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*

CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE

REQUEST FOR PROPOSALS

May 7, 2014

CIRM Human Pluripotent Stem Cell (hPSC) Initiative
Program Evaluation

CIRM RFP # 2491

The California Institute for Regenerative Medicine (CIRM) seeks an outstanding Consultant to perform a qualitative and quantitative program evaluation for the CIRM Human Pluripotent Stem Cell Initiative. 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:

Geoff Lomax
Senior Officer for Medical and Ethical Standards
(415) 396-9134
glomax@cirm.ca.gov

Deadline for Response: All required documents (including CD and hard copy with original signature) must be received at CIRM no later than 5:00 pm Pacific Time on **June 1, 2014**.

CIRM Human Pluripotent Stem Cell (hPSC) Initiative Program Evaluation
Request for Proposals- CIRM 2491

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.

The mission of CIRM is to support and advance stem cell research and regenerative medicine under the highest ethical and medical standards for the discovery and development of cures, therapies, diagnostics and research technologies to relieve human suffering from chronic disease and injury. To date, CIRM's governing board has approved 625 research, training and facility grants totaling more than $1.8 billion, making CIRM the largest source of funding for human embryonic stem cell research in the world. Estimates suggest that these grants will generate tens of thousands of job-years of employment in the state and hundreds of millions of dollars in tax revenues. For more information please see www.cirm.ca.gov.

1.2. Goals for this Contract

CIRM is issuing this RFP to contract for the preparation of a report that: (i) provides in-depth analysis of donors' current understanding with respect to the informed consent process; and (ii) recommendations for education materials that may improve program performance over time. CIRM anticipates entering into a twelve-month contract starting on or about June 30, 2014. The deliverables include both a report and presentation to CIRM's President and Chairman, senior executives, and possibly its governing board.

2. Scope of Services Required

CIRM seeks to contract with a qualified research team to assist the agency in evaluating RFA 12-02: CIRM Tissue Collection for Disease Modeling Awards against our stated mission of ensuring the highest ethical and medical standards. More information about RFA 12-02 is available at http://www.cirm.ca.gov/our-funding/research-rfas/tissue-collection-disease-modeling.

RFA 12-02 is a unique program because it involves the creation of 9,000 iPS cell lines, from 3,000 individuals. Over the course of the program, CIRM anticipates up to 5,000 individuals may be asked to participate. CIRM has invested considerable resource in ensuring that the process for informing donors about the program and obtaining their cells and tissue serves to effectively educate donor participants about the research program.

To date CIRM has invested in developing a comprehensive model informed consent and an educational brochure, to support donor education and the informed consent process. Unique aspects of the Tissue Collection for Disease Modeling Awards that is critical for donors to understand include that researchers intend to:

- Test donors blood and skin samples for infectious disease
- Transform donor cells and make them into immortal iPSC lines
- Record the genetic sequence of donor their cells
- Distribute donor cells and associated medical and genetic information widely
- Use cells and associated information to develop commercial medical products with no financial compensation to donors.

In addition, minors and/or individuals with cognitive impairments will be recruited for this research and consent may be obtained from their legal guardian.

Given CIRMs substantial investment and the duration of tissue collection (approximately 2 years), CIRM would like to evaluate (1) whether donors or their representatives understand the essential aspects of the research and (2) whether there are issues with the existing consent process and/or education materials that could be modified to improve program performance over time.

The research should be performed at one or more of the tissue collection sites. Qualitative and or quantitative methods should be employed to provide an implementation evaluation intended to seek out discrepancies between the goal of fully informing donors and the reality of donor comprehension. The methods should have sufficient validity to support any recommendations to inform mid-course corrections to the informed consent protocol.

2.1 **Report**

The Consultant retained under this RFP will prepare a report that provides a detailed analysis of the informed consent process for the CIRM Human Pluripotent Stem Cell (hPSC) Initiative. CIRM expects that the Consultant has and will maintain appropriate expertise at its own expense. The Consultant shall ensure that the quality and availability of its staff assigned to this engagement will be maintained over the term of the agreement.

