



**Shriners Hospitals**  
for Children®

**International Headquarters**  
Pediatric Specialty Care

May 30, 2019

Kewa Gao, Ph.D.  
Shriners Hospitals for Children – Northern California  
2425 Stockton Boulevard  
Sacramento, CA 95817

Marc Lalande, Ph.D.  
Vice President, Research Programs  
2900 Rocky Point Dr.  
Tampa, FL 33607-1435  
Direct: 813.518.7798  
[mlalande@shrinenet.org](mailto:mlalande@shrinenet.org)

Dear Dr. Gao,

The Shriners Hospitals for Children Medical Research Department is pleased to inform you of Shriners Hospitals for Children Fellowship funding as indicated below:

**84704 Kewa Gao, Ph.D.**

RF Development of stem cell treatments to improve vascularization for deep burn wounds
\$34,456.00
7/1/2019
12/31/2019
Year 1 (6 mos) of 2

Award totals include consortium fees, if any. Continuation of this project beyond 2019 requires annual request, together with reports demonstrating adequate progress. A Final Report is due at project end. Please reference *proposalCENTRAL's Budget Period Details* section for any modifications to your original submission. The 2019 project budget should be expended in accordance with the approved project budget no later than December 31, 2019.

This letter and its attachments outline the terms and conditions of grant acceptance. You should carefully read all the terms and conditions before signing the *Award Acceptance*. The *Award Acceptance*, along with any additional outlined requirements, must be uploaded to proposalCENTRAL by June 14, 2019.

An advanced written request must be sent to my attention if (a) there is a change in the objectives of the grant; (b) there is a change in the protocol or criteria for patient enrollment; or (c) there are changes in projected patient enrollment.

Congratulations on this recognition of your competitive research. We look forward to working with you during the coming year.

Sincerely,

Marc Lalande, Ph.D.

### **Award Acceptance**

- All research awards are subject to annual review and demonstration of adequate progress.
- Each investigator on this project must sign a Shriners Hospitals Intellectual Property (IP) Agreement and upload to *proposalCENTRAL*.
- Funding of this Fellowship is contingent upon compliance of the investigator(s) in all respects with the published policies and procedures, medical and scientific staff bylaws, and regulations of Shriners Hospitals for Children. Funding is also contingent on the completion of any *Special Contingencies* required or described herein.
- The approved project budget is as shown in *proposalCENTRAL*. Shriners Hospitals for Children reserves the right to correct budget clerical errors. PI requested budget modifications require HQ Medical Research pre-approval.
- Any computer purchased using research funds must be acquired through SHC supply chain and managed by SHC IS.
- Shriners Hospitals for Children reserves the right to cancel grant funding with 30-days' notice and will fulfill financial obligations incurred prior to the effective date of cancellation.
- Sites and/or the current Principal Investigator (PI) may not reassign the conduct of the study to a different PI without prior written authorization from the Vice President, Research Programs. PIs may delegate duties and tasks to sub-investigators or research staff only to the extent permitted by the hospital regulations and Federal Code of Regulations governing the conduct of investigators.
- If a new procedure, drug, diet, method, device or other invention is conceived which might merit patent protection, a "Record of Medical Invention" form must be completed as soon as possible, preferably upon concept of invention, and submitted to the Vice President, Research Programs. This form should be completed before any public disclosure of the invention is made.
- Shriners Hospitals for Children must be listed as a supporting institution when authoring scientific and clinical articles for research funded by and/or conducted within SHC facilities.

### **Additional Contingency for Animal Research**

- Funding of studies involving animals is contingent upon approval of the local Animal Care and Usage Committee. Documentation of IACUC approval must be uploaded to *proposalCENTRAL*.

### **Additional Contingencies for Clinical Research**

- Funding of studies involving human participants is contingent upon:
  - Protocol development
    - You are required to prepare and submit a new protocol (and informed consent, if applicable), which contains all the protocol elements required by Code of Federal Regulations and Good Clinical Practice guidelines.
      - Protocol elements found in multiple different documents (e.g. abstracts, other IRB applications, grant applications) are not acceptable as protocol.
    - Protocol templates are available on the SHC Medical Research intranet site and meet the ICH GCP and CFR requirements.
      - The expectation is that your protocol will follow the SHC protocol templates.
  - Protocol approval
    - SHC approval of the protocol and informed consent form as defined in the hospital regulations.
      - The SHC Hospital Regulations require that all research projects utilizing human subjects be consistent with the mission of Shriners Hospital for Children and be

undertaken only after review by the Vice President, Research Programs and the Chief Medical Officer and subsequent approval by an IRB. **The awarding of this grant does not imply approval of the research protocol.**

- The title of the protocol **MUST BE IDENTICAL** to that of the Shrine grant.
- Western Institutional Review Board (WIRB) approval of the protocol and informed consent form.
  - The use of another IRB will only be permitted when required by provincial law to use a local IRB.
- Approvals must occur within **90 days** of the grant start date.
  - Any exception to the 90-day approval requirement must be granted by the Vice President, Research Programs
- Participant accrual
  - The expectation is that this project will be completed as outlined in the grant application.
    - Accrual will be assessed, via OnCore, at the time of continuing reviews.
    - If at the first annual review there are minimal to no accruals reported in OnCore, HQ approval may be withdrawn and the study closed.
    - Minimal accrual will be defined as 10% of the accrual goal stated in the protocol.
    - At the subsequent continuing reviews, the accrual numbers will be again reviewed.
    - If accrual is affecting the ability to complete the study in a reasonable time, without justification provided to HQ, approval will be withdrawn and the IRB notified that the study must be closed.
  - Should you encounter difficulty in meeting any of the conditions, please contact the Medical Research Department as soon as possible to ensure communication about the confounding issues, resolution and to minimize/prevent punitive actions.
- Data safeguards
  - TBD Clinical Coordinator/Data Coordinator must be an SHC employee.
  - Practices of data collection, management, storage, and transmission must be in compliance with SHC policies, procedures, standards, guidelines, and directives.
  - The PI is responsible for ensuring that all members of the research team take the required SHC Management of Research Data training on an annual basis.
  - Data collection, management and storage through the SHC clinical research management system, OnCore.
- Compliance with the stipulations of the protocol, the principles outlined in applicable Federal Regulations, Good Clinical Practice Guidelines, and SHC policies.
  - This would also include any requests from HQ for information such as enrollment numbers, budget inquiries, adverse event report, DSMB review, and changes to protocols.
- Multi-site studies
  - The expectation is that multi-site studies will be run under the leadership of the study's Principal Investigator (PI). The PI's site will be considered the "lead site".
    - The study PI, along with the lead site, is responsible for controlling and standardizing the protocol and research process. This includes the development of one protocol, which contains a precise study plan for executing the clinical trial that all investigators at multiple sites will perform in exactly the same way.
    - Participating sites may not make changes to the protocol. There should not be multiple versions of the same study.
    - It will be the responsibility of the PI and/or lead site to enter data into OnCore for non-SHC sites that do not have access to the database.

