

CIRM GRANTS MANAGEMENT PROCEDURES

PRE-FUNDING ADMINISTRATIVE REVIEW

Pre-Funding Administrative Review is conducted by CIRM Grants Management and Scientific Program Officers to document the grants management and scientific program administrative review process prior to funding an approved application, to identify factors that may affect funding, and to note special terms and conditions to include with the Notice of Grant Award (NGA). All capitalized terms are defined terms found in the CIRM Grants Administration Policy (GAP).

Procedure

Once the Independent Citizens Oversight Committee (ICOC) approves applications for funding, the Grants Management Officer (GMO) or designated Grants Management Specialist (GMS) sends out an email notifying applicants of their approved application and requesting the Just-in-Time (JIT) documents required by the Grants Administration Policy (GAP) prior to issuance of the NGA. Grants Management is responsible for tracking receipt of these documents in the grants management system, on the Grants Management Checklist page, noting any special issues as well as the expiration dates of all assurance approvals, including:

- Updated Other Support
- Human Subject Certification (IRB)
- Stem Cell certification (SCRO)
- Vertebrate Animal Use assurance (IACUC)
- Any other information

The GMO/GMS also reviews the application and ICOC meeting transcript to identify budgetary and administrative concerns including other support that might indicate possible budgetary overlap, and to identify special terms and conditions to include on the NGA (e.g., conditions imposed by the ICOC). All contact with approved applicants as well as any special notes regarding the application must be tracked on the appropriate application review page in the “NOTES” section of the grants management system.

The SPO is responsible for reviewing the approved application for issues affecting human or animal research, other support that might indicate scientific and budgetary overlap, and special terms and conditions to include on the award notice (e.g., delay in use of human subjects to subsequent grant year, select agents, highly pathogenic agents). Any issues requiring discussion between the SPO and applicant and resulting conversations should similarly be noted clearly in the review “NOTES” section of the grants management system.

Once Grants Management and the SPO have both conducted an initial review of the application, GMO/GMS will communicate directly with the applicant (in writing) regarding any pending items that must be resolved prior to funding. If further SPO review is required, GMO/GMS will notify SPO of receipt of pending items and request that SPO conclude review of the application. When both SPO and GMO have completed their reviews and ‘approved’ the application for NGA, the “APPROVED” will turn green and each will give their signature to the checklist. CIRM shall **NOT** issue an NGA until a Pre-Funding Checklist is signed by both the SPO and the GMO and has received any other supervisory clearance, as necessary.

After the checklists are complete, Grants Management prepares an NGA that includes any special terms or conditions of the award, for review and signature of the President or his/her delegate. Grants Management then mails the NGA to the applicant Institution for signature. CIRM’s receipt of the signed NGA triggers preparation of the CIRM Pay Memo by Grants Management, for review and signature by the Chief Scientific Officer and the Chief Financial and Administrative Officer. Grants Management sends the signed Pay Memo to the State Controller’s Officer (SCO) to request issuance of a warrant and release of funds to grantees. SCO returns a copy of the pay memo, upon release of funds, to Grants Management for inclusion in the file of each grantee listed on the pay memo.

Guidance for completing the Initial Funding Checklist follows. This guidance is not intended to be comprehensive, as unanticipated issues may arise that require additional review prior to the issuance of an NGA.

