applicant to choose the elements on which it would like to be evaluated and to provide information to substantiate the research capabilities under each chosen elements. Applicants would also select one of the three following categories of funding in which to compete:

CIRM Institutes—(comprising all three elements--X, Y and Z)—Competitive as a comprehensive research institution with all elements represented within the program;

CIRM Centers of Excellence (comprising two of the three elements--X and Y, X and Z, or Y and Z)—Competitive on two of the three elements considered.

CIRM Special Program (comprising one of the three elements--X, Y or Z)— Competitive on the basis of specialized research concentrating on one of the three elements considered.

The GWG will evaluate each application for the depth and breadth of each element in the proposed stem cell program and will determine if the applicant is competitive for the elements in the funding category that had been self-selected by the applicant. If the GWG determines an applicant is not competitive for all of the self-selected elements, the GWG may recommend reassigning the application to a different funding category (if the applicant is otherwise competitive), or recommend that the application not be considered for funding at all. For example, the GWG may determine that an applicant for a CIRM Institute is competitive in research elements Y and Z, but not competitive in element X. It could then decide whether to recommend that proposal for a Center of Excellence, which only requires two elements, or for a Special Program, which only requires one element, rather than for an Institute.

In summary, CIRM staff and the FWG believe that the proposed three-element/three-category evaluation criteria for Part 1 is highly effective in that it provides the opportunity for competition among applicants at multiple levels of program scale and maturity while meeting the ICOC directive that all levels of facilities grants be considered under a single RFA. **Attachment 3** represents the CIRM staff recommendation for GWG review criteria that is recommended for approval by the ICOC at this time.

4. Allocation of $227 million in bond funding for RFA 07-03 (Attachment 4)

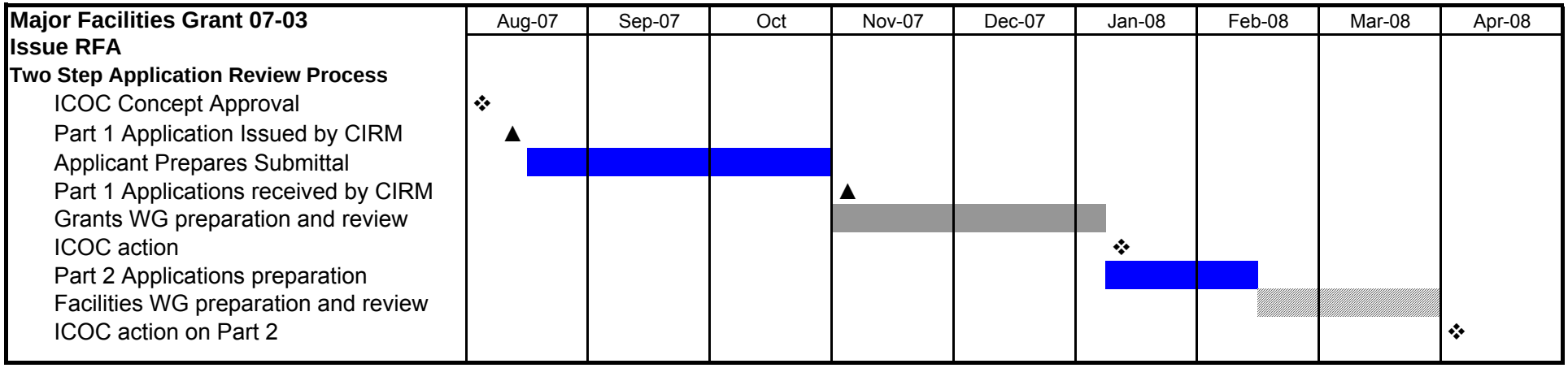
The Scientific Strategic Plan calls for capital funding of $222 million for what it refers to as large and small facilities grants. Capital funding consists of buildings and improvements (cores, shells, and tenant improvements) and capital equipment (also referred to as Group 1 or fixed equipment.) Capital funding does not include research

equipment (referred to as Group 2 or moveable equipment that is typically funded through research grants. (See **Attachment 4** for the CIRM definition of capital and research equipment). The goals expressed for these grants have been combined in the current concept plan for the Major Facilities RFA. CIRM spent less capital funding than anticipated for the Shared Research Laboratory and Stem Cell Techniques Course RFA (07-01) and the projected cost for capitalized interest and cost of issuance of bonds have been refined. These changes have resulted in an additional $5 million in capital funding being available to allow a Major Facilities program of $227 million. CIRM staff recommends that the ICOC approve this amount.

