Notice To RFP Respondents

PUBLIC RELEASE OF PROPOSALS

Under the California Public Records Act, the records of state agencies are generally available to the public upon request. The Proposal you submit will be a public document. If you are awarded the contract, the contract will be a public document.

The Public Records Act allows CIRM to withhold documents, or parts of documents, that reveal trade secrets or information that is confidential or proprietary, or information that would invade personal privacy.

You should submit your Proposal in a form that does not include such information. If you wish to include non-public information, put that information in a separate envelope labeled "Confidential," and include a brief explanation of the reason the information is non-public. If you do not provide an adequate basis for withholding the information, CIRM is required to make it available to the public. CIRM reserves the right to make the final determination whether to withhold or produce a document or portion of a document in response to a Public Records Act request. If CIRM withholds information at your request, you may be required to litigate any claim of trade secret that you assert.

CIRM is not permitted to provide legal advice about the Public Records Act and/or its exemptions. The following documents provide additional information about CIRM obligations under the Public Records Act:

CIRM Public Records Access Guide
http://www.cirm.ca.gov/faq/pdf/guidelines.pdf

Summary of the California Public Records Act
http://*www.ag.ca.gov/**public**ations/summary_**public_records_act**.pdf*

Reviewed and agreed

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name

date

CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE

REQUEST FOR PROPOSALS

March 20, 2015

BUDGET REVIEW Services

CIRM RFP # 2579

The California Institute for Regenerative Medicine (CIRM) seeks an outstanding firm or firms specializing in budget review for Clinical Development Projects. Full details are provided in this Request for Proposals.

If you have questions about the process for submitting a proposal, contact:

Cynthia Schaffer
Contracts Administrator
(415) 396-9241
cschaffer@cirm.ca.gov

If you have questions the scope services to be addressed in a proposal, contact:

Gabriel Thompson
Grants Management Officer
(415) 396-9274
gthompson@cirm.ca.gov

Deadline for Response: This is an open ended RFP with awards planned for multiple vendors. Responses will be considered as they are received. The RFP will be posted and available until June 30, 2015.

1. Introduction

1.1. CIRM

The California Institute for Regenerative Medicine (CIRM) was established in early 2005 following the passage of Proposition 71, the California Stem Cell Research and Cures Initiative. The statewide ballot measure, which provided $3 billion in funding for stem cell research at California universities and research institutions, was approved by California voters on November 2, 2004, and called for the establishment of a new state agency to make grants and provide loans for stem cell research, research facilities and other vital research opportunities.

CIRM's mission is to accelerate the development of stem cell therapies for patients with unmet medical needs. Under the leadership of Dr. C. Randal Mills, the President and CEO of CIRM, CIRM began to implement CIRM 2.0 on January 1, 2015. CIRM 2.0 is a radical overhaul of the way the agency does business, implementing efficient new systems and programs that place added emphasis on speed, partnerships, and patients. CIRM 2.0 makes it easier for both companies and academic researchers with promising projects to partner with CIRM to get the support they need when they need it, reducing the time from application to funding from around two years to just 120 days.

Highlights of CIRM 2.0 improvements include:

> Speed: In addition in to reducing the time to funding to 120 days, new clinical stage projects may be submitted to CIRM year round instead of only once or twice a year as in the past. Applications simply have to be filed by 5pm PT on the last business day of the month to be eligible for consideration in that round of review. If you miss the deadline one month, you only have to wait 30 days for the next one.
>
> Partnerships: Under CIRM 2.0, CIRM will not act as a passive funding source, but instead will be an active investor, devoting significant internal resources and leveraging its vast external team of world-class subject matter experts to advance the projects it selects.

2. Scope of Services Required

CIRM seeks to contract with multiple firms that can provide budget review and analysis for both for-profit and non-profit led clinical development phase projects and to assist CIRM in its evaluation of the budget portion of grant applications. For convenience, the consultant(s) selected to provide these services will be referred to herein as "the Firm".

As part of CIRM 2.0, CIRM has added a budget review element to their Program Announcements and application review procedures. The budget review is to proceed as follows:

> An external team of budget professionals will review the proposed budget to provide information to CIRM regarding how the proposed costs compare with established market rates for similar activities (or how well the costs are justified when market rates are not established). When a proposed budget differs significantly from market rates, adjustments to the budget will be required by CIRM prior to further review of the application. Applicants will be notified of the specific discrepancies and applications will not be forwarded for scientific review until an amended budget has been submitted and approved by CIRM.

In order to develop a standardized set of budget questions for the Program Announcement and a cohesive set of procedures for the budget review, CIRM created a budget template and an internal budget analysis workflow plan. As a result, the Firm selected will be provided with a standardized checklist for an Activity Based Budget with clear definitions and worksheets for areas such as CMC, clinical trials, toxicology studies, animal studies, etc. These worksheets and checklists are broken down into secondary activities to capture budget information for: materials, regulatory and legal, equipment and facilities, analytical development, analytical testing, GMP manufacturing, manufacturing process development and optimization, scale up, packaging, etc. A copy of the budget template is attached as Attachment E to this RFP.

The Firm will follow CIRM's budget analysis process, procedures and workflow. In addition, the Firm will work closely with CIRM's Grants Management team.

CIRM anticipates selecting multiple budget review firms pursuant to this RFP and will alternate work among them based on relative expertise in specific areas, timelines, and the avoidance of potential conflicts of interest.

The Firm will be expected to provide CIRM with the services described below:

- Test validity and sensitivity of budget assumptions.
- Compare proposed budget against established market rates for similar activities.
- Assess integrity and completeness of budget.
- Provide information regarding financial accuracy, potential variance and impact of the budget portion of grant applications. This information should include the expected minimum and maximum range the Firm believes budget should be inside based on Firm's expertise. The Review Report template is included in Attachment E.
- The budget review will need to be performed in a two-week period following the delivery of the applicant budget to Firm from CIRM.

The Firm that is selected must be technically and professionally capable of providing the services in all subject areas described in the Scope of Services and meet the Minimum Qualifications for Proposers in Section B. The Firm must be free from actual conflicts of interest not only at the time of selection, but also throughout the term of the contract.

3. Cost Proposal

The proposal should include all costs for the services to be provided on a per application basis.

4. Qualifications Required

As evidenced by the nature of the tasks listed above, CIRM expects to have a close working relationship with its budget review firm, and requires that the Firm demonstrate a high degree of experience, training and proficiency in the conduct of the various functions performed. The Firm should have extensive background in preparing and analyzing budgets for preclinical work and clinical trials within the biotechnology, academic and/or pharmaceutical industries. In addition, CIRM expects that the Firm will comply with current industry standards and will maintain appropriate expertise at the Firm's own expense. The following minimum qualifications and experience are required:

a) Firm must be a professional Clinical Research Organization/Contract Research Organization ("CRO") with 5 years in business and experience in cell therapy/stem cell/small molecule/biologics clinical trials.

b) Firm must have conducted, within the last 5 years, at least ten successful contracts for clinical trials in the areas outlined above.

c) Firm must have sufficient staff to provide budget review services to CIRM to meet the requirements outlined above in the Scope of Services.

5. Submitting a Proposal

5.1. Documents to be Submitted

There are four parts to a proposal. Part I (Consultant Information) and Part II (References) are included in this RFP as forms to be completed and returned with your proposal. There is no form for Part III (Proposal and Qualifications). You should prepare a PDF or Word document with your responses to the questions listed in the next section, and attach samples of your work. Part IV is the Notice Regarding Public Release of Proposals, which is attached to this RFP as Attachment A, and which explains how you may designate certain materials as "confidential." In order for your proposal to be considered, you must review and sign Attachment A and return it to CIRM with the other parts of your proposal.

5.2. Proposal and Qualifications

Provide straightforward and concise responses to the following in a separate document:

A. Qualifications and Experience of Firm. Discuss how your Firm's overall experience demonstrates your Firm's ability to successfully complete the Scope of Services. Provide a detailed list of CRO services you have provided to clients over the past three years, highlighting your Firm's experience with budget development and budget review capabilities for clinical trials by academic and/or for-profit companies.

B. Qualification of Staff/Resumes. Identify the staff members who will provide the services required by the proposal, including years and type of experience for each person. Experience should include number of years at current Firm as well as all relevant prior service. Experience in budget analysis and budget review within the CRO should be detailed.

C. Comparable Projects. Provide a brief list and description of comparable clients and their budget review projects which were successfully completed within the last three years.

D. Cost Proposal. Provide a detailed cost proposal as described in more detail in Paragraph 3, above.

5.3. Submission

5.3.1. Format

Please submit a hard copy of the proposal, with original signature, and a digital copy on a CD. Both the hard copy and the digital copy must be received at CIRM before the deadline.

Hard Copy: Submit one hard copy, with original signature.

Digital: Submit a CD with a PDF version of the hard copy, as well as digital versions of samples of past work.

5.3.2. Delivery

The proposal envelope(s) should be addressed as follows and must be plainly marked with the RFP number and title:

Cynthia Schaffer, Contracts Administrator
RFP # 2579 Budget Review Services
California Institute for Regenerative Medicine
210 King Street, 3rd Floor
San Francisco, CA 94107

5.3.3. Deadline

This is an open-ended RFP. Responses will be considered as they are received. The RFP will be posted until June 30, 2015.

6. Selection

The purpose of the proposal evaluation process is twofold: (1) to assess the responses for compliance with the RFP's minimum qualifications, content and format requirements; and (2) to identify budget review firms that have the highest probability of satisfactorily performing the services requested by CIRM at the best value. The evaluation process will be conducted in a comprehensive and impartial manner as set forth herein.

Proposals will undergo an evaluation process conducted by CIRM. Based on this evaluation, candidates may be invited to interview with CIRM and may have their references checked.

In evaluating the proposals, CIRM will consider the perceived quality of the response, including Consultant's proposed scope of services, cost proposal, timeline, references, experience and qualifications. Evaluation will include consideration of the following factors:

A. Relevant Experience and Ability. Evaluation of budget review firms will include review of the Firm's overall experience, as well as the Firm's relevant experience. A factor under consideration will be whether the Firm's experience demonstrates its ability to successfully complete the requirements herein.

B. Responsiveness to Project Requirements and Clients. Evaluation of prospective Firms will include consideration of responsiveness to client needs and requirements on previous projects, and the quality of the relationships maintained throughout the duration of these efforts. Attentiveness to and compliance with RFP instructions and other aspects of the selection process will be taken as an indication of responsiveness.

C. Qualifications of Proposed Personnel. Evaluation of prospective consultants will include the particular experience, capabilities, and availability of specific personnel who will be available to provide consulting services to CIRM.

D. Value. Range of services to be delivered within the proposed budget.

7. Key Action Dates

Date	Action
March 20, 2015	RFP available to prospective firms
June 30, 2015 @ 5:00 pm	Final Date for Proposal Submission.
Responses considered as received.	Proposed Award Date – within 3 weeks of Proposal being received.

8. Contract Terms

CIRM's standard Independent Consultant Agreement is attached, and the selected firm will be expected to comply with its terms, including insurance requirements. Please review the contract terms before submitting your proposal.