I have read and agree to the terms and conditions stipulated above and do hereby accept this award.

Kewa Gao

06/12/2019

Signature of Principal Investigator

Date



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**International Headquarters**  
Pediatric Specialty Care

January 22, 2019

Marc Lalande, Ph.D.  
Vice President, Research Programs  
2900 Rocky Point Dr.  
Tampa, FL 33607-1435  
Direct: 813.518.7798  
[mlalande@shrinenet.org](mailto:mlalande@shrinenet.org)

Aijun Wang, Ph.D.  
Shriners Hospitals for Children – Northern California  
2425 Stockton Blvd.  
Sacramento, CA, 95817

Re: Project #85108 / Stem Cell-Based Treatment of Spina Bifida in  
a Naturally Occurring Disease Model

Dear Dr. Wang,

The Shriners Hospitals for Children Medical Research Department is pleased to inform you the  
above-referenced SHC grant was awarded funding as indicated:

**85108 Aijun Wang Ph.D.**

BR	Stem Cell-based Treatment of Spina Bifida in a Naturally Occurring Disease Model		
\$249,291.00	1/1/2019	12/31/2019	Year 1 of 4

Award totals include consortium fees, if any. Continuation of this project beyond 2019 requires annual request, together with reports demonstrating adequate progress. Please reference *proposalCENTRAL's Budget Period Details* section for any modifications to your original submission. The 2019 project budget should be expended in accordance with the approved project budget no later than December 31, 2019.

This letter and its attachments outline the terms and conditions of grant acceptance. You should carefully read all the terms and conditions before signing the *Award Acceptance*. The *Award Acceptance*, along with any additional outlined requirements, must be uploaded to *proposalCENTRAL* by February 14, 2019.

An advanced written request must be sent to my attention if (a) there is a change in the objectives of the grant; (b) there is a change in the protocol or criteria for patient enrollment; or (c) there are changes in projected patient enrollment.

Congratulations on this recognition of your competitive research. We look forward to working with you during the coming year.

Sincerely,

A handwritten signature in black ink, appearing to read 'Marc Lalande'.

Marc Lalande, Ph.D.

### **Award Acceptance**

- All research awards are subject to annual review and demonstration of adequate progress.
- Each investigator on this project must sign a Shriners Hospitals Intellectual Property (IP) Agreement and have the document countersigned by the local Board Chairman or Administrator as a representative of Shriners Hospital. Completed investigator(s) IP Agreements must be uploaded to *proposalCENTRAL* no later than February 14.
- Funding of any research project, shared facility or fellowship is contingent upon compliance of the investigator(s) in all respects with the published policies and procedures, medical and scientific staff bylaws, and regulations of Shriners Hospitals for Children. Funding is also contingent on the completion of any *Special Contingencies* required or described herein.
- The approved project budget is as shown in *proposalCENTRAL*. Shriners Hospitals for Children reserves the right to correct budget clerical errors. PI requested budget modifications require HQ Medical Research pre-approval.
- Any computer purchased using research funds must be acquired through SHC supply chain and managed by SHC IS.
- Shriners Hospitals for Children reserves the right to cancel grant funding with 30-days' notice and will fulfill financial obligations incurred prior to the effective date of cancellation.
- Sites and/or the current Principal Investigator (PI) may not reassign the conduct of the study to a different PI without prior written authorization from the Vice President, Research Programs. PIs may delegate duties and tasks to sub-investigators or research staff only to the extent permitted by the hospital regulations and Federal Code of Regulations governing the conduct of investigators.
- If a new procedure, drug, diet, method, device or other invention is conceived which might merit patent protection, a "Record of Medical Invention" form must be completed as soon as possible, preferably upon concept of invention, and submitted to the Vice President, Research Programs. This form should be completed before any public disclosure of the invention is made.
- All investigators must list Shriners Hospitals for Children as a supporting institution when authoring scientific and clinical articles for research funded by and/or conducted within SHC facilities.

### **Additional Contingency for Animal Research**

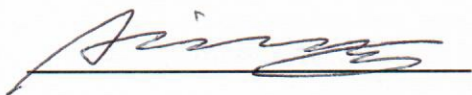
- Funding of studies involving animals is contingent upon approval of the local Animal Care and Usage Committee. Documentation of IACUC approval must be uploaded to *proposalCENTRAL* no later than February 14.