With the three categories of research capabilities established for competitive purposes, it is appropriate that the capital resources be aligned with these categories. The amount of capital funding in each category would need to reflect a step function similar to the scientific capabilities. There is no analytical basis at this time to determine the appropriate amount of funds to be allocated to each category, and this information will not be available to the ICOC until the GWG submits its recommendations. CIRM staff has evaluated several scenarios for funding and recommends that the following funding ranges be adopted:

Table 1
Major Facilities Grants
Ranges within CIRM Funding Categories

CIRM Category	Funding Range	Total Funding
CIRM Institute	$25-$40 million	$227 million for all categories; amount for each category to be determined by ICOC
CIRM Center of Excellence	$10-$20 million	
CIRM Special Program	$5-$10 million	


Major Facilities Grant 07-03
Issue RFA
Two Step Application Review Process
ICOC Concept Approval
Part 1 Application Issued by CIRM
Applicant Prepares Submittal
Part 1 Applications received by CIRM
Grants WG preparation and review
ICOC action
Part 2 Applications preparation
Facilities WG preparation and review
ICOC action on Part 2
Aug-07
Sep-07
Oct
Nov-07
Dec-07
Jan-08
Feb-08
Mar-08
Apr-08

CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE—RFA 07-03 PART 2
FACILITIES WORKING GROUP CRITERIA, DEFINITIONS AND EVALUATION CRITERIA

Criteria/points	Definition	Evaluation Standards
Value **25 points**	The investment represents a good return to the taxpayer while considering costs, quality, geographic location, and benefits of the project. The facility has innovative elements that encourage conservation and renewable resources. The project costs are reasonable and necessary.	• Costs (up to 15 points) An evaluation of cost and program space provided from CIRM funds will establish the "net CIRM" cost and benefits. The project costs are reasonable and necessary based on CIRM's review. • Sustainability (up to 5 points). These facilities elements have been documented and respond to CIRM objective in a cost-effective way. Full points will be allocated based on (1) meeting the equivalent rating of "certified" under the US Green Building Standards or (2) including elements in the project that the applicant demonstrates are equivalent to or exceed green building standards. • Innovation (up to 5 points) The facility offers some elements that demonstrate innovation in design or research capabilities.

APPROVED BY FWG ON JULY 30, 2007

CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE—RFA 07-03 PART 2
FACILITIES WORKING GROUP CRITERIA, DEFINITIONS AND EVALUATION CRITERIA

Criteria/points	Definition	Evaluation Standards
Leverage **25 points**	The CIRM investment prompts additional investments that are consistent with the CIRM objectives; these investments are additional capital funding for the project. These costs include project cash expenditures prior to the ICOC approval of Part 2 of the application and may include (1) the purchase of land and/or a building at the documented cost to the institution (2) purchase of the initial complement of major equipment for the project and (3) other capitalized project cost. The project leverage attributable to internal project overhead and architectural and engineering costs will be no more than 10% of the total project costs.	• Project Leverage ratio: The Additional Institutional cash funding for the project divided by the CIRM funding. (e.g. $90/$30=3x)
Urgency **20 points**	Places a high priority on completion of the project within two years; and the delivery of projects on an expedited scheduled. The institution, the team and approach has a historic and proven track record of delivering capital projects on an expedited schedule and the applicant has proposed an accelerated schedule. Start Date: Notice of Grant Award End Date: The base building is available for occupancy and/or installation of equipment.	• 2 year completion (up to 10 points) • Proven track record (up to 10 points) The Applicants that show a plan of how the project will be completed within two years, and the plan is supported by a track record, receive higher score than those with longer completion.

CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE—RFA 07-03 PART 2
FACILITIES WORKING GROUP CRITERIA, DEFINITIONS AND EVALUATION CRITERIA

Criteria/points	Definition	Evaluation Standards
Shared Resources **15 points**	The project benefits from facilities, equipment, or core laboratories (including dedicated staff) at the applicant site or collaborating institutions that reduce the costto CIRM and increase the value for the mission.	• Shared Resources: facilities, equipment and core laboratories (up to 15 points) Applicants will document (1) how existing or proposed new resources will be shared and (2) the savings to CIRM and benefit attributable to the sharing arrangement.
Functionality **15 points**	The planned space design for the base building and tenant improvements is consistent with the CIRM objectives of meeting current programmatic needs and expanding regenerative medicine research capacity and capabilities. The facility provides for long term flexibility while meeting scientific objectives.	• The applicant has described the program to be housed in the new space. The facilities plan coincides with the program. The project provides the appropriate improvements to expand capacity and/or capability of regenerative medicine programs at this institution.

APPROVED BY FWG ON JULY 30, 2007

CALIFORNIA INSTITUTE FOR REGENERATRIVE MEDICINE – RFA 07-03 PART 1
GRANTS WORKING GROUP EVALUATION CRITERIA

The Grants Working Group (GWG) will evaluate the overall stem cell research program described in each application and its relationship to the proposed facility. Each proposal will be judged on the breadth and depth of the research program. (See Chart on page 3.)

The **Breadth** of the stem cell program refers to the range of research along the spectrum from basic to clinical elements. The scope of each application can cover one or more of the following three elements:

- **Element X** covers basic and discovery research
- **Element Y** focuses on preclinical research where basic discoveries and technologies are applied toward the development of treatments, and may include research such as in vitro assays, in vivo models and drug discovery.
- **Element Z** involves preclinical development and clinical research with programs to test outcomes of the use of therapeutics or procedures.

The **Depth** of each of the above elements will be evaluated for strengths and weaknesses in four key areas:

- **Proposed scientific, preclinical and clinical program in stem cell research** (e.g., scientific excellence, track record, interdisciplinary synergy)
- **Formal partnerships and consortia**
- **Core services** (e.g. existing and planned core services that support or will support the program)
- **Capacity for growth** (e.g., commitment to programs, faculty recruitment and retention, use of space, expansion of special innovative programs)

Criteria for review of scientific, preclinical and clinical programs include:

- Strength and integration of the research programs
- Quality and types of programs to be housed in the proposed facility
- Quality and types of auxiliary programs at the organization
- Track record of organization and participants (PIs) [e.g. number of CIRM-approved applications and relevant NIH grants per PI; number of relevant publications (& patent applications) in past 5 years]
- Interdisciplinary synergy and collaboration
- Development of therapies and conduct of clinical studies, especially in cell-based therapy (for Element Z)

Criteria for review of formal partnerships and consortia include:

- Number and types of formal partnerships (e.g., MOUs and contracts with industry, non-profit organizations)

- Number and types of relevant shared resources
- Evidence of productivity and effectiveness (e.g. number of relevant co-publications, patents filed with partners)
- Length of time partnerships have existed
- Evidence of institutional resources and ability to handle technology transfer

Criteria for review of core services include:

- Types and number of core services available and/or planned for the program
- 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 use of existing cores
- Quality of management, maintenance and productive use of cores.

Criteria for review of capacity for growth include:

- Plans for development, expansion, and continuity of the stem cell programs described (e.g. multi-year plans for faculty recruitment)
- Description of planned use of space in the proposed facility and how this reflects needs in described scientific program
- Plans for continuity of operations

Applicant organizations will select and compete in the scientific elements (X, Y, Z) where they have strength.