CIRM expects the chosen budget review firm will be able to start as soon as possible after the agreement is executed. CIRM anticipates entering into a contract with an initial expiration date of June 30, 2016 with two possible one-year extensions.

All contracts will contain a cancellation clause at CIRM's election per CIRM's standard Consulting Agreement.

9. Additional Information

A. A proposal may be rejected if it is conditional or incomplete, or if it contains any alterations of form or other irregularities of any kind. CIRM may waive any immaterial deviation in a proposal. CIRM's waiver of an immaterial deviation shall in no way modify the RFP document or excuse the proposer from full compliance with all requirements if awarded the contract.

B. CIRM may reject any or all proposals.

C. Costs incurred for developing proposals and in anticipation of award of the agreement are entirely the responsibility of the proposer and shall not be charged to CIRM.

D. A proposer may withdraw its proposal by submitting a written withdrawal request to CIRM, signed by the Proposer or an authorized agent.

E. A proposer may not modify a proposal after its submission. If the submission deadline has not passed, a proposer may withdraw its original proposal and submit a new proposal. Proposal modifications offered in any other manner, oral or written, will not be considered.

F. CIRM may modify the RFP prior to the date fixed for submission of proposals by posting the modified RFP on its website. If you are preparing a proposal, you should check the CIRM website for modifications to the RFP.

G. CIRM will not consider more than one proposal from an individual, firm, partnership, corporation or association, under the same or different names.

H. No oral understanding or agreement shall be binding on either party.

10. Public Release of Proposals

All documents submitted in response to this RFP will become the property of CIRM, and will be regarded as public records under the California Public Records Act (Government Code Section 6250 et seq.) and subject to review by the public. Attachment A to this RFP (Notice Regarding Public Release of Proposals) contains important details about the California Public Records Act and requirements for submitting any information in support of your proposal that you believe may legally be withheld from public disclosure. **In order for your proposal to be considered, you must review and sign Attachment A and return it to CIRM, along with your proposal.**

11. Attached Documents

A. Notice Regarding Public Release of Proposals
B. Form I: Consultant Information
C. Form II: References
D. CIRM's Standard Independent Consultant Agreement
E. Budget Template and Review Report

Purpose	The purpose of this budget workbook is to provide an activities based breakdown of the proposed budget to allow for evaluation. The following Activities-Based Budget (ABB) is both a planning tool to help you reasonably allocate your resources across primary and secondary activities as well as a tool for CIRM to gauge the appropriateness of the costs in relation to the activities proposed. Except for the "Summary" worksheet, you are to only budget allowable Total Direct Project Costs in all the worksheets; this means exclusive of Facilities/Indirect costs and irrespective of the sources of funds. For ex-CA organizations, this also means only budgeting the total direct project costs incurred in California. Refer to parts of this ABB in the budget justification section of the application to help clarify the cost composition of the activities.

Worksheet Definitions	This file is broken down into multiple worksheets, each of which covers a discrete part of pre-clinical through clinical development.
Activities Examples	This worksheet contains a list of primary and secondary activities (for more information, see "Primary Activity" and "Secondary Activity" below). The primary activities are pre-defined and not editable. The secondary activities are examples and not meant to cover every possible activity for the wide variety of therapeutic candidates. Use them as guidance for the level of specificity expected in secondary activities.
General Info	General information related to the grant application and treatment. This includes an optional worksheet to convert the quarterly schedule into month and year.
CMC & Analytical	This sheet is the location to enter all activities related to the creation, analytical characterization, preparation and supply of the final therapeutic candidate product. This includes CMC, manufacturing, manufacturing optimization, process development, analytical testing, analytical assay development, formulation, formulation optimization, regulatory CMC, stability, storage. This section will contain all costs of the investigational therapeutic candidate for clinical and non-clinical studies.
Animal Studies	This worksheet collects the information and builds a budget summary for each animal study. This includes animal acquisition, animal related costs, treatment, testing, management, analysis and reporting costs. This does not include costs of the investigational therapeutic candidate supply, which are entered in "CMC & Analytical". The results of these descriptions feed into the "Non-Clinical" worksheet. If there are animal studies proposed, fill out this worksheet prior to the "Non-Clinical" worksheet.
Non-Clinical	This sheet is the location to enter non-clinical activities excluding CMC & Analytical and investigational therapeutic candidate supply. If there are animal studies, fill out the "Animal Studies" Worksheet first. The "Animal Studies" Worksheet summary information is shown at the top of this sheet.
Clinical Trial Worksheet	This worksheet collects the information and builds a budget summary for the patient costs and selected fees from the clinical trial. Other clinical trial costs are entered in the clinical worksheet, which should be filled out first. This does not include costs of the investigational therapeutic candidate supply, which are entered in "CMC & Analytical". The results of these descriptions feed into the "Clinical" worksheet.
Clinical	This sheet is the location to enter all activities and costs related to clinical activities and non-CMC related regulatory activities not collected on the "Clinical Trial" Worksheet. This excludes supply of the investigational therapeutic, which is entered in the "CMC & Analytical" worksheet.
Summary	This is a summary of the primary activities pulled from the other worksheets. In addition, the applicant is asked to enter the percentage (%) of **allowable direct project cost funding requested of CIRM** by primary activity and then break out the **total direct project cost funding quarter by quarter.** This exercise will help CIRM determine the Milestone-based payments schedule for the project, so please budget based on when you expect to need funds for activities (i.e. a cash basis). CIRM expects the proportionality of co-funding to be relatively even over time. The exercise allows for up to 20 quarters; if you think you will need more quarters, contact CIRM before continuing.

Terms and Definitions	
Quarter Start	The integer value of the quarter of the grant term where the activities will commence. Quarter 1 is defined as the first 3 months after the award is issued. This value is constrained to integers.
Quarter End	The integer value of the quarter of the grant term where the activities will end. Quarter 1 is defined as the first 3 months after the award is issued. This value is constrained to integers.
Quotes and Other Budget Data	Place quotes and other budget data (ex. internal cost benchmarks) in "Quotes and Other Budget Data" portion of the "Uploads" section of the grant application.
Primary Activity	Primary activities are high level activities. Select name of the activity from the dropdown menu. Activities are restricted to those listed in the dropdown menu. The same primary activity may be performed more than once. For example, analytical assay development and methods validation may be performed for different assays.
Secondary Activity	Enter the name of secondary activity. Secondary activities are activities that are integral to and required for the primary activity. A list of relevant examples is shown in the Activities Examples worksheet.
Primary Activity Costs When Secondary Activities Are Present	If there are secondary activities, enter the cost values for each secondary activity. Enter only direct project costs. The cost of the primary activity is a summation of the costs of the secondary activities, so all costs need to be included in the secondary activities if any secondary activities are listed. Small secondary activities (<$10,000 each) should be grouped together in a like category, the "Other" category or the "Ancillary Expenses" category. Use the notes section to clarify activities and provide details and justification for review.
Primary Activity Costs without Secondary Activities	Enter the cost of the primary activity and leave the secondary activities section empty. Enter only direct costs.
Direct Costs Only	Enter only allowable direct project costs (US dollars), whether the cost is CIRM or Co-funded. This amount excludes Facilities and Indirect overhead costs.
Intellectual Property Development and Patent Costs	Include only if proposing as a direct cost. This requires justification why costs are not covered by indirect/administrative overhead funding.

Equipment	Non-expendable, free-standing, tangible personal property with a normal life expectancy of one year or more and an acquisition cost which equals or exceeds the lesser of the capitalization level established by the Grantee for financial management purposes or $5,000. Acquisition costs include items such as delivery. Costs to modify facilities in order to install equipment are not appropriate for this category as they are covered in overhead funding.
Sample Testing	All sample testing that is part of an animal or clinical study should be included in that study. Testing not related to an animal or clinical study should be captured as a secondary activity under the relevant primary activity.
Allowable and Unallowable Costs	A partial list can be found at http://www.cirm.ca.gov/grants-administration-policy#VB3

Sheet Modification	
Rearranging the sheet	Please do not attempt to rearrange the sheet (add rows or cells, delete rows or cells). This may result in the associations between cells breaking. If you wish to remove rows or columns from the screen, please use the Hide function.
Adding primary activities	The number of primary activities is fixed and more cannot be added. Consider if the level of detail being used is too specific and if activities can be combined into a single entry.

Adding Information to Cells	
Select	Select appropriate value from dropdown list.
Fill	Enter relevant text or numbers.
$ -	Enter relevant direct cost in US Dollars.
Blue cell	Fixed text or calculated value. Do not enter values.
Grey Cell	Fill in text, number or select value from dropdown menu.
Orange Cell	Value for primary activity cost, quarter start or quarter end. Enter value only if there are no secondary activities. If there are secondary activities, the value for this cell is derived from the secondary activity values.

Worksheet Instructions	Instructions for how to fill out each of the worksheets are below.
General Info	
Application Number	Fill in application number.
Project Title	Fill in title of application.
Name of Principal Investigator	Fill in name of principal investigator.
Program Announcement Type	Select the desired program announcement type from drop down list.
Worksheets to fill out	Automatically populated by program announcement type.
Therapeutic Candidate Type	Select from drop down list.
Description of Therapeutic Candidate	Enter description of the therapeutic candidate (drug) being developed.
Device	Select yes or no from the drop down list if a device is a part of the investigational therapeutic candidate.
Therapeutic Area	Select from drop down list.
Indication	Describe indication used in this clinical trial for the therapeutic candidate being developed.
Regulatory agencies	Indicate regulatory agencies to be interacted with as a part of the grant (ex. FDA, EMEA, Health Canada, PMDA, etc...).
Country (Countries) Trial Is Conducted In	The country or list of the countries in which the clinical trial is to be performed.
Quarter Definition Sheet	This table translates application submission date into a calendar of quarters. It provides a breakdown of the months the various quarters start and end. It does not provide the day the quarters actually start and end. It assumes that activities begin 4 months from the submission deadline. The project must start within 130 days from application submission as required by the program announcements. If grant period is expected to last beyond 5 years, contact CIRM prior to application submission.
Input Month of Submission	Select the month of submission from the drop down menu.
Input Year of Submission (YYYY)	Enter the Year in the YYYY format (for example, 2015).
Printing	Please review print preview before you print. The worksheets have been formatted to print in a way to minimize paper. However, the embedded formatting can change due to different operating systems and versions of Excel.

CMC & Analytical Worksheet	For each primary activity, select the primary activity name from the dropdown list. Fill in the secondary activities which comprise the primary activity and the direct costs for those secondary activities. The cost of the primary activity is a summation of the costs of the secondary activities, so all costs need to be included in the secondary activities if any secondary activities are listed. Small secondary activities (<$10,000 each) should be grouped together in a like category, the "Other" category or the "Ancillary Expenses" category. Use the notes section to clarify activities and provide details and justification for review. Also include references to associated quotes in the notes section. Examples of secondary activities are shown in the "Activities Example" worksheet. This sheet is limited to 10 primary activities and 10 secondary activities per primary activity. The same primary activity may be used more than once to represent repetitions of the same activity or different variations of the primary activity.