### **Additional Contingencies for Clinical Research**

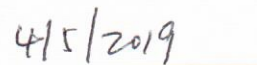
- Funding of studies involving human participants is contingent upon:
  - Protocol development
    - You are required to prepare and submit a new protocol (and informed consent, if applicable), which contains all the protocol elements required by Code of Federal Regulations and Good Clinical Practice guidelines.
      - Protocol elements found in multiple different documents (e.g. abstracts, other IRB applications, grant applications) are not acceptable as protocol.
    - Protocol templates are available on the SHC Medical Research intranet site and meet the ICH GCP and CFR requirements.
      - The expectation is that your protocol will follow the SHC protocol templates.
  - Protocol approval

- SHC approval of the protocol and informed consent form as defined in the hospital regulations.
  - The SHC Hospital Regulations require that all research projects utilizing human subjects be consistent with the mission of Shriners Hospital for Children and be undertaken only after review by the Vice President, Research Programs and the Chief Medical Officer and subsequent approval by an IRB. **The awarding of this grant does not imply approval of the research protocol.**
  - The title of the protocol **MUST BE IDENTICAL** to that of the Shrine grant.
- Western Institutional Review Board (WIRB) approval of the protocol and informed consent form.
  - The use of another IRB will only be permitted when required by provincial law to use a local IRB.
- Approvals must occur within **90 days** of the grant start date.
  - Any exception to the 90-day approval requirement must be granted by the Vice President, Research Programs
- Participant accrual
  - The expectation is that this project will be completed as outlined in the grant application.
    - Accrual will be assessed, via OnCore, at the time of continuing reviews.
    - If at the first annual review there are minimal to no accruals reported in OnCore, HQ approval may be withdrawn and the study closed.
    - Minimal accrual will be defined as 10% of the accrual goal stated in the protocol.
    - At the subsequent continuing reviews, the accrual numbers will be again reviewed.
    - If accrual is affecting the ability to complete the study in a reasonable time, without justification provided to HQ, approval will be withdrawn and the IRB notified that the study must be closed.
  - Should you encounter difficulty in meeting any of the conditions, please contact the Medical Research Department as soon as possible to ensure communication about the confounding issues, resolution and to minimize/prevent punitive actions.
- Data safeguards
  - Practices of data collection, management, storage, and transmission must be in compliance with SHC policies, procedures, standards, guidelines, and directives.
  - The PI is responsible for ensuring that all members of the research team take the required SHC Management of Research Data training on an annual basis.
  - Data collection, management and storage through the SHC clinical research management system, OnCore.
- Compliance with the stipulations of the protocol, the principles outlined in applicable Federal Regulations, Good Clinical Practice Guidelines, and SHC policies.
  - This would also include any requests from HQ for information such as enrollment numbers, budget inquiries, adverse event report, DSMB review, and changes to protocols.
- Multi-site studies
  - The expectation is that multi-site studies will be run under the leadership of the study's Principal Investigator (PI). The PI's site will be considered the "lead site".
    - The study PI, along with the lead site, is responsible for controlling and standardizing the protocol and research process. This includes the development of one protocol, which contains a precise study plan for executing the clinical trial that all investigators at multiple sites will perform in exactly the same way.
    - Participating sites may not make changes to the protocol. There should not be multiple versions of the same study.
    - It will be the responsibility of the PI and/or lead site to enter data into OnCore for non-SHC sites that do not have access to the database.

I have read and agree to the terms and conditions stipulated above and do hereby accept this award.

A handwritten signature in black ink, appearing to be "A. J. ...", written over a horizontal line.

Signature of Principal Investigator

The date "4/5/2019" handwritten in black ink, positioned above a horizontal line.

Date



Grantee	Wang, Aijun	Award ID	85119-NCA-18
Institution	Shriners Hospitals for Children - Northern California	Program	Developmental Grants (SHC Scientific/Medical Staff Only)
Award Amount	\$119,197.00 [\$109,882.00] ⓘ	Project Title	Placental Mesenchymal Stromal Cell-derived Cell-Free Therapy for Multiple Sclerosis
Award Start - Award End	1/1/2018 - 12/31/2019		84%
Paid	\$0.00		0%
Spent	\$0.00		0%

Award Information

Grant Maker	Shriners Hospitals for Children
Cycle	FY2017
Proposal Status	Awarded
Award Status	Active
Total Awarded	\$109,882.00
Total Expenditures	\$0.00



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Pediatric Specialty Care

January 22, 2019

Marc Lalande, Ph.D.  
Vice President, Research Programs  
2900 Rocky Point Dr.  
Tampa, FL 33607-1435  
Direct: 813.518.7798  
[mlalande@shrinenet.org](mailto:mlalande@shrinenet.org)

Diana Farmer, M.D.  
Shriners Hospitals for Children – Northern California  
2425 Stockton Blvd.  
Sacramento, CA, 95817

Re: Project #85120 / Early Gestation Placental Mesenchymal  
Stromal Cells for the Treatment of Spina Bifida

Dear Dr. Farmer,

The Shriners Hospitals for Children Medical Research Department is pleased to inform you the above-referenced SHC grant was awarded funding as indicated:

**85120 Diana Farmer MD, FACS, FRCS**

BR Early Gestation Placental Mesenchymal Stromal Cells for the Treatment of Spina Bifida

\$217,379.00

1/1/2019

12/31/2019

Year 4 of 4

Award totals include consortium fees, if any. Continuation of this project beyond 2019 requires annual request, together with reports demonstrating adequate progress. Please reference *proposalCENTRAL's Budget Period Details section* for any modifications to your original submission. The 2019 project budget should be expended in accordance with the approved project budget no later than December 31, 2019.

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Sincerely,

Marc Lalande, Ph.D.