RFA 07-03

Part I: Scientific Application

Each element will be evaluated by the following criteria:

Element X	Element Y	Element Z
Basic and discovery research Focused on understanding the fundamental biology of stem cells and pluripotency	**Preclinical research** Applying basic discoveries and technologies in model systems toward the development of treatments. Preclinical research such as in vitro models, in vivo models, drug discovery	**Preclinical development & Clinical research** Human clinical research: Programs in preclinical product development and/or to test outcomes of the use of therapeutics or procedures

I STEM CELL RESEARCH PROGRAM	- Scientific excellence and track record of the institution and of participants a. Resident Programs: What programs or disciplines are going to be housed in this facility? b. Auxiliary programs: What programs or disciplines are going to use this facility, but not be residing in it? c. How strong and integrated are the resident programs, the auxiliary programs? d. Are clinicians and clinical programs brought in and integrated into the stem cell program? If so, how? e. What resources or plans are laid out to bring promising findings to the next step toward therapy development?
II FORMAL PARTNERSHIPS AND CONSORTIA	Is there evidence of established partnerships/consortia? If so, what is the evidence that they are critical and productive? How able (strong and experienced) is the organization to handle intellectual property and technology transfer?
III CORE SERVICES	Are core facilities and services necessary for the program available or planned? Presence of or plans for critical core services What core facilities are in existence? Is there evidence of productive use? Evidence of management, maintenance, & productive use of cores at the applicant organization
IV BUILDING CAPACITY	What plans are laid out to build capacity and/or programs and recruit new faculty? How will the programs be housed; how will the arrangements contribute to the building of stem cell programs. Plans for continuity of operations.

DISCUSSION AND CONSIDERATION OF THE DEFINITION OF "CAPITAL EQUIPMENT" UNDER PROPOSITION 71

Description

This request seeks concurrence from the Facilities Working Group and the ICOC regarding the definitions for capital equipment and research equipment.

Background

The term "equipment" is used in Proposition 71 *125290.65. Scientific and Medical Facilities Working Group* as referenced below:

(C) The requirement that all funded facilities and equipment be located solely within California.

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

(4) Recognizing the priority of immediately building facilities that ensure the independence of the scientific and medical research of the institute, up to 10 percent of the proceeds of the bonds authorized pursuant to Section 125291.30, net of costs described in paragraphs (2), (4), and (5) of subdivision (a) of Section 125291.20 shall be allocated for grants to build scientific and medical research facilities of nonprofit entities which are intended to be constructed in the first five years.

In Proposition 71, the terms "equipment" or "capital equipment" are not defined. The term "facilities" is defined in Section 125292, subdivision (f), as follows:

"(f) 'Facilities' means buildings, building leases, or capital equipment."

A definition of equipment and capital equipment is required to classify the amount of funds available under Proposition 71 for facilities and research as well as provide guidance to applicants. Several institutions and agencies were surveyed regarding their definition of equipment and capital equipment--specifically any designations used regarding fixed versus research equipment or instrumentations. The result of the survey can be found on Exhibit A.

Recommendation

This item requests that the Facilities Working Group recommend to the ICOC for consideration at their December 7, 2006 meeting approval of the definition for capital and research equipment as follows:

Capital Equipment: Capital equipment (Group 1) is defined as equipment which is fixed, built-in or permanently affixed to a building or structure. Examples are building hardware, general building construction, such as heating systems, exhaust and air conditioning systems, fixed seating in auditoriums and lecture hall, and permanent television distribution equipment. Also included are fixed laboratory benches, fixed sterilizing equipment, fume hoods, autoclaves and biological safety cabinets. Capital equipment shall be funded through the Facilities grants program.

Research Equipment: Research equipment (Group 2) and instrumentation is moveable equipment necessary to meet program needs of a research grant and costing more than $5,000. For example, cell sorters, microscopes, centrifuges and freezers. Research equipment shall be funded through the Research grants program.

This recommendation is based on the results of the survey of institutions identified in Attachment 1 and conforms with the standard practice established by those institutions.