Animal Studies Worksheet	If there are animal studies proposed, fill out this worksheet prior to the "Non-Clinical" worksheet. Fill out an animal study worksheet for each animal study requested as a part of the grant application. Line by line instructions are found below. These worksheets do not include costs of therapeutic candidate supply, which are entered in "CMC & Analytical". There are 10 animal study worksheets available. A list of study purpose examples is shown on this worksheet.
Study Name	Enter the name of the study.
Study Purpose	Enter Reason for conducting the study (ex. Toxicity). Examples are shown on the "Activities Examples" and the "Animal Studies" worksheets.
GLP	Select whether the study uses Good Laboratory Practices (GLP) or not. "Mixed" indicates that part of the study is conducted under GLP and part is not. Please explain why "Mixed" was used in the Notes section.
Animal Species and Strain	Enter the species and strain of the animal used in the study.
Quotes and Other Budget Data Title(s)	Enter the title of the study related quote(s) and other budget data (for example, internal cost benchmarks).
Quarter Start	Enter the quarter that the animal study will start.
Quarter End	Enter the quarter that the animal study will end.
In Life Length of Study (Months)	Enter the duration of the in life portion of the study in either days or months. Include the units (days or months).
Total One Time/Start up Costs	Enter the cost of one time start up costs for the study.
Animal Costs	
Number of Animals	Enter the number of animals used in the study.
Animal Acquisition Costs	Enter the cost to acquire all of the animals used in the study.
Screening Costs	Enter the cost to screen the animals to determine if they are suitable for inclusion in the study.
Housing and Animal Care Costs	Enter the cost of housing and caring for all of the animals used in the study. This includes routine care, husbandry and janitorial costs.
Treatment Costs	Enter the cost of treating all of the animals. This includes administration, labor, veterinary supply costs. This does not include study treatment (therapeutic candidate). All study therapeutic candidate costs are in "CMC & Analytical".
Non-Study Drug Medications	Enter the cost of non-study (concomitant) drug medications for all of the animals. This includes immunosuppressants and other medications given to the animals which are not the therapeutic candidate being studied. All therapeutic candidate (test article) costs are in "CMC & Analytical".
Labs and Assay Costs	Enter the cost of performing all sample collection, laboratory work, pathology and assays.
Other Costs	Enter the other costs directly related to care, maintenance, treatment and performance of assays that are not listed above.
List sources of other animal related costs	List the purpose of the other animal related costs in the text box.
Total Animal Costs	A summation of all of the animal related costs for the study.
Analysis and Report Costs	Enter the cost of data handling, data analysis and generation of reports.
Management Costs	Enter the costs due to study management. This includes project management and related travel.
Non-Animal Related Other Costs	Enter the other costs not directly related to care, maintenance, or treatment of animals and performance of assays that are not listed above.
List sources of other non-animal related costs	List the purpose of the other non-animal related costs in the relevant text box.
Total	The total cost of the study and directly supporting activities such as project management and reporting.
Notes:	Enter notes in the text box below.
Enter notes here	The notes section for further justification and explanation.

Non-Clinical Worksheet	For each primary activity, select the primary activity name from the dropdown list. Fill in the secondary activities which comprise the primary activity and the direct costs for those secondary activities. The cost of the primary activity is a summation of the costs of the secondary activities, so all costs need to be included in the secondary activities if any secondary activities are listed. Small secondary activities (<$10,000 each) should be grouped together in a like category, the "Other" category or the "Ancillary Expenses" category. Use the notes section to clarify activities and provide details and justification for review. Also include references to associated quotes in the notes section. Examples of secondary activities are shown in the "Activities Example" worksheet. This sheet is limited to 10 primary activities and 10 secondary activities per primary activity. The same primary activity may be used more than once to represent repetitions of the same activity or different variations of the primary activity.

Clinical Trial Worksheet	If there is a clinical trial as a part of the grant application, fill out this worksheet prior to "Clinical" worksheet. Data from the Clinical Trial Worksheet will be summarized on the Clinical Worksheet. Line by line instructions are found below. This worksheet does not include costs of therapeutic candidate supply, which are entered in "CMC & Analytical". CIRM will only fund the initial data-driven trial. Any long term follow up companion trial should be discussed in this application, but CIRM will not fund the long term, open ended follow up. Data from the Clinical Trial Worksheet will be summarized on the Clinical Worksheet.
Trial Summary	
Phase	Select the clinical trial phase from the dropdown list.

Clinical Trial Name	Enter the name of the study.
Study Timelines	
Recruitment Period	Period from first patient first visit to last patient first visit. Enter duration in months.
Treatment Period (for one patient)	Maximum period that one patient could be on study therapy (i.e. from Last Patient First Visit to Last Patient Last Visit). Enter duration in months.
Follow Up Period (for one patient)	Maximum follow up period for one patient (i.e. from Last Patient Last Visit to Last Patient Follow Up Visit). Enter duration in months.
Total Study Duration	A summation of the Recruitment, Treatment and Follow Up periods.
Subjects	
Number of Screened Subjects	Enter number of subjects to be screened to meet the required number of enrolled subjects.
Number of Enrolled Subjects	Enter the required number of enrolled subjects to start study therapy.
Number of Completing Subjects	Enter number of subjects expected to complete the study (i.e. those that will not drop out).
Subject Visits	
Number of Study Visits (per Completed Subject)	Enter the maximum number of visits a subject could complete while on study therapy.
Number of Follow Up Visits (per Subject)	Enter the maximum number of follow up visits a subject could complete.
Sites	
Number of Sites in California	Enter the number of clinical trial sites located in California.
Number of Sites in the Rest of the USA (CA excluded)	Enter the number of clinical trial sites located within the USA but outside of California.
Number of Sites Outside of the USA	Enter number value of clinical trial sites located outside of the USA.
Total Sites	A summation of the number of sites on the study.
Patient Visit Costs	
Screening Cost (per Patient Screened)	Enter the investigator fees per screening visit.
Average Investigator Fees (per Study Visit, Excluding Screening Visit)	Enter the average investigator fees per study visit.
Administration of Study Therapeutic Candidate (per Study Visit)	Enter the average per visit cost for administration of study therapy to the subject. This will be multiplied by the number of study visits, excluding screening and follow up visits.
Labs & Special Tests (per Study Visit)	Enter the average per visit cost for labs and special tests per study visit. These tests should not be included in investigator fees. This will be multiplied by the number of screening and study visits, excluding follow up visits.
Immune Monitoring (per Study Visit)	Enter the average per visit cost for immune monitoring. This will be multiplied by the number of study visits, excluding screening and follow up visits.
Screening Visit Patient Support (e.g. Travel) (per Study Visit)	Enter the average patient support cost for the screening visit. This will be multiplied by the number of patients screened.
Patient Support (Hospital Stays, Travel) (per Study Visit)	Enter the average patient support cost per study visit. This will be multiplied by the number of patients randomized, and the total number of study visits.
Other Patient Care Costs (per Study Visit)	Enter the any other patient care costs that will be incurred during the study. The value entered should be the average for each study visit. These will be multiplied by the number of study visits, and randomized subjects.
Patient Visit Costs - Follow Up	Any long term follow up companion trial should be discussed in this application, but CIRM will not fund the long term, open ended follow up.
Average Investigator Fees (per Follow Up Visit)	Enter the average investigator fees per follow up visit. This will be multiplied by the number of follow up visits, and the number of completing subjects.
Labs & Special Tests (per Follow Up Visit)	Enter the average per visit cost for labs and special tests per study visit. These tests should not be included in investigator fees. This will be multiplied by the number of follow up visits and the number of completing subjects.
Follow Up Visit Patient Support (e.g. Travel) (per Study Visit)	Enter the average per visit cost for immune monitoring or other follow up activities. This will be multiplied by the number of study visits, excluding screening and follow up visits.
Other Patient Care Costs (per Follow Up Visit)	Enter the any other patient care costs that will be incurred during the follow up period. The value entered should be the average for each study visit. These will be multiplied by the number of follow up visits and completing subjects.

Clinical Worksheet	Fill out the "Clinical Trial Worksheet" first. For each primary activity, select the primary activity name from the dropdown list. Fill in the secondary activities which comprise the primary activity and the direct costs for those secondary activities. The cost of the primary activity is a summation of the costs of the secondary activities, so all costs need to be included in the secondary activities if any secondary activities are listed. Small secondary activities (<$10,000 each) should be grouped together in a like category, the "Other" category or the "Ancillary Expenses" category. Use the notes section to clarify activities and provide details and justification for review. Also include references to associated quotes in the notes section. Examples of secondary activities are shown in the "Activities Example" worksheet. This sheet is limited to 15 primary activities and 10 secondary activities per primary activity. The same primary activity may be used more than once to represent repetitions of the same activity or different variations of the primary activity. Valid primary activities on this worksheet for Late Stage Pre-Clinical program announcement applications include Fees, Pre-Study Activities, Study Start-Up and Initiation Activities and Regulatory Activities (For Clinical Trials). Other primary activities on this worksheet are out of scope for Late Stage Pre-Clinical program announcements.
Summary Worksheet	The sheet summarizes the total allowable direct project cost for all primary activities, activity categories (CMC & Analytical, Non-Clinical and Clinical) as well as when the activities will occur. The "Percentage of Funding from CIRM" values for each primary activity are required to be entered to calculate the "CIRM Direct Project Cost" values. Consider only allowable direct costs and the percentage of the direct cost that CIRM is requested to fund. Finally, the timing of **total allowable direct project cost funding** needed on a quarterly, cash basis also needs to be entered for each primary activity. For instance, enter direct project cost dollars for any contract activity in the quarter you anticipate the contractor will require payment (not across the period a contractor will conduct the activity). The "Summed Quarterly Direct Project Costs ($)" must match the "Total Direct Project Cost" and the worksheet will highlight whether there is a match or not.

Acronyms

ADME	Absorption, Distribution, Metabolism, and Excretion
ADR	Adverse Drug Reaction
ASPR	Anonymized Single Patient Report
cGMP	Current Good Manufacturing Practices
CIRM	California Institute for Regenerative Medicine
CMC	Chemistry, Manufacturing, and Controls
CMO	Contract Manufacturing Organization
CRA	Clinical Research Associate
CRF	Clinical Research Form
CRO	Contract Research Organization
DMPK	Drug Metabolism and Pharmacokinetics
DQ	Design Qualification
DSMB	Data and Safety Monitoring Board
EDC	Electronic Data Capture
GLP	Good Laboratory Practices
GMP	Good Manufacturing Practices
IND	Investigational New Drug Application
IOQ	Installation and Operational Qualification
IP	Intellectual Property
IQ	Installation Qualification
OQ	Operational Qualification
PQ	Performance Qualification
QC	Quality Control
QP	Qualified Person
QTPP	Quality Target Product Profile
SADR	Suspected Adverse Drug Reaction
SAE	Significant Adverse Event
SUSAR	Suspected, Unexpected, Serious Adverse Reaction

Important: The secondary activities listed here are examples and not meant to cover every possible activity for the wide variety of therapeutic candidates. Use them as guidance for the level of specificity expected in secondary activities.