### **Award Acceptance**

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- Each investigator on this project must sign a Shriners Hospitals Intellectual Property (IP) Agreement and have the document countersigned by the local Board Chairman or Administrator as a representative of Shriners Hospital. Completed investigator(s) IP Agreements must be uploaded to *proposalCENTRAL* no later than February 14.
- Funding of any research project, shared facility or fellowship is contingent upon compliance of the investigator(s) in all respects with the published policies and procedures, medical and scientific staff bylaws, and regulations of Shriners Hospitals for Children. Funding is also contingent on the completion of any *Special Contingencies* required or described herein.
- The approved project budget is as shown in *proposalCENTRAL*. Shriners Hospitals for Children reserves the right to correct budget clerical errors. PI requested budget modifications require HQ Medical Research pre-approval.
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  - Protocol development
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- SHC approval of the protocol and informed consent form as defined in the hospital regulations.
  - The SHC Hospital Regulations require that all research projects utilizing human subjects be consistent with the mission of Shriners Hospital for Children and be undertaken only after review by the Vice President, Research Programs and the Chief Medical Officer and subsequent approval by an IRB. **The awarding of this grant does not imply approval of the research protocol.**
  - The title of the protocol **MUST BE IDENTICAL** to that of the Shrine grant.
- Western Institutional Review Board (WIRB) approval of the protocol and informed consent form.
  - The use of another IRB will only be permitted when required by provincial law to use a local IRB.
- Approvals must occur within **90 days** of the grant start date.
  - Any exception to the 90-day approval requirement must be granted by the Vice President, Research Programs
- Participant accrual
  - The expectation is that this project will be completed as outlined in the grant application.
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  - The PI is responsible for ensuring that all members of the research team take the required SHC Management of Research Data training on an annual basis.
  - Data collection, management and storage through the SHC clinical research management system, OnCore.
- Compliance with the stipulations of the protocol, the principles outlined in applicable Federal Regulations, Good Clinical Practice Guidelines, and SHC policies.
  - This would also include any requests from HQ for information such as enrollment numbers, budget inquiries, adverse event report, DSMB review, and changes to protocols.
- Multi-site studies
  - The expectation is that multi-site studies will be run under the leadership of the study's Principal Investigator (PI). The PI's site will be considered the "lead site".
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    - Participating sites may not make changes to the protocol. There should not be multiple versions of the same study.
    - It will be the responsibility of the PI and/or lead site to enter data into OnCore for non-SHC sites that do not have access to the database.

I have read and agree to the terms and conditions stipulated above and do hereby accept this award.



Signature of Principal Investigator

1/23/19

Date

Grantee	Wang, Aijun	Award ID	87200-NCA-19
Institution	Shriners Hospitals for Children - Northern California	Program	Developmental Grants (SHC Scientific/Medical Staff Only)
Award Amount	\$119,885.00	Project Title	Development of regenerative treatments to improve healing of burn wounds
Award Start - Award End	1/1/2019 - 12/31/2020	33%	
Paid	\$0.00	0%	
Spent	\$0.00	0%	

Award Information

Grant Maker	Shriners Hospitals for Children
Cycle	FY2018
Proposal Status	Awarded
Award Status	Active
Total Awarded	\$119,885.00
Total Expenditures	\$0.00

**NOTICE OF AWARD – CLIN 1: Partnering Opportunity for Late Stage Preclinical Projects  
California Institute for Regenerative Medicine****Issue Date:** 12/6/2018

Award Number: **CLIN1-11404** Project Period Start: **01/01/2019**  
Awardee Name: **University of California, Davis** Project Period End (estimated): **12/31/2020**  
Principal Investigator: **Diana L. Farmer** Total Award Amount: **\$5,666,077**  
Project Title: **Placental Mesenchymal Stem Cell Augmentation of Fetal Myelomeningocele Repair**

Authorized Organizational Official and Address: Official and Address to Receive Electronic Fund  
Transfer Remittance Advice:  
**Alexis R Chacon-Munoz**  
**Contracts and Grants Analyst**  
**1850 Research Park Drive**  
**Davis, CA 95618**  
**University of California Davis**  
**PO Box 989062 Cashier's Office**  
**West Sacramento, CA 95798-9062**

Electronic Remittance Advice will be sent to:  
**cashier@ucdavis.edu**

The California Institute for Regenerative Medicine (CIRM) hereby awards the amount of **\$5,666,077** to **University of California, Davis** in support of the above referenced project. This award is made pursuant to the [California Stem Cell Research and Cures Act](#) (Health and Safety Code section 125290.10 *et. seq.*) and is subject to terms and conditions referenced below. (Capitalized terms are defined in the [CIRM Grants Administration Policy for Clinical Stage Projects](#) (GAP).

In accepting this Award, the Awardee warrants to CIRM that any funds expended under the Award will be for the purposes set forth in the approved Application and agrees to comply with all applicable CIRM regulations and standards.

**To accept this Award, the Principal Investigator and Authorized Organizational Official must sign and return this Notice of Award (NOA) to CIRM within 30 days of the issuance of the NOA. Payment will be issued only after the fully signed NOA is received by CIRM.** Award payments will be sent to the organization's address listed above under *Official and Address to Receive Payments* via Electronic Funds Transfer (EFT) if EFT details were provided to CIRM via the Grants Management System. If the Applicant cannot accept the award, including the legal obligation to perform in accordance with the provisions of this NOA, it should notify CIRM immediately.

If you have any questions about this award, please contact the CIRM staff referenced on page 3.



Abba A. Creasey, Ph.D.  
Vice President, Therapeutics & Strategic Infrastructure  
California Institute for Regenerative Medicine

**AWARD ACCEPTANCE:** The Principal Investigator and Authorized Organizational Official or delegate must sign below and return the entire NOA to CIRM to accept the Award.

	Principal Investigator	Authorized Organizational Official
<b>Name</b>	Diana L. Farmer, M.D.	Ahmad Hakim-Elahi
<b>Signature</b>	<i>Diana L Farmer</i>	<i>Ahmad Hakim-Elahi</i>
<b>Date</b>	12/12/2018	12/12/2018

**TERMS AND CONDITIONS:**

- A.** This award is based on the application submitted to CIRM, and as approved by the Application Review Subcommittee of the Independent Citizens' Oversight Committee (ICOC) on 11/15/2018 on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:
1. The [California Stem Cell Research and Cures Act](#) (Health and Safety Code Section 125290.10 *et. seq.*) and regulations adopted by the ICOC.
  2. The [CIRM Grants Administration Policy for Clinical Stage Projects](#) (Title 17, California Code of Regulations, Section 100503), *CIRM Intellectual Property and Revenue Sharing Requirements for Non-Profit and For-Profit Grantees (Title 17, California Code of Regulations. Section 100650)*, the *CIRM Medical and Ethical Standards Regulations* (Title 17, California Code of Regulations, Sections 100010-1000120), and any subsequently adopted or amended applicable [regulations](#).
  3. The terms and requirements detailed in CLIN 1: Partnering Opportunity for Late Stage Preclinical Projects Program Announcement. ([Effective April 2017](#))
  4. The Operational Milestones (OM) and Suspension Events set forth in Appendix A to this NOA.
  5. Budget and payment detail set out below in "Award Detail."
- B. Noncompliance:** If CIRM determines, in its sole discretion, that Awardee has not complied with the terms and conditions of this award, CIRM may suspend or permanently cease Disbursements, or pursue other remedies as allowed by law as indicated in section V.Q. *Failure of Compliance and Award Termination*, of the GAP.
- C.** The timing of the distribution of funds pursuant to this grant shall be contingent upon the availability of funds in the California Stem Cell Research and Cures Fund in the State Treasury, as determined by CIRM in its sole discretion.