CIRM GRANTS MANAGEMENT PROCEDURES

GRANTS MANAGEMENT

1. INSTITUTIONAL ELIGIBILITY

- **Basic requirement:** The applicant institution must have non-profit status in order to be eligible to apply for the RFA, as specified in the RFA.
- **Action:** If the RFA specifies non-profit status for applicants, confirm non-profit status of applicant institution on IRS website, using Publication 78 (<http://www.irs.gov/charities/article/0,,id=96136,00.html>) to check for the applicant institution name. Publication 78, *Cumulative List of Organizations described in Section 170(c) of the Internal Revenue Code of 1986*, is a list of organizations eligible to receive tax-deductible charitable contributions.
 - If applicant institution name appears on Publication 78, print out a copy (preferably to Adobe) of the search results to file with the application and note in tracking sheet. If applicant institution name does not appear on Publication 78, make note in tracking sheet. Skip this step and move to next step if CIRM has previously funded this applicant institution.
 - Next, check suspensions, additions to, and recent revocations to Publication 78 for the applicant institution name. Print out copies of search results and note in **tracking sheet**. If no results are returned, make note in tracking sheet.
 - If applicant institution name does not appear in any section of Publication 78, a call to the applicant institution is required. The first point of contact is the individual listed as the Authorized Organizational Official on the application. The AOO may refer questions to a financial officer of the institution. Confirmation of tax-exempt status is a necessary step in CIRM's due diligence before release of funds to any applicant, and the following item(s) are necessary to confirm status (when Publication 78 returns no results):
 - Letter of Determination of tax-exempt status from the IRS
 - Ask for the date on the letter, note in tracking sheet.
 - If the letter is dated within the last 2 years, ask the institution to provide a copy of form 1023, note in tracking sheet.
 - If the letter is dated prior to the last 2 years, ask the institution to provide a copy of their most recent form 990, note in tracking sheet.
 - Most recent amendments to articles of incorporation
 - The applicant institution will need to provide copies of these forms to CIRM. Request the forms by email (preferred) or by fax or hard copy. Note in tracking sheet.
 - If the applicant institution is unable to provide information about the IRS, or if the applicant institution is listed as suspended or revoked, notify CIRM legal counsel immediately and note accordingly in tracking sheet.
- **Basic requirement:** If CIRM has previously distributed funds to the applicant institution, the institution must be in good standing with CIRM.
- **Action:** Check with CIRM "Not in Good Standing" list (TBD). If the applicant institution is listed on CIRM's "Not in Good Standing" list, refer the application to the Chief Scientific Officer (CSO) and Chief Finance and Administrative Officer (CFAO). CIRM shall not issue an NGA until the application in question has been cleared for funding by the CSO and CFAO.
- **Action:** Check the CIRM "CIRM CRISP List". (CRISP (Computer Retrieval of Information on Scientific Projects) is a searchable database of federally funded biomedical research projects conducted at universities, hospitals, and other research institutions. The database, maintained by the Office of Extramural Research at the National Institutes of Health, includes projects funded by the National Institutes of Health (NIH), Substance Abuse and Mental Health Services (SAMHSA), Health Resources and Services Administration (HRSA), Food and Drug Administration (FDA), Centers for Disease Control and Prevention (CDCP), Agency for Health Care Research and Quality (AHRQ), and Office of Assistant Secretary of Health (OASH).
 - Grants Management will originate the CIRM CRISP List by conducting a CRISP search on two grant applicants from each applicant institution as of June 1, 2007.
 - Grants Management will update the list in July of each year (starting in 2008) by conducting a CRISP search on two randomly selected grantees from each currently CIRM-funded

CIRM GRANTS MANAGEMENT PROCEDURES

grantee institution. The list will also be updated throughout the year when a “new to CIRM” institution is approved for funding.

- **Action:** If the applicant institution has no CIRM or federal grant history, refer the application to the CSO and CFAO to determine if there is a need for additional review in the form of a request of additional information from the institution or a site visit. CIRM shall not issue an NGA until the application in question has been cleared for funding by the CSO and CFAO.

2. PRINCIPAL INVESTIGATOR/PROGRAM DIRECTOR ELIGIBILITY

- **Basic requirement:** Unless otherwise stated in the RFA, the individual serving as PI or PD on the research project shall possess an M.D., Ph.D., or equivalent degree.
- **Action:** Check CIRM list of equivalent degrees (per the NIH for training grants) provided below. Notify Chief Scientific Officer of equivalent degree stated on application and whether or not degree is on CIRM list of equivalent degrees (which is not comprehensive); and request review and approval if equivalent degree is given. CIRM shall not issue an NGA until the application in question has been cleared for funding by the CSO and CFAO.
 - Equivalent degrees include but are not limited to: D.O., D.C., D.D.S., D.V.M., O.D., D.P.M., Sc.D., Eng.D., Dr. P.H., D.N.S., N.D., Pharm.D., D.S.W., Psy.D.