CMC & Analytical Activities

Primary	Materials	Regulatory & Legal	Equipment & Facilities	Analytical Development: Explain Assay In Notes
Examples of Secondary Activities	Cost Of Goods (Process Input Materials) Cost Of Goods (Single-Use Equipment) Cost Of Goods (Support Materials e.g. Resins) Raw Material Test Methods Development Raw Material Test Methods Validation Testing & Release Of Materials Vendor Qualification	Dossier Preparation & Publishing IND Application Regulatory Agency Fees (Submission, Meeting Etc.)	Equipment Acquisition Equipment Installation (No Facilities Costs) Equipment Maintenance Equipment Qualification (DQ / IOQ / PQ) Qualification Of Facilities, Utilities & Support Systems (DQ/ IOQ / PQ) Validation Of Cleaning & Sterilization Procedures	Method Development & Optimization Method Transfer Method Validation For Early Development Method Full Validation Reference Material Qualification Reference Standards Or Materials Reporting Specification Development Supplies
	Vendor Services Other (Explain In Notes) Ancillary (Explain In Notes) Project Management	Vendor Services Other (Explain In Notes) Ancillary (Explain In Notes) Project Management	Vendor Services Other (Explain In Notes) Ancillary (Explain In Notes)	Vendor Services Other (Explain In Notes) Ancillary (Explain In Notes) Project Management

Animal Studies	Animal Study Purposes	Stability and Storage	Intellectual Property Development and Patent Costs (Justification Required- See Instructions)
	Biodistribution Bioanalysis Bioavailability Bioequivalence Biomarker Bridging Study Cell persistence / fate Developmental and Reproductive Toxicology Device testing Dose and/or Schedule Optimization Drug Drug Interaction Efficacy Genetic Toxicology Immunogenicity In Vivo Micronucleus Multipurpose (Purpose A, Purpose B, Purpose C) Pharmacokinetics (DMPK) PK/PD Potency Assay	Reference Standards Or Materials Reporting Stability Characterization (e.g. Stress Testing, Photostability, Freeze- Stability Methods Development Stability Methods Materials Creation/Acquisition Stability Method Validation For Early Development Stability Method Full Validation Stability Studies (Real-Time/Temperature, Accelerated) Storage (Warehouse Fees) Supplies Technology Transfer	Patent Costs Patent Preparation And Filing Other IP Costs (Explain In Notes)
	Preliminary Toxicology Repeat-Dose Toxicology Safety Other Safety/Toxicity study Teratoma/Tumorgenicity studies Toxicokinetics	Vendor Services Other (Explain In Notes) Ancillary (Explain In Notes) Project Management	Vendor Services Other (Explain In Notes) Ancillary (Explain In Notes)

Non-Clinical Activities

Primary	Animal Model	Biomarker Assay Development	Clinical Assay Development	Potency Assay Development
Examples of Secondary Activities	Animal Model Development Supplies Sample Acquisition Reporting	Biomarker Exploratory Testing Biomarker Assay Development Biomarker Assay Qualification/Validation Biomarker Assay Full Validation Biomarker Assay Materials Creation/Acquisition Technology Transfer Supplies Sample Acquisition Reporting	Clinical Assay Development Clinical Assay Qualification/Validation Clinical Assay Materials Creation/Acquisition Technology Transfer Supplies Sample Acquisition Reporting	Potency Assay Development Potency Assay Qualification/Validation Technology Transfer Supplies Sample Acquisition Reporting
	Vendor services Other (Explain In Notes) Ancillary (Explain In Notes) Project Management	Vendor services Other (Explain In Notes) Ancillary (Explain In Notes) Project Management	Other (Explain In Notes) Ancillary (Explain In Notes) Project Management	Other (Explain In Notes) Ancillary (Explain In Notes) Project Management

Clinical Activities	Eligible Activities for All Program Announcement Types Including Late Stage Pre-Clinical			
Primary Activities	**Fees**	**Pre-Study Activities**	**Study Start-Up and Initiation Activities**	**Regulatory Activities (for clinical trials)**
Examples of Secondary Activities	Investigator meetings	CRF Design	Assemble/Ship Study Documents	Drug Import Licenses
	CRA costs/Clinical trial management	Immunosuppression plan	Clinical sites contracts costs	Investigator Contracts: Negotiation of Budget/Contract
	Data management	Informed Consent Template Preparation	Kick-Off Meeting	Prepare Regulatory Applications and Support Multi-Country Trials
	Database lock/Biostatistics/Study Report	Investigator Drug Brochure Preparation	Project Planning and Team Training	Regulatory Assistance with Import of Study Drug
	DSMB	IRB Submission	Site Identification	Regulatory Review of Regulatory Document Packets
	IRB	Protocol Preparation	Site Selection Visit	Regulatory Support and Consulting
	Medical monitoring	Randomization Plan	Site Training/Initiation	Submit National Regulatory Documents (e.g. FDA)
	Other costs - Clinical end point analyses	Randomization Scheme	Translations performed by Clinical Staff	
	Team/Management	Study Reference Manual Development		
		Study Reference Manual Distribution		
		Vendor Patient Diary Review		
		Vendor Services	Vendor Services	Vendor Services
	Other (Explain In Notes)	Other (Explain In Notes)	Other study start up/one time costs (Explain In Notes)	Other (Explain In Notes)
	Ancillary (Explain In Notes)	Ancillary (Explain In Notes)	Ancillary (Explain In Notes)	Ancillary (Explain In Notes)

Regulatory Activities	**Safety Assay Development**	**Sample Collection, Processing and Handling/Shipping Process Development**	**Toxicity Assay Development**	**Intellectual Property Development and Patent Costs (Justification Required- See Instructions)**
IND preparation	Safety Assay Development	Sample Collection Methods Development	Toxicity Assay Development	Patent Preparation and Filing
Regulatory Meetings	Safety Assay Qualification/Validation	Sample Processing Methods Development	Toxicity Assay Qualification/Validation	Patent Costs
IND Filing	Safety Assay Materials Creation/Acquisition	Sample Handling and Shipping Methods Development	Toxicity Assay Materials Creation/Acquisition	Other IP (Explain in Notes)
Target Product Profile/ Labe	Technology Transfer	Sample Collection Methods Qualification/Validation	Technology Transfer	Vendor services
Investigational Therapeutic M	Supplies	Sample Processing Methods Qualification/Validation	Supplies	
	Sample Acquisition	Sample Handling and Shipping Methods Qualification/Validation	Sample Acquisition	
	Reporting	Technology Transfer	Reporting	
		Supplies		
		Sample Acquisition		
Vendor services	Vendor services	Vendor services	Vendor services	Vendor services
Other (Explain In Notes)	Other (Explain In Notes)	Other (Explain In Notes)	Other (Explain In Notes)	
Ancillary (Explain In Notes)	Ancillary (Explain In Notes)	Ancillary (Explain In Notes)	Ancillary (Explain In Notes)	
Project Management	Project Management	Project Management	Project Management	

Analytical Testing	**GMP Manufacturing**	**Manufacturing Process Development and Optimization**	**Scale Up**
Analytical Characterization St	cGMP Clinical Manufacturing Run	Cell Banking & Characterization	End Of Process Characterization
Analytical Comparability Stuc	cGMP Documentation	Cell Line Optimization	Engineering Lot Production / In-Process Testing
Analytical Testing (Explain In	cGMP Run Manufacturing Materials	End Of Process Characterization	Generation / Selection Of Production Cell Line
CRO Screening And Selection	CMO Screening And Selection	Engineering Lot Production / In-Process Testing	Process Characterization
Laboratory Audits	End Of Process Characterization	Generation / Selection Of Production Cell Line	Process Development & Optimization
Reference Standards Or Mat	Facility Audits	Process Characterization (Incl. Design Space Development)	Process Validation
Release Testing (Materials &	Fill/Finish	Process Development & Optimization	Reference Standards Or Materials
Reporting	GMP Production / In-Process Testing - Phase 1	Process Validation	Reporting
Supplies	GMP Production / In-Process Testing - Phase 2	Reference Standards Or Materials	Supplies
Technology Transfer	GMP Production / In-Process Testing - Phase 3	Reporting	Technology Transfer
	In-Process Analytics	Supplies	
	Inter-Site Transport Fees	Technology Transfer	
	Manufacturing Process Risk Analysis (FMEA)	Upstream Process Optimization	
	Materials Procurement Control, Quarantine, Testing Release		
	Process Transfer		
	Reference Standards Or Materials		
	Regulatory Support And Performance		
	Site Qualification		
Vendor Services	Vendor Services	Vendor Services	Vendor Services
Other (Explain In Notes)	Other (Explain In Notes)	Other (Explain In Notes)	Other (Explain In Notes)
Ancillary (Explain In Notes)	Ancillary (Explain In Notes)	Ancillary (Explain In Notes)	Ancillary (Explain In Notes)
Project Management	Project Management	Project Management	Project Management

Immunology Sample Testing (Non-Animal Study Related)	In Vitro Pharmacokinetics (ADME, DMPK) Assay Development	In Vitro Pharmacokinetics (ADME, DMPK) (Non-Animal Study Related)	In Vitro Safety and Pharmacology Study (Non-Animal Study Related)
Preclinical Sample Testing an	DMPK Assay Development	In Vitro Drug Metabolism (ex. CYP)	hERG
Neutralization Studies	DMPK Assay Qualification	In Vitro Biotransformation	In Vitro Safety Other (Explain In Notes)
In Vivo and Ex Vivo Immunoli	DMPK Assay Validation	Bioanalysis (non-Animal)	Tissue & Species Cross-Reactivity Study
Supplies	DMPK Assay Materials Creation/Acquisition	Preclinical Sample Testing and Analysis	Potency Testing
Sample Acquisition	Technology Transfer	Metabolite Profiling	Supplies
Reporting	Supplies	Technology Transfer	Sample Acquisition
	Sample Acquisition	Supplies	Reporting
	Reporting	Sample Acquisition	
		Reporting	
Vendor services	Vendor services	Vendor services	Vendor services
Other (Explain In Notes)	Other (Explain In Notes)	Other (Explain In Notes)	Other (Explain In Notes)
Ancillary (Explain In Notes)	Ancillary (Explain In Notes)	Ancillary (Explain In Notes)	Ancillary (Explain In Notes)
Project Management	Project Management	Project Management	Project Management

Device Development (Non-Animal)	Diagnostics Assay Development	Equipment	Immunoassay Development
Technology Transfer	Diagnostic Assay Development	Equipment Acquisition	Immunology Assay Development
Supplies	Diagnostic Assay Qualification/Validation	Equipment Qualification & Validation	Immunology Assay Development
Sample Acquisition	Diagnostic Assay Full Validation	Equipment Maintenance	Immunology Assay Qualification/Validation
Reporting	Diagnostic Assay Materials Creation/Acquisition	Equipment Installation (No Facilities Costs)	Immunology Assay Full Validation
	Technology Transfer		Immunology Assay Materials Creation/Acquisition
	Supplies		Technology Transfer
	Sample Acquisition		Supplies
	Reporting		Sample Acquisition
			Reporting
Vendor services	Vendor services	Vendor services	Vendor services
Other (Explain In Notes)	Other (Explain In Notes)	Other (Explain In Notes)	Other (Explain In Notes)
Ancillary (Explain In Notes)	Ancillary (Explain In Notes)	Ancillary (Explain In Notes)	Ancillary (Explain In Notes)
Project Management	Project Management	Project Management	Project Management