Please check the following website for updated policy documents: <http://www.cirm.ca.gov/cirm-operations/Regulations>

**AWARD DETAIL (U.S. Dollars):**

	<b>Budget</b>
<b>Total CIRM-Funded Direct Project Costs</b>	<b>\$3,858,288</b>
Awardee Facilities Rates Category A	16.80%
Awardee Facilities Rates Category B	14.20%
CIRM Facilities Costs	\$979,746
Awardee Indirect Cost Rate	20.00%
CIRM Indirect Costs	\$828,043
<b>TOTAL CIRM BUDGET</b>	<b>\$5,666,077</b>

**DISBURSEMENT SCHEDULE:**

<b>Payment #</b>	<b>Schedule Date</b>	<b>Disbursement Amount*</b>
1	Upon fully executed agreement	\$1,714,000
2	Upon achievement of OM #1	\$1,296,000
3	Upon achievement of OM #2	\$1,412,000
4	Upon achievement of OM #3	\$334,000
5	Upon achievement of OM #4	\$860,077
6	Upon achievement of OM #5	\$50,000

\*Any interest accrued by the Awardee from the Award payments must be used for the Partnering Opportunity for Late Stage Preclinical Projects.



**PROGRESS & FINANCIAL REPORTS SCHEDULE:**

<b>Report Type</b>	<b>Notes</b>	<b>Due Date</b>
Quarterly Progress Report	Year 1 Q1	04/01/2019
Quarterly Financial Report	Year 1 Q1	04/16/2019
Operational Milestone Progress Report	Operational Milestone #1	05/31/2019 (estimated)
Operational Milestone Financial Report	Operational Milestone #1	Due 60 days after achievement of each Operational Milestone
Quarterly Progress Report	Year 1 Q2	07/01/2019
Quarterly Financial Report	Year 1 Q2	07/16/2019
Operational Milestone Progress Report	Operational Milestone #2	09/30/2019 (estimated)
Operational Milestone Financial Report	Operational Milestone #2	Due 60 days after achievement of each Operational Milestone
Quarterly Progress Report	Year 1 Q3	10/01/2019
Quarterly Financial Report	Year 1 Q3	10/16/2019
Full Progress Report	Year 1	01/01/2020
Quarterly Financial Report	Year 1 Q4	01/16/2020
Quarterly Progress Report	Year 2 Q1	04/01/2020
Quarterly Financial Report	Year 2 Q1	04/16/2020
Operational Milestone Progress Report	Operational Milestone #3	04/30/2020 (estimated)
Operational Milestone Financial Report	Operational Milestone #3	Due 60 days after achievement of each Operational Milestone
Operational Milestone Progress Report	Operational Milestone #4	06/30/2020 (estimated)
Operational Milestone Financial Report	Operational Milestone #4	Due 60 days after achievement of each Operational Milestone
Quarterly Progress Report	Year 2 Q2	07/01/2020
Quarterly Financial Report	Year 2 Q2	07/16/2020
Quarterly Progress Report	Year 2 Q3	10/01/2020
Quarterly Financial Report	Year 2 Q3	10/16/2020
Final Operational Milestone Progress Report	Final Operational Milestone #5	12/31/2020 (estimated)
Final Operational Milestone Financial Report	Final Operational Milestone #5	Due 60 days after achievement of each Operational Milestone

For an explanation of reporting requirements, please refer to the Grants Administration Policy. Additional reporting requirements may include cases such as Suspension Events, substantial delays in Operational Milestones, Clinical Advisory Panel requests for information and any other events that threaten the ability to meet the terms of the award.

**CIRM CONTACTS:**

Jennifer Mielnicki, Associate Director, Grants Management Operations

Phone/Fax: 510-340-9179 Email: [jmielnicki@cirm.ca.gov](mailto:jmielnicki@cirm.ca.gov)

Lisa Kadyk, Senior Science Officer

Phone/Fax: 510-340-9141 Email: [lkadyk@cirm.ca.gov](mailto:lkadyk@cirm.ca.gov)

The CIRM home page is at <http://www.cirm.ca.gov>

**CIRM Mailing Address:**

California Institute for Regenerative Medicine

Attn: Jennifer Mielnicki, Associate Director, Grants Management Operations

1999 Harrison Street, Suite 1650

Oakland, CA 94612

**CIRM USE ONLY:** 6445-601-6047001/H&S Code 125291.20 Statutes 2004

**APPENDIX A****CLIN1-11404**

## **NOTICE OF AWARD – CLIN 1: Partnering Opportunity for Late Stage Preclinical Projects California Institute for Regenerative Medicine**

Operational Milestone achievement is an important indicator of progress and will determine award disbursements. An initial disbursement will be made upon execution of this agreement to the fund the work needed to get to the first Operational Milestone. Subsequent funds will not be disbursed until each Operational Milestone is achieved. Costs incurred above what is provided by the milestone disbursement prior to achievement of the Operational Milestone will be the sole responsibility of the recipient to be covered by non-CIRM contingency funds. Achievement of the final Operational Milestone determines the final award end date, which defines the period in which Awardee can conduct CIRM-funded activities and incur CIRM-funded expenditures. The Operational Milestones selected by CIRM are listed below. These Operational Milestones will be used as a basis for award disbursement unless further modified with Prior Approval from CIRM. Changes to Operational Milestones and/or Suspension Events shall be accomplished only by agreement of both parties via an amendment to this NOA.