3. FACILITIES COSTS

- **Basic requirement:** Requested facilities costs in application must match the current federally negotiated rates (F&A rates) – broken down for all 6 categories - in the individual agreements for each institution that are kept on file and annually updated at CIRM. The categories are:
 - Operations & Maintenance
 - Library
 - Depreciation or Use - Building
 - Depreciation or Use - Equipment
 - Depreciation or Use – Capital Improvements
 - Interest on Capital Debt
- **Action:** If facilities costs in application do not match those in current F&A agreement, notify CIRM Chief Finance and Administrative Officer and contact institution’s grants administrator or AOO in writing to request revised budget pages with correct facilities costs. If there is not a current F&A rate agreement in place, notify Chief Finance and Administrative Officer who will provide direction on requesting additional information from the applicant institution. CIRM shall not issue an NGA unless the facilities costs requested in the application match current F&A rates.
- **Basic requirements:** If the application contains a request for off campus or “Part B” facilities costs, documentation certifying the off campus facilities costs must be provided.
- **Action:** If costs are not provided with application, request in writing from the AOO documentation certifying the off campus facilities costs for the exact space where the PI proposes to conduct his/her research (e.g., lease agreement). CIRM shall not issue an NGA until “Part B” facilities costs are appropriately documented.

4. BUDGET PAGES

- **Basic requirement:** The requested budget in the application must meet requirements and/or restrictions of the GAP as well as requirements and/or restrictions of RFA.
- **Action:** If requested budget does not meet requirements of CIRM GAP or specific RFA, contact institution’s grants administrator or AOO in writing; note specific budget issue and request revised budget pages within 2 weeks of request. CIRM shall not issue an NGA until budget requirements have been met.

CIRM GRANTS MANAGEMENT PROCEDURES

5. VERTEBRATE ANIMAL ASSURANCES

- **Basic requirement:** If the application indicates a need for IACUC approval or a CIRM Program Officer has reviewed the application and determined that there is a need for IACUC approval, the applicant must provide current IACUC approval documentation for the proposed research.
- **Action:** If IACUC approvals were not included with JIT documents, or if documents received were incomplete, contact PI's grant administrator again to request documents certifying IACUC approval. The approval documents must contain an expiration date. CIRM shall not issue an NGA until the correct IACUC approvals are received.

6. IRB/HUMAN SUBJECTS ASSURANCES

- **Basic requirement:** If the application indicates a need for IRB approval or a CIRM Program Officer has reviewed the application and determined that there is a need for IRB approval, the applicant must provide current IRB approval documentation for the proposed research.
- **Action:** If IRB approvals were not included with JIT documents, or if documents received were incomplete, contact PI's grant administrator to request documents certifying IRB approval. The approval documents must contain an expiration date. CIRM shall not issue an NGA until the correct IRB approvals are received.

7. SCRO ASSURANCES

- **Basic requirement:** If the application indicates a need for SCRO approval or notification or a CIRM Program Officer reviewed the application and determined that there is a need for SCRO approval or notification, the applicant must provide current SCRO approval documentation for the proposed research.
- **Action:** If SCRO approvals were not included with JIT documents, or if documents received were incomplete, contact PI's grant administrator to request documents certifying SCRO approval or notification. The approval documents must contain an expiration date.

8. BIOSAFETY

- **Basic requirement:** The application must include certification of institutional approval to use biohazardous materials and certification that key personnel will obtain formal training and appropriate authorization for the use of biohazardous materials prior to commencing their work on the proposed project/activity.
- **Action:** If Biosafety approvals were not certified in the application, contact PI's grant administrator to request revised biosafety page of the application to certify biosafety approval.