Biostatistical Services	Medical Writing and Report Publishing Activities	Study Management Activities	Equipment
Analysis	Clinical Trial Registry Report	Project Management	Equipment Acquisition
Analysis Files	Clinical Study Report		Equipment Qualification & Validation
Intermediate Statistical Dry			
Run(s)	IND Annual Report		Equipment Maintenance
Statistical Analysis Plan	Manuscript Preparation		Equipment Installation (No Facilities Costs)
Tables, Listings & Graphs			Technology Transfer
			Supplies
Vendor Services	Vendor Services	Vendor Services	Vendor Services
Other (Explain In Notes)	Other (Explain In Notes)	Other (Explain In Notes)	Other (Explain In Notes)
Ancillary (Explain In Notes)	Ancillary (Explain In Notes)	Ancillary (Explain In Notes)	Ancillary (Explain In Notes)

In Vitro Toxicity Studies	Other (Explain In Notes)	Other Assay Development (Explain In Notes)	Other Sample Testing (Non-Animal Study Related; Explain In Notes)
AMES Testing		Other Assay Development	Preclinical Sample Testing and Analysis (Explain in Notes)
Chromosome Aberration		Other Assay Qualification/Validation	Supplies
Tissue & Species Cross-Reactivity Study		Other Assay Materials Creation/Acquisition	Sample Acquisition
Genetic Toxicology		Technology Transfer	Reporting
In Vitro Toxicity Study		Supplies	
Micronucleus		Sample Acquisition	
Reporting		Reporting	
Sample Acquisition			
Supplies			
Technology Transfer			
Vendor services	Vendor services	Vendor services	Vendor services
Other (Explain In Notes)	Other (Explain In Notes)	Other (Explain In Notes)	Other (Explain In Notes)
Ancillary (Explain In Notes)	Ancillary (Explain In Notes)	Ancillary (Explain In Notes)	Ancillary (Explain In Notes)
Project Management	Project Management	Project Management	Project Management

Patient Recruitment Services	Clinical Trial Meetings	Clinical Monitoring and Site Management Activities	Medical and Scientific Services
Media Planning and Support	DSMB	Interim Monitoring Visit	Medical Monitoring
Production of Media			
Materials	Investigator	Site Close-Out Visit	Review of Data Listings
		Site Initiation Visit	Review Results from patient testing
Vendor Services	Vendor Services	Vendor Services	Vendor services
Other (Explain In Notes)	Other (Explain In Notes)	Other (Explain In Notes)	Other (Explain In Notes)
Ancillary (Explain In Notes)	Ancillary (Explain In Notes)	Ancillary (Explain In Notes)	Ancillary (Explain In Notes)

Non-GMP Manufacturing	Packaging	Device	Formulation
CMO Screening And Selectio	Component Design	Device Manufacturing	Compatibility Studies
End Of Process Characterizat	Component Test Methods Development	Device Optimization	Container Closure System Selection & Testing
In-Process Analytics	Component Test Methods Validation	Device Test Methods Development	Formulation Analytics
Manufacturing Materials	Packaging Process Development	Device Qualification/Validation	Formulation Development
Manufacturing Run	Packaging Process Test Methods Development	Device Testing	Formulation Methods Development
Methods Transfer	Packaging Process Test Methods Validation	Reference Standards Or Materials	Formulation Optimization
Reference Standards Or Materials		Reporting	QTPP Development & CQA Selection
Reporting		Supplies	Reference Standards Or Materials
Site Qualification		Technology Transfer	Reporting
			Supplies
			Technology Transfer
Vendor Services	Vendor Services	Vendor Services	Vendor Services
Other (Explain In Notes)	Other (Explain In Notes)	Other (Explain In Notes)	Other (Explain In Notes)
Ancillary (Explain In Notes)	Ancillary (Explain In Notes)	Ancillary (Explain In Notes)	Ancillary (Explain In Notes)
Project Management	Project Management	Project Management	Project Management

Audits	Pharmacovigilance Activities		Clinical Data Management Activities
	ASPRs	Prepare ASR for Central Ethics Committee	Data Coding
	Distribution of Investigator Alert Notifications	Prepare ASR for Regulatory Authorities	Data Entry and QC, CRF Tracking
	Distribute and Track ASR to Central Ethics Committee	Regulatory Submission	Data Monitoring
	European QP	SAE Processing	Database & Query Management
	Medical Review of Non-Serious ADRs	Safety Project Set-Up Activities	Database Set-Up
	Medical Review of other Post-Marketing ADRs	Spontaneous Non-Serious ADR Processing	Electronic Data Capture (EDC) Training
	Medical Review of SADRs	Spontaneous Serious ADR Processing	IVR Integration
	Medical Review of SAEs	Status and Maintenance Reports	Review Patient Data Listings
Vendor Services	Vendor Services		Vendor Services
Other (Explain In Notes)	Other (Explain In Notes)		Other (Explain In Notes)
Ancillary (Explain In Notes)	Ancillary (Explain In Notes)		Ancillary (Explain In Notes)

Application Number	Fill
Project Title	Fill
Name of Principal Investigator	Fill

Program Announcement Type	Select
Worksheets to fill out	Select Program Announcement Type Above
Therapeutic Candidate Type	Select
Description of Therapeutic Candidate	Fill
Device	Select
Therapeutic Area	Select
Indication	Fill
Regulatory agencies	Fill
Country (Countries) Trial Is Conducted In	Fill

Quarter Definition Sheet	(optional)	
Input Month of Submission	Select	
Input Year of Submission (YYYY)	YYYY	

Note: This table provides a breakdown of the months the various quarters start and end. It does not provide the day the quarters actually start and end.

Quarter #	Quarter Start		Quarter End	
	Month	Year	Month	Year
Q1	Error	#VALUE!	Error	#VALUE!
Q2	Error	#VALUE!	Error	#VALUE!
Q3	Error	#VALUE!	Error	#VALUE!
Q4	Error	#VALUE!	Error	#VALUE!
Q5	Error	#VALUE!	Error	#VALUE!
Q6	Error	#VALUE!	Error	#VALUE!
Q7	Error	#VALUE!	Error	#VALUE!
Q8	Error	#VALUE!	Error	#VALUE!
Q9	Error	#VALUE!	Error	#VALUE!
Q10	Error	#VALUE!	Error	#VALUE!
Q11	Error	#VALUE!	Error	#VALUE!
Q12	Error	#VALUE!	Error	#VALUE!
Q13	Error	#VALUE!	Error	#VALUE!
Q14	Error	#VALUE!	Error	#VALUE!
Q15	Error	#VALUE!	Error	#VALUE!
Q16	Error	#VALUE!	Error	#VALUE!
Q17	Error	#VALUE!	Error	#VALUE!
Q18	Error	#VALUE!	Error	#VALUE!
Q19	Error	#VALUE!	Error	#VALUE!
Q20	Error	#VALUE!	Error	#VALUE!

If grant period is expected to last beyond 5 years, contact CIRM prior to application.

Application Number	Fill
Project Title	Fill
PI Name	Fill

	Activity	Timeline			
Activity ID	**Activity Name**	**Quarter Start**	**Quarter End**	**Cost ($)**	**Notes**
Primary Activity 1	Select	0	0	$ -	Enter Notes Here
Secondary Activity 1	Fill			$ -	Enter Notes Here
Secondary Activity 2	Fill			$ -	Enter Notes Here
Secondary Activity 3	Fill			$ -	Enter Notes Here
Secondary Activity 4	Fill			$ -	Enter Notes Here
Secondary Activity 5	Fill			$ -	Enter Notes Here
Secondary Activity 6	Fill			$ -	Enter Notes Here
Secondary Activity 7	Fill			$ -	Enter Notes Here
Secondary Activity 8	Fill			$ -	Enter Notes Here
Secondary Activity 9	Fill			$ -	Enter Notes Here
Secondary Activity 10	Fill			$ -	Enter Notes Here

Application Number	Fill
Project Title	Fill
PI Name	Fill

Animal Study #	1
Study Name	Fill
Study Purpose	Fill
GLP	Select
Animal Species and Strain	Fill
Quote and Other Budget Data Title(s)	Fill
Quarter Start	0
Quarter End	0
In Life Length of Study (Months)	0
Total One Time/Start up Costs	**$ -**

Animal Costs	**N**	**$ Total**
Number of Animals	1	
Animal Acquisition Costs		$ -
Screening Costs		$ -
Housing and Animal Care Costs		$ -
Treatment Costs		$ -
Non-Study Drug Medications		$ -
Labs and Assay Costs		$ -
Other Costs		$ -
List sources of other animal related costs		
Total Animal Costs		**$ -**
Analysis and Report Costs		**$ -**
Management Costs		**$ -**
Non-Animal Related Other Costs		**$ -**
List sources of other non-animal related costs		
Total		**$ -**

Notes:
Enter notes here

Animal Study #	2
Study Name	Fill
Study Purpose	Fill
GLP	Select
Animal Species and Strain	Fill
Quote and Other Budget Data Title(s)	Fill
Quarter Start	0
Quarter End	0
In Life Length of Study (Months)	0
Total One Time/Start up Costs	**$ -**

Animal Costs	**N**	**$ Total**
Number of Animals	1	
Animal Acquisition Costs		$ -
Screening Costs		$ -
Housing and Animal Care Costs		$ -
Treatment Costs		$ -
Non-Study Drug Medications		$ -
Labs and Assay Costs		$ -
Other Costs		$ -
List sources of other animal related costs		
Total Animal Costs		**$ -**
Analysis and Report Costs		**$ -**
Management Costs		**$ -**
Non-Animal Related Other Costs		**$ -**
List sources of other non-animal related costs		
Total		**$ -**

Notes:
Enter notes here

Application Number	**Fill**
Project Title	**Fill**
PI Name	**Fill**

	Activity	Timeline						
	Animal Study Name	**Quarter Start**	**Quarter End**	**Cost ($)**	**Species**	**GLP**	**Purpose**	**Notes**
Total	Animal Studies	#REF!	#REF!	#REF!				Enter Notes Here
1	Fill	0	0	$ -	Fill	Select	Fill	Enter notes here
2	Fill	0	0	$ -	Fill	Select	Fill	Enter notes here
3	#REF!	#REF!	#REF!	#REF!	#REF!	#REF!	#REF!	#REF!
4	#REF!	#REF!	#REF!	#REF!	#REF!	#REF!	#REF!	#REF!
5	#REF!	#REF!	#REF!	#REF!	#REF!	#REF!	#REF!	#REF!
6	#REF!	#REF!	#REF!	#REF!	#REF!	#REF!	#REF!	#REF!
7	#REF!	#REF!	#REF!	#REF!	#REF!	#REF!	#REF!	#REF!
8	#REF!	#REF!	#REF!	#REF!	#REF!	#REF!	#REF!	#REF!
9	#REF!	#REF!	#REF!	#REF!	#REF!	#REF!	#REF!	#REF!
10	#REF!	#REF!	#REF!	#REF!	#REF!	#REF!	#REF!	#REF!