### **Operational Milestones (OM):**

<b>OM</b>	<b>Milestone</b>	<b>Projected Date</b>	<b>Payment</b>
	Project start	January 2019	\$1,714,000
1	M1: Complete tissue procurement and maternal blood draw	May 2019	\$1,296,000
2	M2: Complete PMSC lot testing and product bank expansion	September 2019	\$1,412,000
3	M3: Complete GLP safety study in NSG mice and safety and efficacy study in sheep	April 2020	\$334,000
4	M4: File IND application with the FDA	June 2020	\$860,077
5	M5: Complete clinical trial start-up activities completed	December 2020	\$50,000
	<b>Total CIRM funds disbursed</b>		<b>\$5,666,077</b>

### **\*Success Criteria**

- OM1 Pre-term placental tissue (14-21 weeks of gestation) will be obtained from at least 15 consented, healthy volunteer donors and maternal blood samples will be tested for adventitious viruses.
- OM2 Up to five product banks (as defined in the application) will undergo lot testing (viability, sterility, karyotype, identity, pluripotency, bioactivity) and a single bank will be selected as optimal per bioactivity criteria.
- OM3 A GLP safety study of PMSC-ESCM transplanted subcutaneously in NSG mice will be completed as outlined in the application and study reports will be shared with CIRM. A long-term safety study of PMSC-ESCM transplanted subdurally to the spinal cord in fetal lambs will be completed as outlined in the application and study reports will be shared with CIRM.
- OM4 Notice of receipt of IND application from FDA will be shared with CIRM.
- OM5 Case Report Forms, Informed Consent documents, plans for safety reporting and the clinical protocol will be finalized.

### **Suspension Events:**

Any event that halts or terminates the planned project including but not limited to:

- A failure to manufacture and release the cell product

The Awardee must immediately report the occurrence of a Suspension Event to CIRM and can use CIRM funds for allowable Project Costs up to 30 days following the occurrence of a Suspension Event after which the Awardee must use its own contingency funding for the project. The Awardee must report to CIRM a plan to resolve the issues associated with the Suspension Event within 30 days and then show evidence that the Suspension Event has been resolved in order to re-initiate use of CIRM funds.



UC DAVIS HEALTH  
OFFICE OF RESEARCH  
2921 Stockton Blvd, Suite 1400  
Sacramento, CA 95817

July 13, 2018

Aijun Wang, PhD  
Associate Professor  
Department of Surgery  
UC Davis, School of Medicine

Dear Dr. Wang,

Thank you for your recent application for the SOM Deans Fellowship in Entrepreneurship. We received several outstanding applications along with excellent letters of support making the selection process extremely challenging. I am excited to inform you that your application was selected for the SOM Deans Fellowship in Entrepreneurship. The successful Dean's Fellow candidate in Entrepreneurship needed to clearly articulate how to advance the UC Davis School of Medicine infrastructure in innovation, entrepreneurship, startup company organization and financing. The successful candidates will be interested in collaborating with distinguished business and science leaders as mentors to study how entrepreneurship fits within the academic enterprise in dimensions ranging from the practical elements of engaging in innovation activities while practicing medicine to policy issues of how entrepreneurship fits with promotion and career advancement. Congratulations on your achievement.

I would like to personally thank you for giving me the personal opportunity to learn more about your future research plans in regard to the fellowship and looking forward to seeing an increase in SOM's institutional capacity in Entrepreneurship.

Sincerely,

A handwritten signature in cursive script, reading "Lars Berglund".

Lars Berglund, MD, PhD  
Interim Dean, UC Davis School of Medicine  
Associate Vice Chancellor for Biomedical Research



NATIONAL INSTITUTE OF NEUROLOGICAL DISORDERS AND STROKE

**Grant Number:** 5R01NS100761-02  
**FAIN:** R01NS100761

**Principal Investigator(s):**  
Aijun Wang, PHD

**Project Title:** Fetal Tissue Engineering to Treat Spina Bifida Before Birth

JINGER SNYDER  
Contracts and Grants Analyst  
1850 Research Park Drive, Suite 300  
Davis, CA 956186153

**Award e-mailed to:** awards@ucdavis.edu

**Period Of Performance:**

**Budget Period:** 05/01/2018 – 04/30/2019

**Project Period:** 08/01/2017 – 04/30/2022

Dear Business Official:

The National Institutes of Health hereby awards a grant in the amount of \$309,094 (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to Regents of the University of California in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award including the "Terms and Conditions" is acknowledged by the grantee when funds are drawn down or otherwise obtained from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the National Institute Of Neurological Disorders And Stroke of the National Institutes of Health under Award Number R01NS100761. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website <http://grants.nih.gov/grants/policy/coi/> for a link to the regulation and additional important information.

If you have any questions about this award, please contact the individual(s) referenced in Section IV.

Sincerely yours,

Elizabeth E Conklin  
Grants Management Officer  
NATIONAL INSTITUTE OF NEUROLOGICAL DISORDERS AND STROKE

Additional information follows

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**SECTION I – AWARD DATA – 5R01NS100761-02****Award Calculation (U.S. Dollars)**

Federal Direct Costs	\$196,875
Federal F&A Costs	\$112,219
Approved Budget	\$309,094
Total Amount of Federal Funds Obligated (Federal Share)	\$309,094
<b>TOTAL FEDERAL AWARD AMOUNT</b>	<b>\$309,094</b>

<b>AMOUNT OF THIS ACTION (FEDERAL SHARE)</b>	<b>\$309,094</b>
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SUMMARY TOTALS FOR ALL YEARS		
YR	THIS AWARD	CUMULATIVE TOTALS
2	\$309,094	\$309,094
3	\$343,438	\$343,438
4	\$343,438	\$343,438
5	\$343,438	\$343,438