The Consultant will be expected to provide CIRM with the services described below.

2.2 **Interviews/ Independent Research As Required**

In the event that Consultant plans to interview a sample of the 5,000 individuals who may be asked to participate in the hPSC Initiative, the Consultant will need to create a viable work plan with the relevant principal investigators under CIRM RFA12-02 awards.

2.3 The report shall include recommendations relating to the informed consent process including donor education, educational brochures, training of principal investigators and their staff, etc. The report shall identify specifics relating to whether any changes are desirable to improve hPSC program performance over time and specific details on implementing those changes including estimated funding necessary to perform same.

2.4 CIRM anticipates that consultant will be required to provide two progress updates to CIRM leadership and staff in San Francisco to ensure the project is proceeding according to CIRM's expectations. There will also be periodic discussions and communications between the parties.

2.5 The Consultant shall review its draft findings and recommendations with CIRM prior to issuing a final report.

2.6 The Consultant shall make a presentation of the report and its findings to CIRM leadership. The Consultant may also be required to assist in presenting the report to CIRM's governing board.

3. Budget

The proposal should include cost detail and requirements (inclusive of administrative and/or overhead expenses, if any) and shall not exceed $150,000. Fees must be stated either: (1) on an hourly basis for the services with a stated maximum total fee; or (2) a flat total fee with break–outs for various tasks. If hourly, the proposal should include a break out of hourly fees for each of the professionals expected to provide services under the contract, as well as all anticipated reimbursable expenses. Selection criteria will include competitiveness of the proposed budget. In order to adequately evaluate budget, please include a breakdown of the survey methodology you intend to use and detail the specific steps to be included as well as the proposed timeline. CIRM reserves the right to negotiate the total fee for the services as part of the evaluation of the RFP responses.

3.1. Qualifications Required

To be considered a qualified research team the applicant must:

- Demonstrate experience in design, implementation and publication of studies employing the proposed or similar research methods.
- Have appropriate expertise available to conduct the research described.
- Have 10 years of experience with issues related to consent in Human Subjects research.
- Have 5 years of experience with comparative effectiveness research or performance evaluations in a basic or clinical research setting.
- Have access to an institutional review board (IRB) or any other oversight body required to satisfy regulatory requirements.

4. Submitting a Proposal

4.1. Documents to be submitted

Three sets of information shall be included with a submission. Part I (Consultant Information) and Part II (References) are included in this RFP as separate forms to be completed and returned with your proposal. The third set of information consists of the Proposal and Qualifications (see Section 4.2 below), and there are no special forms to be completed in this regard.

4.2. Proposal and Qualifications

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

A. Qualifications and Experience of Consulting Organization. Discuss how your organization's overall experience demonstrates your ability to successfully complete the Scope of Services Required. Provide a detailed list of similar research or services you have performed over the past five years (including, but not limited to, projects relating to informed consent in basic or clinical research). Highlight your organization's experience working on similar engagements; experience and knowledge relating to ethical issues in stem cell research. Discuss the organization's experience with program evaluation or comparative effectiveness methodologies.

B. Qualification of Staff/Resumes. Identify the staff that will be providing the services required by the proposal, including years and type of experience for each person. Experience should include number of years at current organization as well as all prior service.

C. Comparable Projects. Provide a brief list and description of comparable projects successfully concluded within the last five years. Provide samples of your work on these and similar projects. Please also provide the references required on Form II.

D. Proposal. Provide a detailed proposal identifying the activities and timelines that are proposed in response to this RFP, and describe the sources of information and expertise you will rely upon in preparing the report. Specifically address the quantitative and qualitative methodology and approach you intend to use as well as the project budget and timeline.

4.3. Submission Format

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

4.4. 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 # 2491
hPSC Initiative Program Evaluation
California Institute for Regenerative Medicine
210 King Street, 3rd Floor
San Francisco, CA 94107

4.4.1. Deadline

All submittals must be received at CIRM no later than 5:00 pm Pacific Time
June 1, 2014.