9. OTHER

- **Basic requirement:** If the application or summary statement makes note of any administrative or budgetary issues that require further review, further review must be conducted. If the ICOC has imposed any specific conditions on the approved application, said conditions must be met prior to funding the application (e.g., conditions met prior to the issuance of NGA or included in the NGA and as such, met by execution of the NGA).
- **Action:** Alert CSO and Scientific Program Officer to any other concerns. CSO will determine if there is a need for additional follow-up review in the form of a request for additional information from the institution or a site visit. CIRM shall not issue an NGA until any Other Issues are corrected.

CIRM GRANTS MANAGEMENT PROCEDURES

SCIENTIFIC PROGRAM OFFICER

1. SCIENTIFIC OVERLAP

- **Basic requirement:** If the application requests that CIRM fund research or specific aims that are substantially similar, over any part of the project period, to research or specific aims actively funded by or pending funding from another source, as reported in the application and/or Just In Time (JIT) Other Support documents, the PI must certify that the overlap will be corrected.
- **Action:** Notify GMO of scientific overlap. GMO will request documentation (in writing) to certify how the PI will correct the scientific overlap. CIRM shall not issue an NGA until the overlap is corrected.

2. BUDGETARY OVERLAP

- **Basic requirement:** If it is determined that an application contains Scientific Overlap, the GMO must review the application, with the Scientific Program Officer, for any budgetary overlap resulting from the scientific overlap.
- **Action:** Discuss the scientific overlap with GMO and review the application for budgetary overlap. If budgetary overlap is found, GMO will follow-up with institutional officials regarding budgetary adjustments, requesting documentation to certify how the PI/institution will correct the budgetary overlap. CIRM shall not issue an NGA until the overlap is corrected.

3. PI PERCENT EFFORT

- **Basic requirement:** The percent effort for all active projects for the PI as provided in the Other Support documents in the application and/or JIT documents shall not exceed 100%.
- **Action:** Alert Grants Management to PI percent effort exceeding 100%. GMO will follow-up with PI, requesting documentation to reconcile overall percent effort. CIRM shall not issue an NGA until the PI's percent effort is 100% or less.

4. ANIMAL ASSURANCES

- **Basic requirement:** If the application indicates use of vertebrate animals, appropriate IACUC approvals must be provided.
- **Action:** If PI has not provided IACUC approvals or has provided the wrong IACUC approvals for the proposed CIRM-funded project, contact PI for further explanation of the research proposal. If it is determined that IACUC approval is needed, alert Grants Management to the need for an IACUC approval. GMO will request the IACUC approval from PI in writing. CIRM shall not issue an NGA until the correct IACUC approvals are received.

5. IRB ASSURANCES

- **Basic requirement:** If the application proposes research using human subjects that would require IRB approval, appropriate IRB approvals must be provided.
- **Action:** If PI has not provided IRB approvals or has provided the wrong IRB approvals for the proposed CIRM-funded project, contact PI for further explanation of the research proposal. If it is determined that IRB approval is needed, alert Grants Management to the need for an IRB approval. GMO will request IRB approval from PI in writing. CIRM shall not issue an NGA until the correct IRB approvals are received.

CIRM GRANTS MANAGEMENT PROCEDURES

6. SCRO ASSURANCES

- **Basic requirement:** If the application proposes research using covered stem cell lines, human embryos, or human oocytes, which require SCRO approval or notification, appropriate SCRO approvals must be provided.
- **Action:** If PI has not provided SCRO approvals or has provided the wrong SCRO approvals for the proposed CIRM-funded project, contact PI for further explanation of the research proposal. If it is determined that SCRO approval or notification is needed, alert Grants Management to the need for an SCRO approval/notification. GMO will request SCRO approval from PI in writing. CIRM shall not issue an NGA until the correct SCRO approvals are received.

7. OTHER

- **Basic requirement:** If there are any scientific issues apparent in the application that might impact CIRM's release of funds to the applicant institution, such issues must be discussed with SCO and GMO.
- **Action:** Alert Chief Scientific Officer and Grants Management to any other concerns. Chief Scientific Officer will determine if there is a need for additional follow-up review in the form of a request for additional information from the institution or a site visit. CIRM shall not issue an NGA until any Other Issues are corrected.