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

**Fiscal Information:**

<b>CFDA Name:</b>	Extramural Research Programs in the Neurosciences and Neurological Disorders
<b>CFDA Number:</b>	93.853
<b>EIN:</b>	1946036494A1
<b>Document Number:</b>	RNS100761A
<b>PMS Account Type:</b>	P (Subaccount)
<b>Fiscal Year:</b>	2018

IC	CAN	2018	2019	2020	2021
NS	8472428	\$309,094	\$343,438	\$343,438	\$343,438

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

**NIH Administrative Data:**

**PCC:** MORRIJNG / **OC:** 414E / **Released:** CONKLINE 04/10/2018

**Award Processed:** 04/12/2018 12:11:41 AM

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**SECTION II – PAYMENT/HOTLINE INFORMATION – 5R01NS100761-02**

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at <http://grants.nih.gov/grants/policy/awardconditions.htm>

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**SECTION III – TERMS AND CONDITIONS – 5R01NS100761-02**

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

- The grant program legislation and program regulation cited in this Notice of Award.
- Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
- 45 CFR Part 75.
- National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
- Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
- This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at <http://grants.nih.gov/grants/policy/awardconditions.htm> for certain references cited above.)

**Research and Development (R&D):** All awards issued by the National Institutes of Health (NIH) meet the definition of "Research and Development" at 45 CFR Part§ 75.2. As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

This institution is a signatory to the Federal Demonstration Partnership (FDP) Phase VI Agreement which requires active institutional participation in new or ongoing FDP demonstrations and pilots.

An unobligated balance may be carried over into the next budget period without Grants Management Officer prior approval.

This grant is subject to Streamlined Noncompeting Award Procedures (SNAP).

This award is subject to the requirements of 2 CFR Part 25 for institutions to receive a Dun & Bradstreet Universal Numbering System (DUNS) number and maintain an active registration in the System for Award Management (SAM). Should a consortium/subaward be issued under this award, a DUNS requirement must be included. See <http://grants.nih.gov/grants/policy/awardconditions.htm> for the full NIH award term implementing this requirement and other additional information.

This award has been assigned the Federal Award Identification Number (FAIN) R01NS100761. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Based on the project period start date of this project, this award is likely subject to the Transparency Act subaward and executive compensation reporting requirement of 2 CFR Part 170. There are conditions that may exclude this award; see <http://grants.nih.gov/grants/policy/awardconditions.htm> for additional award applicability information.

In accordance with P.L. 110-161, compliance with the NIH Public Access Policy is now mandatory. For more information, see NOT-OD-08-033 and the Public Access website: <http://publicaccess.nih.gov/>.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than \$10,000,000 must report and maintain information in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75. This term does not apply to NIH fellowships.

**Treatment of Program Income:**  
Additional Costs



Clinical Trial Indicator: No

This award does not support any NIH-defined Clinical Trials. See the NIH Grants Policy Statement Section 1.2 for NIH definition of Clinical Trial.

**NOTE:** The status of resource sharing should be indicated in the next progress report in section C.5.

In accordance with NOT-OD-18-136, (<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-136.html>), NIH is currently operating under the Fiscal Year 2018 Continuing Appropriations Act, 2018 (H.R. 601). Therefore, NIH will issue non-competing research grant awards at a level below that indicated on the most recent Notice of Award. Upward adjustments to awarded levels will be considered after our FY 2018 appropriations are enacted; NIH expects institutions to monitor their expenditures carefully during this period.

In accordance with the Notice: NOT-OD-17-003, published on December 15, 2016, in the NIH Guide for Grants and Contracts, total direct costs (salary, fringe benefits and tuition remission) for graduate students are provided at a level not to exceed the NIH maximum allowable amount (zero level of the Ruth L. Kirschstein National Research Service Award stipend in effect at the time of the competing award). Support recommended for future years has been adjusted accordingly, if applicable.

The full guide Notice describing the level of compensation allowed for a graduate student can be found at: <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-003.html>.

In future years, awards under the Streamlined Non-competing Award Process (SNAP) must submit a non-competing application via the eRA Commons by the 15th of the month preceding the month in which the budget period ends. The non-competing application can be submitted using the Research Performance Progress Report (RPPR) format via the RPPR link in eRA Commons.

The use of the eRA Research Performance Progress Report (RPPR) Module for submitting Type 5 Progress Reports is required for all awards with start dates on or after October 17, 2014. See Guide Notice: NOT-OD-15-014 <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-014.html>

The funds in this award shall not be used to pay the salary of an individual at a rate in excess of Executive Level II (\$189,600) per year effective January 7, 2018. See NIH Guide Notice: NOT-OD-18-137 <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-137.html>

To register to use the Commons go to <https://commons.era.nih.gov/commons/>. Questions regarding the Commons should be addressed to Commons Support at 1-866-504-9552 or [commons@od.nih.gov](mailto:commons@od.nih.gov).

Other documents applicable to this grant should be faxed to (301) 451-5635 or mailed to:

Grants Management Branch  
National Institutes of Neurological Disorders and Stroke  
6001 Executive Boulevard, Suite 3290, MSC 9537  
Rockville, MD 20852 (Express Mail)  
Bethesda, MD 20892-9537 (Regular Mail)

For additional information, you may access the NIH home page at <http://www.nih.gov/> and the NINDS Home Page at <http://www.ninds.nih.gov>.

## **STAFF CONTACTS**

The Grants Management Specialist is responsible for the negotiation, award and administration of this project and for interpretation of Grants Administration policies and provisions. The Program Official is responsible for the scientific, programmatic and technical aspects of this project. These individuals work together in overall project administration. Prior approval requests (signed by an

Authorized Organizational Representative) should be submitted in writing to the Grants Management Specialist. Requests may be made via e-mail.