5. Selection

Proposals will undergo a comprehensive and impartial evaluation process conducted by a working group consisting of CIRM leadership and staff. The proposals that CIRM believes best meet the requirements for services sought under this RFP will be considered finalist candidates. The finalist candidates may be interviewed by CIRM and may have their references checked.

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 a Consultant organization that has 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.

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. Desired Experience and Ability. Evaluation of applicants will include review of the organization's overall experience, its experience and knowledge relating to informed consent in basic and clinical research, and its track record of developing and implementing program evaluations or comparative effectiveness studies. A factor under consideration will be whether the organization's experience demonstrates their ability to successfully complete the requirements herein.

B. Responsiveness to Project Requirements and Clients. Evaluation of prospective Consultants 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, especially studies that led to the continuation of services for projects that were completed. 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 stated budget.

E. Other relevant factors identified by CIRM. Sensitivity with regard to donors in various states of health and cognitive impairment is crucial to effectively performing these services. CIRM will evaluate the Consultant's ability to successfully work with the principal investigators of RFA 12-02: CIRM Tissue Collection for Disease Modeling Awards at one or more of their tissue collection sites. Having an Institutional Review Board available to Consultant is also a crucial factor for success. The oversight body that is identified by the Consultant will be part of the factors evaluated.

6. Key Action Dates

Date	Action
May 7, 2014	RFP available to prospective organizations
June 1, 2014 @ 5:00 pm	Final Date for Proposal Submission
June 20, 2014	Proposed Award Date (Note: The actual award date may be earlier or later.)
June 30, 2014	Contract execution and commencement of services

7. Contract Terms

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

CIRM expects the chosen Consultant 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, 2015 with a possible extension based on mutual agreement.

8. 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 and reserves the right (but has no obligation) to negotiate a different scope or budget with any of the applicants.

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. Proposals may not be withdrawn without cause subsequent to proposal submission deadline.

E. 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.

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

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

H. CIRM reserves the right to do the following at any time:
   i. Reject any or all proposal(s), without indicating any reason for the rejection;
   ii. Waive or correct any minor or inadvertent defect, irregularity or technical error in a proposal or the RFP process, or as part of any subsequent contract negotiation;
   iii. Request that bidders supplement or modify all or certain aspects of their proposals or other documents or materials submitted;

iv. Terminate the RFP and, at its option, issue a new RFP, or decline to reissue the RFP;
v. Extend a deadline specified in this RFP, including deadlines for accepting proposals;
vi. Negotiate with any or none of the bidders;
vii. Modify in the final agreement any terms and/or conditions described in this RFP;
viii. Terminate failed negotiations with a bidder without liability, and negotiate with other bidders;
ix. Disqualify any bidder on the basis of a real or apparent conflict of interest, evidence of collusion that is disclosed by the proposal or other data available to CIRM, or other state contracting requirements or prohibitions;
x. Eliminate, reject, or disqualify a proposal of any bidder who is not a responsible bidder or fails to submit a responsive offer as determined solely by CIRM;
xi. Accept all or a portion of a bidder's proposal; and Undertake any investigation, including, without limitation, contacting third parties, for assessing the background, experience, qualification, and expertise of any or all bidders.

9. California Public Records Act

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. If a bidder is awarded a contract as a result of this procurement, the contract will be a public document. (See Attachment A to this RFP for additional information.)

The Public Records Act allows CIRM to withhold documents, or parts of documents, that reveal trade secrets or other information that is confidential or proprietary, or that would invade personal privacy. Proposals should be submitted in a form that does not include such information. Any proprietary or other non-public information submitted in response to this RFP should be placed in a separate envelope labeled "Confidential," together with a brief explanation of the reason the information should be protected from disclosure. If a bidder does not provide an adequate explanation for withholding the information, CIRM may be required to make it publicly available in the event CIRM receives a request under the Public Records Act. CIRM has the right and obligation to make the final determination whether a document or portion of a document must be disclosed in response to a Public Records Act request. If CIRM withholds or discloses information, the bidder may be required to litigate any claim that the information is legally protected from disclosure.

10. 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

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