Exhibit A

University of California Facilities Manual
(http://www.ucop.edu/facil/fmc/facilman/volume1/rpequip.html)
Group 1 Equipment
Fixed Equipment (Group 1) is defined as equipment which is built-in or permanently affixed to a building or structure. Examples are fixed laboratory benches, fixed sterilizing equipment, fixed seating in auditoriums and lecture halls, and permanent television distribution equipment. Equipment units related to basic building operation are part of general building construction and are excluded from the definition of Fixed Equipment. Examples [of such excluded equipment] are building hardware, building service units such as heating systems, exhaust and air conditioning systems, and elevators.

Group 2 & 3 Equipment
(Groups 2 and 3). Movable Equipment is divided into the following subclassifications: General-Use Building Furniture and Furnishings, Generally Assignable Classroom Furniture, Generally Assignable Office Furniture, Specialized Equipment, and Expendable Equipment. These classifications shall be used in the preparation of the capital outlay and support budget requests to the state of California. This does not preclude use of a different classification system when required by the rules and definitions of non-state agencies, corporations, and foundations which provide funds for equipment acquisition or use.

- Specialized Equipment is defined as Movable Equipment with an expected useful life of a year or more. It has been grouped for University purposes into two categories: (1) office equipment, and (2) laboratory and other equipment. Classification of equipment into one of these categories is determined by the principal use of the equipment. For example, calculating machines, which are normally office equipment, could be classified as laboratory equipment if they are to be used in a statistical laboratory for students in the social sciences.
- Expendable Equipment is defined as noninventorial equipment, supplies, and materials. The need for Expendable Equipment should be anticipated in department support budgets. Such equipment should not be included in requests for capital outlay funds unless required during the fiscal year of building occupancy for laboratories which are new to the department at the time the building is occupied, or which represent substantial expansion or change in equipment required for teaching and research activities.

State Administrative Manual (http://sam.dgs.ca.gov/TOC/6000/6855.htm)

6855 EQUIPMENT (Revised 5/98)

Group 1 and 2 equipment: Capital outlay equipment is categorized either as *Group 1 or Group 2* equipment:

1. Group 1 equipment is installed equipment such as heating and air conditioning units and is budgeted as part of the construction phase.
2. Group 2 equipment is movable equipment, such as tables and chairs (but not replacement equipment) and is budgeted as its own project phase, typically following construction.

Not all equipment is classified as capital outlay: See Section 6806 (http://sam.dgs.ca.gov/TOC/6000/6806.htm) for the difference between equipment budgeted through the support appropriation versus capital outlay equipment.

- SAM sections 6855 and 6806.
- State projects use the definition of equipment in SAM. Group 1, fixed equipment, is incorporated into or attached to the facility and therefore is included in the construction phase of a project. Group 2, movable equipment, is budgeted as a separate phase. Definitions of Group 1 and Group 2 equipment are provided in SAM Section 6855. Movable equipment that does not meet the definition of capital outlay per SAM Section 6806 is not a capital outlay expenditure. These costs are proposed and funded in the state operations appropriation.

Stanford

Project Delivery Process (http://cpm.stanford.edu/pdp.html), under budgeting, makes a simple statement regarding equipment:

1. Under basic construction as equipment in contract or
2. Fixture, Furniture, and Equipment (FF&E) – not in contract

Buck Institute

Citation: Extramural Research Facilities Improvement Program-RFA-RR-03-011
Released 08/11/2003
Funds authorized from the National Center for Research Resources (NCRR)

Allowable Cost for Construction under this RFA:

"The acquisition and installation of fixed equipment such as casework, fume hoods, large autoclaves, or biological safety cabinets are allowed. Support for instrumentation or equipment that usually would be requested as part of a research project grant will not be provided."

Caltech

Capital Construction Policy (http://finance.caltech.edu/policies/policy_capital_construction.pdf) budgeted into two areas (on page 2):
Equipment ("built-in" only, i.e. identify separate funding for "free-standing" equipment).