	Activity	Timeline			
Activity ID	**Activity Name**	**Quarter Start**	**Quarter End**	**Cost ($)**	**Notes**
Primary Activity 1	Select	0	0	$ -	Enter Notes Here
Secondary Activity 1	Fill			$ -	Enter Notes Here
Secondary Activity 2	Fill			$ -	Enter Notes Here
Secondary Activity 3	Fill			$ -	Enter Notes Here
Secondary Activity 4	Fill			$ -	Enter Notes Here
Secondary Activity 5	Fill			$ -	Enter Notes Here
Secondary Activity 6	Fill			$ -	Enter Notes Here
Secondary Activity 7	Fill			$ -	Enter Notes Here
Secondary Activity 8	Fill			$ -	Enter Notes Here
Secondary Activity 9	Fill			$ -	Enter Notes Here
Secondary Activity 10	Fill			$ -	Enter Notes Here
Primary Activity 2	Select	0	0	$ -	Enter Notes Here
Secondary Activity 1	Fill			$ -	Enter Notes Here
Secondary Activity 2	Fill			$ -	Enter Notes Here
Secondary Activity 3	Fill			$ -	Enter Notes Here
Secondary Activity 4	Fill			$ -	Enter Notes Here
Secondary Activity 5	Fill			$ -	Enter Notes Here
Secondary Activity 6	Fill			$ -	Enter Notes Here
Secondary Activity 7	Fill			$ -	Enter Notes Here
Secondary Activity 8	Fill			$ -	Enter Notes Here
Secondary Activity 9	Fill			$ -	Enter Notes Here
Secondary Activity 10	Fill			$ -	Enter Notes Here
Primary Activity 3	Select	0	0	$ -	Enter Notes Here
Secondary Activity 1	Fill			$ -	Enter Notes Here
Secondary Activity 2	Fill			$ -	Enter Notes Here
Secondary Activity 3	Fill			$ -	Enter Notes Here
Secondary Activity 4	Fill			$ -	Enter Notes Here
Secondary Activity 5	Fill			$ -	Enter Notes Here
Secondary Activity 6	Fill			$ -	Enter Notes Here
Secondary Activity 7	Fill			$ -	Enter Notes Here
Secondary Activity 8	Fill			$ -	Enter Notes Here
Secondary Activity 9	Fill			$ -	Enter Notes Here
Secondary Activity 10	Fill			$ -	Enter Notes Here
Primary Activity 4	Select	0	0	$ -	Enter Notes Here
Secondary Activity 1	Fill			$ -	Enter Notes Here
Secondary Activity 2	Fill			$ -	Enter Notes Here
Secondary Activity 3	Fill			$ -	Enter Notes Here
Secondary Activity 4	Fill			$ -	Enter Notes Here
Secondary Activity 5	Fill			$ -	Enter Notes Here
Secondary Activity 6	Fill			$ -	Enter Notes Here
Secondary Activity 7	Fill			$ -	Enter Notes Here
Secondary Activity 8	Fill			$ -	Enter Notes Here
Secondary Activity 9	Fill			$ -	Enter Notes Here
Secondary Activity 10	Fill			$ -	Enter Notes Here

Application Number	Fill
Project Title	Fill
PI Name	Fill
Quotes and Other Budget Data Title(s)	Fill

Trial Summary	
Phase	Select
Clinical Trial Name	Fill

Study Timelines	**Months**
Recruitment Period	1
Treatment Period (for one patient)	2
Follow up Period (for one patient)	3
Total Study Duration	**6**

Subjects	**N**
Number of Screened Subjects	10
Number of Enrolled Subjects	8
Number of Completing Subjects	7

Subject Visits	**N**
Number of Study Visits (per Completed Subject)	10
Number of Follow Up Visits (per Subject)	20

Sites	**N**
Number of Sites in California	2
Number of Sites in the Rest of the USA (CA excluded)	2
Number of Sites Outside of the USA	1
Total Sites	**5**

	Quarter Start	**Quarter End**	**$ Per Unit**	**TOTAL ($)**	**Notes**
Patient Visit Costs	0	0		$ -	
Screening Cost (per Patient Screened)			$ -	$ -	
Average Investigator Fees (per Study Visit, Excluding Screening Visit)			$ -	$ -	
Administration of Study Therapeutic Candidate (per Study Visit)			$ -	$ -	
Labs & Special Tests (per Study Visit)			$ -	$ -	
Immune Monitoring (per Study Visit)			$ -	$ -	
Screening Visit Patient Support (e.g. Travel) (per Study Visit)			$ -	$ -	
Patient Support (Hospital Stays, Travel) (per Study Visit)			$ -	$ -	
Other Patient Care Costs (per Study Visit)			$ -	$ -	

	Quarter Start	**Quarter End**	**$ Per Unit**	**TOTAL ($)**	**Notes**
Patient Visit Costs - Follow Up	0	0		$ -	
Average Investigator Fees (per Follow Up Visit)			$ -	$ -	
Labs & Special Tests (per Follow Up Visit)			$ -	$ -	
Follow Up Visit Patient Support (e.g. Travel) (per Study Visit)			$ -	$ -	
Other Patient Care Costs (per Follow Up Visit)			$ -	$ -	

Application Number	Fill
Project Title	Fill
PI Name	Fill

Activity ID	Activity Name	Timeline Quarter Start	Timeline Quarter End	Cost ($)	Notes
Clinical Trial Worksheet	Total Costs	0	0	$ -	Enter Notes Here
Clinical Trial Worksheet 1	Patient Visit Costs	0	0	$ -	Enter Notes Here
Clinical Trial Worksheet 2	Patient Visit Costs - Follow Up	0	0	$ -	Enter Notes Here

Activity ID	Activity Name	Timeline Quarter Start	Timeline Quarter End	Cost ($)	Notes
Primary Activity 1	Select	0	0	$ -	Enter Notes Here
Secondary Activity 1	Fill			$ -	Enter Notes Here
Secondary Activity 2	Fill			$ -	Enter Notes Here
Secondary Activity 3	Fill			$ -	Enter Notes Here
Secondary Activity 4	Fill			$ -	Enter Notes Here
Secondary Activity 5	Fill			$ -	Enter Notes Here
Secondary Activity 6	Fill			$ -	Enter Notes Here
Secondary Activity 7	Fill			$ -	Enter Notes Here
Secondary Activity 8	Fill			$ -	Enter Notes Here
Secondary Activity 9	Fill			$ -	Enter Notes Here
Secondary Activity 10	Fill			$ -	Enter Notes Here
Primary Activity 2	Select	0	0	$ -	Enter Notes Here
Secondary Activity 1	Fill			$ -	Enter Notes Here
Secondary Activity 2	Fill			$ -	Enter Notes Here
Secondary Activity 3	Fill			$ -	Enter Notes Here
Secondary Activity 4	Fill			$ -	Enter Notes Here
Secondary Activity 5	Fill			$ -	Enter Notes Here
Secondary Activity 6	Fill			$ -	Enter Notes Here
Secondary Activity 7	Fill			$ -	Enter Notes Here
Secondary Activity 8	Fill			$ -	Enter Notes Here
Secondary Activity 9	Fill			$ -	Enter Notes Here
Secondary Activity 10	Fill			$ -	Enter Notes Here
Primary Activity 3	Select	0	0	$ -	Enter Notes Here
Secondary Activity 1	Fill			$ -	Enter Notes Here
Secondary Activity 2	Fill			$ -	Enter Notes Here
Secondary Activity 3	Fill			$ -	Enter Notes Here
Secondary Activity 4	Fill			$ -	Enter Notes Here
Secondary Activity 5	Fill			$ -	Enter Notes Here
Secondary Activity 6	Fill			$ -	Enter Notes Here
Secondary Activity 7	Fill			$ -	Enter Notes Here
Secondary Activity 8	Fill			$ -	Enter Notes Here
Secondary Activity 9	Fill			$ -	Enter Notes Here
Secondary Activity 10	Fill			$ -	Enter Notes Here
Primary Activity 4	Select	0	0	$ -	Enter Notes Here
Secondary Activity 1	Fill			$ -	Enter Notes Here
Secondary Activity 2	Fill			$ -	Enter Notes Here
Secondary Activity 3	Fill			$ -	Enter Notes Here
Secondary Activity 4	Fill			$ -	Enter Notes Here
Secondary Activity 5	Fill			$ -	Enter Notes Here
Secondary Activity 6	Fill			$ -	Enter Notes Here
Secondary Activity 7	Fill			$ -	Enter Notes Here
Secondary Activity 8	Fill			$ -	Enter Notes Here
Secondary Activity 9	Fill			$ -	Enter Notes Here
Secondary Activity 10	Fill			$ -	Enter Notes Here

Application Number	Fill
Project Title	Fill
PI Name	Fill

Activity Number	Activity Name	Timeline: Quarter Start	Timeline: Quarter End	Total Direct Project Costs ($)	Summed Quarterly Direct Project Costs ($)	Do Project Costs and Summed Quarterly Costs Match?	Percentage of Funding from CIRM (%)	CIRM Direct Project Costs ($)	Total Direct Project Costs: Total Direct Project Cost Spending Broken Down by Quarter: Q1	Q2	Q3	Q4	Q5	Q6
		#N/A	#N/A	#N/A	$ -	#N/A	#N/A	#N/A	$ -	$ -	$ -	$ -	$ -	$ -
CMC & Analytical Total	Activity Name	#N/A	#N/A	#N/A	$ -	#N/A	#N/A	#N/A	$ -	$ -	$ -	$ -	$ -	$ -
Primary Activity 1	Select	0	0	$ -	$ -	Yes		$ -	$ -	$ -	$ -	$ -	$ -	$ -
Primary Activity 2	#N/A	#N/A	#N/A	#N/A	$ -	#N/A		#N/A	$ -	$ -	$ -	$ -	$ -	$ -
Primary Activity 3	#N/A	#N/A	#N/A	#N/A	$ -	#N/A		#N/A	$ -	$ -	$ -	$ -	$ -	$ -
Primary Activity 4	#N/A	#N/A	#N/A	#N/A	$ -	#N/A		#N/A	$ -	$ -	$ -	$ -	$ -	$ -
Primary Activity 5	#N/A	#N/A	#N/A	#N/A	$ -	#N/A		#N/A	$ -	$ -	$ -	$ -	$ -	$ -
Primary Activity 6	#N/A	#N/A	#N/A	#N/A	$ -	#N/A		#N/A	$ -	$ -	$ -	$ -	$ -	$ -
Primary Activity 7	#N/A	#N/A	#N/A	#N/A	$ -	#N/A		#N/A	$ -	$ -	$ -	$ -	$ -	$ -
Primary Activity 8	#N/A	#N/A	#N/A	#N/A	$ -	#N/A		#N/A	$ -	$ -	$ -	$ -	$ -	$ -
Primary Activity 9	#N/A	#N/A	#N/A	#N/A	$ -	#N/A		#N/A	$ -	$ -	$ -	$ -	$ -	$ -
Primary Activity 10	#N/A	#N/A	#N/A	#N/A	$ -	#N/A		#N/A	$ -	$ -	$ -	$ -	$ -	$ -
Non-Clinical Total	Activity Name	#REF!	#REF!	#REF!	$ -	#REF!	#REF!	#REF!	$ -	$ -	$ -	$ -	$ -	$ -
Animal Studies	Animal Studies	#REF!	#REF!	#REF!	$ -	#REF!		#REF!	$ -	$ -	$ -	$ -	$ -	$ -
Primary Activity 1	Select	0	0	$ -	$ -	Yes		$ -	$ -	$ -	$ -	$ -	$ -	$ -
Primary Activity 2	Select	0	0	$ -	$ -	Yes		$ -	$ -	$ -	$ -	$ -	$ -	$ -
Primary Activity 3	Select	0	0	$ -	$ -	Yes		$ -	$ -	$ -	$ -	$ -	$ -	$ -
Primary Activity 4	Select	0	0	$ -	$ -	Yes		$ -	$ -	$ -	$ -	$ -	$ -	$ -
Primary Activity 5	#N/A	#N/A	#N/A	#N/A	$ -	#N/A		#N/A	$ -	$ -	$ -	$ -	$ -	$ -
Primary Activity 6	#N/A	#N/A	#N/A	#N/A	$ -	#N/A		#N/A	$ -	$ -	$ -	$ -	$ -	$ -
Primary Activity 7	#N/A	#N/A	#N/A	#N/A	$ -	#N/A		#N/A	$ -	$ -	$ -	$ -	$ -	$ -
Primary Activity 8	#N/A	#N/A	#N/A	#N/A	$ -	#N/A		#N/A	$ -	$ -	$ -	$ -	$ -	$ -
Primary Activity 9	#N/A	#N/A	#N/A	#N/A	$ -	#N/A		#N/A	$ -	$ -	$ -	$ -	$ -	$ -
Primary Activity 10	#N/A	#N/A	#N/A	#N/A	$ -	#N/A		#N/A	$ -	$ -	$ -	$ -	$ -	$ -
Clinical Total	Activity Name	#N/A	#N/A	#N/A	$ -	#N/A	#N/A	#N/A	$ -	$ -	$ -	$ -	$ -	$ -
Clinical Trial	Clinical Trial	0	0	$ -	$ -	Yes		$ -	$ -	$ -	$ -	$ -	$ -	$ -
Primary Activity 1	Select	0	0	$ -	$ -	Yes		$ -	$ -	$ -	$ -	$ -	$ -	$ -
Primary Activity 2	Select	0	0	$ -	$ -	Yes		$ -	$ -	$ -	$ -	$ -	$ -	$ -
Primary Activity 3	Select	0	0	$ -	$ -	Yes		$ -	$ -	$ -	$ -	$ -	$ -	$ -
Primary Activity 4	Select	0	0	$ -	$ -	Yes		$ -	$ -	$ -	$ -	$ -	$ -	$ -
Primary Activity 5	#N/A	#N/A	#N/A	#N/A	$ -	#N/A		#N/A	$ -	$ -	$ -	$ -	$ -	$ -
Primary Activity 6	#N/A	#N/A	#N/A	#N/A	$ -	#N/A		#N/A	$ -	$ -	$ -	$ -	$ -	$ -
Primary Activity 7	#N/A	#N/A	#N/A	#N/A	$ -	#N/A		#N/A	$ -	$ -	$ -	$ -	$ -	$ -
Primary Activity 8	#N/A	#N/A	#N/A	#N/A	$ -	#N/A		#N/A	$ -	$ -	$ -	$ -	$ -	$ -
Primary Activity 9	#N/A	#N/A	#N/A	#N/A	$ -	#N/A		#N/A	$ -	$ -	$ -	$ -	$ -	$ -
Primary Activity 10	#N/A	#N/A	#N/A	#N/A	$ -	#N/A		#N/A	$ -	$ -	$ -	$ -	$ -	$ -
Primary Activity 11	#N/A	#N/A	#N/A	#N/A	$ -	#N/A		#N/A	$ -	$ -	$ -	$ -	$ -	$ -
Primary Activity 12	#N/A	#N/A	#N/A	#N/A	$ -	#N/A		#N/A	$ -	$ -	$ -	$ -	$ -	$ -
Primary Activity 13	#N/A	#N/A	#N/A	#N/A	$ -	#N/A		#N/A	$ -	$ -	$ -	$ -	$ -	$ -
Primary Activity 14	#N/A	#N/A	#N/A	#N/A	$ -	#N/A		#N/A	$ -	$ -	$ -	$ -	$ -	$ -
Primary Activity 15	#N/A	#N/A	#N/A	#N/A	$ -	#N/A		#N/A	$ -	$ -	$ -	$ -	$ -	$ -

Proposal Part I
Consultant Information

Name of firm or individual proposed consultant

Business or trade name, if different from above

Business Form (check only one)

- ○ Corporation
- ○ Partnership
- ○ LLC
- ○ Individual/Sole Proprietor
- ○ Other:

Mailing Address

City State ZIP

Website

Firm Contact:

Name

Email

Telephone Fax

Total dollar amount of consultant work that the firm has performed for CIRM in the last 12 months.

The name and position of any CIRM employee who holds a position of director, officer, partner, trustee, manager or employee in the consultant organization, as well as the names of any near relatives who are employed by CIRM.

Certification

I hereby certify under penalty of perjury that I am authorized by the proposed consultant to submit this proposal on its behalf. I have reviewed all information provided in the accompanying proposal, and it is true and complete to the best of my knowledge.

Signature _____ Date

Name

Title

Proposal Part II
Proposer References

Submission of this attachment is mandatory. Failure to complete and return this attachment with your bid may cause your bid to be rejected and deemed non-responsive.

List below three references for services performed within the last five years, which are similar to the scope of work to be performed in this contract.

REFERENCE 1

Name of Firm			
Street Address	City	State	Zip Code
Contact Person		Telephone Number	
Email address			
Dates of Service			
Value or Cost of Service			
Brief Description of Service Provided			

REFERENCE 2

Name of Firm			
Street Address	City	State	Zip Code
Contact Person		Telephone Number	
Email address			
Dates of Service			
Value or Cost of Service			
Brief Description of Service Provided			

REFERENCE 3

Name of Firm			
Street Address	City	State	Zip Code
Contact Person		Telephone Number	
Email address			
Dates of Service			
Value or Cost of Service			
Brief Description of Service Provided			

Agreement No. CIRM ____

CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE
INDEPENDENT CONSULTANT AGREEMENT

THIS AGREEMENT to furnish certain consultant services is made by and between the California Institute for Regenerative Medicine hereinafter called (CIRM), and _____[Name]_____ (Consultant).

I. NATURE AND PLACE(S) OF SERVICE

A. The Consultant shall furnish to CIRM the following described services including a time schedule by which the Consultant is to produce or provide specified materials or perform certain consulting services as well as reports on the progress of the services:

i. See attachment A.

B. If the Consultant is an entity other than an individual, CIRM requires that staff be assigned according to Attachment A to perform the work set forth herein. No reassignment of work to individuals other than those described in Attachment A may be made without the written approval of CIRM.

C. Place(s) of performance of such services shall be:

Consultant's location:	CIRM's location:
[ ]	210 King Street
[ ]	San Francisco, CA 94107

D. CIRM will provide working space, equipment, furniture, utilities, and services, as follows:

II. TERM OF AGREEMENT

A. The term of this Agreement shall be from _____ through _____.

B. CIRM reserves the right to terminate this Agreement subject to 30 days written notice to the Consultant. Consultant may submit a written notice to terminate this Agreement only if CIRM should substantially fail to perform its responsibilities as provided herein. In addition, CIRM may terminate this Agreement immediately for cause. The term "for cause" shall mean that the Consultant fails to meet the terms, conditions, and/or responsibilities of this Agreement. In this instance, the termination shall be effective as of the date indicated on CIRM's notification to the Consultant. Upon termination by CIRM, CIRM shall have no further obligations other than to pay Consultant a pro-rata fee for services performed, as well as any non-cancellable fees, as of the date of termination.

C. The term of this Agreement may be extended by the mutual, written consent of both parties.

III. COMPENSATION AND REIMBURSEMENT FOR EXPENSES

A. CIRM shall pay the Consultant for services performed on the following basis:

1. Professional Fees:

2. Other Expenses

MAXIMUM TO BE PAID UNDER THIS AGREEMENT

$_____

* Reimbursement for travel and per diem shall be in accordance with established CIRM rates and policies.

B. Payments shall be made upon the Consultant's submission of invoices indicating the Agreement Number and setting forth charges in accordance with rates detailed in Article III-A. Consultant must submit a completed Payee Data Record (State Standard Form 204) before CIRM will issue payment. Each invoice shall include the Consultant's taxpayer identification number (Social Security or employer identification number). Invoices shall be submitted not more frequently than monthly in arrears to:

California Institute for Regenerative Medicine
Finance Officer
210 King Street
San Francisco, CA 94107

Payment will be made in accordance with, and within the time specified in, Government Code Chapter 4.5, commencing with Section 927.

IV. REPORTING

In performing consulting services under this Agreement, the Consultant shall be accountable to CIRM and shall provide progress reports to CIRM upon CIRM's request.

V. NOTIFICATION

Notices concerning this Agreement shall be addressed as follows:

CIRM: TO CONSULTANT:

California Institute for Regenerative Medicine
General Counsel
210 King Street
San Francisco, CA 94107

VI. TAXES

The compensation stated in Article III includes all applicable taxes and will not be changed hereafter as the result of Consultant's failure to include any applicable tax or as the result of any change in the Consultant's tax liabilities. The Consultant acknowledges that compensation payable hereunder may be subject to withholding of state and federal income tax, including state income tax subject to withholding pursuant to California Revenue and Taxation Code Sections 18661-18677.

VII. INDEPENDENT CONTRACTOR STATUS

A. Both parties agree that in the performance of this Agreement the Consultant shall not be an agent or employee of CIRM, shall not be covered by the State's Worker's Compensation Insurance or Unemployment Insurance, shall not be eligible to participate in State employee retirement programs, and shall not be entitled to any other CIRM employee benefits.

B. The Consultant shall be solely responsible for the conduct and control of the work to be performed by the Consultant under this Agreement, except that the Consultant is accountable to CIRM for the results of such work. The Consultant's services for CIRM shall be performed in accordance with currently approved methods and ethical standards applicable to the Consultant's professional capacity.

C. California State Contract Code 10515 (a) states: No person, firm, or subsidiary thereof who has been awarded a consulting services contract may submit a bid for, nor be awarded a contract on or after July 1, 2003, for the provision of services, procurement of goods or supplies, or any other related action that is required, suggested, or otherwise deemed appropriate in the end product of the consulting services contract.

VIII. ASSIGNMENT OR SUBCONTRACTING

The Consultant may not assign or transfer this Agreement, or any interest or claim, or subcontract any portion of the work, without the prior written approval of CIRM. The withholding or granting of such approval is totally discretionary with CIRM. If CIRM consents to such assignment or transfer, the terms and conditions of this Agreement shall be binding upon any assignee or transferee.

IX. PROPERTY RIGHTS, INCLUDING PATENTS AND COPYRIGHTS

All written and other tangible material ("Material") produced pursuant to this Agreement by the Consultant shall be considered a work-made-for-hire under the Copyright Act. To the extent said Material does not qualify as a work-made-for-hire, Consultant hereby assigns all right, title, and interest, including, but not limited to, copyright and all copyright rights in the Material to CIRM and shall execute any and all documents necessary to effectuate such assignment. In the event Consultant uses any individual who is not a full-time employee of Consultant or uses any other entity to perform any of the work required by Consultant hereunder, Consultant shall require said individual or entity to sign an agreement before commencing work that contains identical wording to the foregoing two sentences except that the word "Consultant" shall be replaced with the individual's or entity's name.

X. CONSULTANT'S LIABILITY AND INSURANCE REQUIREMENTS

A. The Consultant agrees to defend and, at CIRM's election, indemnify and hold harmless CIRM, its officers, agents, and employees from and against any and all claims, losses, expenses (including costs and reasonable attorney's fees), claims for injury, or damages that are caused by or result from the negligent or intentional acts or omissions or breach of this Agreement by the Consultant or its officers, employees, or agents. In addition, Consultant agrees to defend and, at CIRM's election, indemnify, and hold harmless CIRM, its officers, agents, and employees from and against any and all claims, losses, expenses (including costs and reasonable attorney's fees), claims for injury, or damages accruing or resulting to any and all contractors, subcontractors, suppliers, or any other person, firm or corporation furnishing services or supplying goods in connection with Consultant's performance of this Agreement

B. The Consultant shall furnish a Certificate of Insurance or statement of self-insurance (contractual liability included) showing minimum coverage as follows:

1. General Liability: Comprehensive or Commercial Form (Minimum Limits)

(i)	General Aggregate (BI, PD)*	$2,000,000
(ii)	Products, Completed Operations Aggregate	$2,000,000
(iii)	Personal and Advertising Injury	$1,000,000
(iv)	Each Occurrence	$1,000,000

* (not applicable to comprehensive form)

However, if such insurance is written on a claims-made form following termination of this Agreement, coverage shall survive for a period no less than three years. Coverage must include a Primary and Non-Contributory provision and a Severability of Interest provision. Coverage shall also provide for a retroactive date of placement coinciding with the effective date of this Agreement.

2. Business Auto Liability: (Minimum Limits) for Owned, Scheduled, Non-Owned, or Hired Automobiles with a combined single limit of no less than $1,000,000 per occurrence. [Alternative: Business Auto Liability is waived because Consultant will not drive in the course of performing services for CIRM.]

3. Workers' Compensation: as required under California State Law.

4. Professional Liability Insurance: (Minimum Limits)

(1) Each occurrence	$2,000,000
(2) Project Aggregate	$2,000,000

If this insurance is written on a claims-made form, it shall continue for three years following termination of this Agreement. The insurance shall have a retroactive date of placement prior to or coinciding with the effective date of this Agreement. The insurance must include Contractual Liability Coverage and Defense and Indemnification of CIRM by the contracting party.

5. Other insurance in amounts as from time to time may reasonably be required by the mutual consent of CIRM and the Consultant against such other insurable hazards relating to performance.

6. Certificate(s) of Insurance shall name CIRM as an additional insured under 1, 2 and 4 above, obligate the insurer to notify CIRM at least thirty (30) days prior to cancellation of or changes in any of the required insurance and include a provision that the coverage will be primary and will not participate with nor be excess to any valid and collectible insurance program of self-insurance carried or maintained by CIRM. Premiums on all insurance policies shall be paid directly by the Consultant.

XI. RECORDS ABOUT INDIVIDUALS

A. The Consultant acknowledges that the creation and maintenance of records pertaining to individuals is subject to certain requirements set forth by the California Information Practices Act (Civil Code 1798, et seq.) and by CIRM policy. Such requirements include provisions governing the collection, maintenance, accuracy, dissemination, and

disclosure of information about individuals, including the right of access by the subject individuals.

B. If the Consultant creates confidential or personal records about an individual, as defined by the Information Practices Act, including notes or tape recordings, the information shall be collected to the greatest extent practicable directly from the individual who is the subject of the information. When collecting the information, the Consultant shall inform the individual that the record is being made and of the purpose of the record.

C. Records containing confidential or personal information about individuals are the property of CIRM and subject to CIRM's policies and applicable federal and state laws. The Consultant agrees to deliver all such records, including originals and all copies and summaries, to CIRM upon termination of this Agreement.

D. The Consultant shall not use recording devices in discussions with CIRM's employees without notifying all parties to the discussion that the discussion is being recorded.

XII. EXAMINATION OF RECORDS

The Consultant agrees that CIRM and its authorized agents shall have the right to review and copy any records and supporting documentation pertaining to the performance of this Agreement including, but not limited to, all documents, records and work papers whether obtained or copied from CIRM or developed by the Consultant. Consultant agrees to maintain such records for a minimum of five (5) years after final payment, unless a longer period of records retention is stipulated. Consultant agrees to allow CIRM and its authorized agent's access to such records during normal business hours. Further, Consultant agrees to include a similar right of access in any subcontract related to the performance of this Agreement.

In accordance with state law, the Consultant agrees that CIRM, its authorized agents, the State Controller's Office, and the Bureau of State Audits (collectively, the "Auditors") shall have the right, in connection with an audit, to review and copy any records and supporting documentation pertaining to the performance of this Agreement including, but not limited to, all documents, records and work papers whether obtained or copied from CIRM or developed by the Consultant. Consultant agrees to maintain such records for possible audit for a minimum of five (5) years after final payment, unless a longer period of records retention is stipulated. Consultant agrees to allow the Auditors access to such records during normal business hours and to allow interviews of any employees who might reasonably have information related to such records. Further, Consultant agrees to include a similar right of the Auditors to audit records and interview staff in any subcontract related to the performance of this Agreement.

XIII. CONFLICT OF INTEREST

A. The Consultant will not hire any officer or employee of CIRM to perform any service covered by this Agreement. If the work is to be performed in connection with a federal or state contract or grant, the Consultant will not hire any employee of the government agency concerned to perform any service covered by this Agreement.

B. The Consultant affirms that to the best of his/her knowledge there exists no actual or potential conflict between the Consultant's family, business or financial interest and the services provided under this Agreement, and in the event of change in either private interests or service under this Agreement, any question regarding possible conflict of interest which may arise as a result of such change will be raised with CIRM.

C. The Consultant shall not be in a reporting relationship to a CIRM employee who is a near relative, nor shall the near relative be in a decision-making position with respect to the Consultant.

D. The Consultant may be required to execute a Form 700 Statement of Economic Interests as published by the Fair Political Practices Commission. Statements of Economic Interests are public documents. More information about Form 700 is available at www.fppc.ca.gov.

XIV. AFFIRMATIVE ACTION

The Consultant recognizes that as a state government contractor or subcontractor, the Consultant is obligated to comply with all state laws and regulations regarding equal opportunity and affirmative action in government contracts. When applicable, the Consultant agrees that all such laws and their implementing regulations are incorporated herein as though set forth in full. These laws include the nondiscrimination requirements of Government Code sections 12990 and 11135, and the nondiscrimination program and clause required by Title 2, Division 4, Chapter 5 of the California Code of Regulations.

XV. CONFIDENTIALITY

The Consultant shall keep confidential any and all information provided by CIRM, and/or by a CIRM grantee, including by any of their agents or representatives, and any information conveyed orally to the Consultant by CIRM and/or by a CIRM grantee, including any of their agents or representatives, with oral notification of its confidentiality (the "Confidential Information"). The Consultant agrees to maintain the secrecy of CIRM's Confidential Information and agrees not to use it except in performing the Services under this Agreement and not to disclose it to anyone outside CIRM or anyone within CIRM's organization who does not have a need to know it to perform under this Agreement. This non-disclosure provision shall not apply to any of the following:

1. Information which the Consultant can demonstrate by written records was known to him or her prior to the effective date of this Agreement;
2. Is currently in, or in the future enters, the public domain other than through a breach of this Agreement or through other acts or omissions of Advisor; or
3. Is obtained lawfully from a third party.

XVI. APPLICABLE LAW

The laws of the State of California shall govern this Agreement.

XVII. TERMS TO BE EXCLUSIVE

This Agreement constitutes the entire understanding between the parties regarding the subject matter hereof and supersedes any prior understanding between the parties, oral or written, regarding the same subject matter.

XVIII. WAIVER OR MODIFICATION OF TERMS

No waiver, amendment or other modifications of the terms of this Agreement shall be binding upon either party unless expressed in writing and signed by both parties hereto.

XIX. STANDARD FOR PERFORMANCE

The parties acknowledge that CIRM, in selecting the Consultant to perform the services hereunder, is relying upon the Consultant's reputation for excellence in the performance of the services required

hereunder. The Consultant shall perform the services in the manner of one who is a recognized specialist in the types of services to be performed. All deadlines set forth in the Agreement are binding and may be modified only by subsequent written agreement of the parties. The Consultant shall devote such time to performance of its, her, or his duties under this Agreement as is reasonably necessary for the satisfactory performance of such duties within the deadlines set forth herein. Nothing in the foregoing shall be construed to alter the requirement that time is of the essence in this Agreement.

XX. EXCLUSION.

Independent Consultant warrants that it is not excluded from participation in any governmental sponsored program, including, without limitation, the Medicare, Medicaid, or Champus programs (http://exclusions.oig.hhs.gov/search.aspx) and the Federal Procurement and Nonprocurement Programs (http://www.epls.gov/epls/search.do). This Agreement shall be subject to immediate termination in the event that the Independent Consultant is excluded from participation in any federal healthcare or procurement program.

XXI RESOLUTION OF DISPUTES

If the Consultant disputes any action by CIRM arising under or out of the performance of this contract, the Consultant shall notify CIRM of the dispute in writing and request a claims decision. CIRM shall issue a decision within 30 days of the Consultant's notice. If the Consultant disagrees with CIRM's claims decision, the Consultant shall submit a formal claim to the President of CIRM. The decision by the President of CIRM shall be final and conclusive on the claim unless the decision is arbitrary, capricious or grossly erroneous or if any determination of fact is unsupported by substantial evidence. The decision may encompass facts, interpretation of the contract and determinations or applications of law. The decision shall be in writing following an opportunity for the Consultant to present oral or documentary evidence and arguments in support of the claim. Consultant shall continue with the responsibilities under this Agreement during any dispute.

XXI SURVIVAL.

The following sections survive the expiration or early termination of this Agreement: IX, X, XI, XII, XV, XVI, XXI.

INDEPENDENT CONSULTANT	THE CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE
_____	_____
Signature Date	Date
Name _____	Name _____
Title _____	Title _____
Company _____	

Item 6445-502-6047001/H&S Code 125291.20/Statutes 2004/ FY 11/12
Account/Fund to be charged