**Grants Management Specialist:** Yvonne C. Talley  
**Email:** talleyy@mail.nih.gov **Phone:** 301-496-7432 **Fax:** 301-451-5635

**Program Official:** Jill A Morris  
**Email:** morrisja2@mail.nih.gov **Phone:** 301-496-5745

**SPREADSHEET SUMMARY**  
**GRANT NUMBER:** 5R01NS100761-02

**INSTITUTION:** Regents of the University of California

Budget	Year 2	Year 3	Year 4	Year 5
TOTAL FEDERAL DC	\$196,875	\$218,750	\$218,750	\$218,750
TOTAL FEDERAL F&A	\$112,219	\$124,688	\$124,688	\$124,688
TOTAL COST	\$309,094	\$343,438	\$343,438	\$343,438

Facilities and Administrative Costs	Year 2	Year 3	Year 4	Year 5
F&A Cost Rate 1	57%	57%	57%	57%
F&A Cost Base 1	\$196,875	\$218,750	\$218,750	\$218,750
F&A Costs 1	\$112,219	\$124,688	\$124,688	\$124,688



**SMALL RESEARCH GRANT**  
Department of Health and Human Services  
National Institutes of Health

Notice of Award

**Federal Award Date:** 06/21/2018



EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT

**Grant Number:** 5R03HD091601-02  
**FAIN:** R03HD091601

**Principal Investigator(s):**  
Aijun Wang, PHD

**Project Title:** Guinea pigs as a model of in utero stem cell therapy for spina bifida

Larsen, Christine L  
Contracts and Grants Analyst  
1850 Research Park Drive, Suite 300  
Davis, CA 956186153

**Award e-mailed to:** awards@ucdavis.edu

**Period Of Performance:**

**Budget Period:** 07/01/2018 – 06/30/2019

**Project Period:** 07/01/2017 – 06/30/2019

Dear Business Official:

The National Institutes of Health hereby awards a grant in the amount of \$78,500 (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to Regents of the University of California in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award including the "Terms and Conditions" is acknowledged by the grantee when funds are drawn down or otherwise obtained from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the Eunice Kennedy Shriver National Institute Of Child Health & Human Development of the National Institutes of Health under Award Number R03HD091601. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website <http://grants.nih.gov/grants/policy/coi/> for a link to the regulation and additional important information.

If you have any questions about this award, please contact the individual(s) referenced in Section IV.

Sincerely yours,

Ryan Talesnik  
Grants Management Officer  
EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN  
DEVELOPMENT

Additional information follows

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**SECTION I – AWARD DATA – 5R03HD091601-02****Award Calculation (U.S. Dollars)**

Federal Direct Costs	\$50,000
Federal F&A Costs	\$28,500
Approved Budget	\$78,500
Total Amount of Federal Funds Obligated (Federal Share)	\$78,500
<b>TOTAL FEDERAL AWARD AMOUNT</b>	<b>\$78,500</b>
 <b>AMOUNT OF THIS ACTION (FEDERAL SHARE)</b>	 <b>\$78,500</b>

SUMMARY TOTALS FOR ALL YEARS		
YR	THIS AWARD	CUMULATIVE TOTALS
2	\$78,500	\$78,500

**Fiscal Information:**

**CFDA Name:** Child Health and Human Development Extramural Research  
**CFDA Number:** 93.865  
**EIN:** 1946036494A1  
**Document Number:** RHD091601A  
**PMS Account Type:** P (Subaccount)  
**Fiscal Year:** 2018

IC	CAN	2018
HD	8014702	\$78,500

**NIH Administrative Data:**

**PCC:** DBSVB-DH / **OC:** 414E / **Released:** TALESNIKR 06/20/2018  
**Award Processed:** 06/21/2018 12:13:21 AM

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**SECTION II – PAYMENT/HOTLINE INFORMATION – 5R03HD091601-02**

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at <http://grants.nih.gov/grants/policy/awardconditions.htm>

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**SECTION III – TERMS AND CONDITIONS – 5R03HD091601-02**

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

- The grant program legislation and program regulation cited in this Notice of Award.
- Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
- 45 CFR Part 75.
- National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
- Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
- This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at <http://grants.nih.gov/grants/policy/awardconditions.htm> for certain references cited above.)

**Research and Development (R&D):** All awards issued by the National Institutes of Health (NIH) meet the definition of "Research and Development" at 45 CFR Part§ 75.2. As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal

Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

This institution is a signatory to the Federal Demonstration Partnership (FDP) Phase VI Agreement which requires active institutional participation in new or ongoing FDP demonstrations and pilots.

An unobligated balance may be carried over into the next budget period without Grants Management Officer prior approval.

This grant is subject to Streamlined Noncompeting Award Procedures (SNAP).

This award is subject to the requirements of 2 CFR Part 25 for institutions to receive a Dun & Bradstreet Universal Numbering System (DUNS) number and maintain an active registration in the System for Award Management (SAM). Should a consortium/subaward be issued under this award, a DUNS requirement must be included. See <http://grants.nih.gov/grants/policy/awardconditions.htm> for the full NIH award term implementing this requirement and other additional information.

This award has been assigned the Federal Award Identification Number (FAIN) R03HD091601. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Based on the project period start date of this project, this award is likely subject to the Transparency Act subaward and executive compensation reporting requirement of 2 CFR Part 170. There are conditions that may exclude this award; see <http://grants.nih.gov/grants/policy/awardconditions.htm> for additional award applicability information.

In accordance with P.L. 110-161, compliance with the NIH Public Access Policy is now mandatory. For more information, see NOT-OD-08-033 and the Public Access website: <http://publicaccess.nih.gov/>.

This award represents the final year of the competitive segment for this grant. See the NIH Grants Policy Statement Section 8.6 Closeout for complete closeout requirements at: <http://grants.nih.gov/grants/policy/policy.htm#gps>.

A final expenditure Federal Financial Report (FFR) (SF 425) must be submitted through the eRA Commons (Commons) within 120 days of the period of performance end date; see the NIH Grants Policy Statement Section 8.6.1 Financial Reports, <http://grants.nih.gov/grants/policy/policy.htm#gps>, for additional information on this submission requirement. The final FFR must indicate the exact balance of unobligated funds and may not reflect any unliquidated obligations. There must be no discrepancies between the final FFR expenditure data and the Payment Management System's (PMS) quarterly cash transaction data. A final quarterly federal cash transaction report is not required for awards in PMS B subaccounts (i.e., awards to foreign entities and to Federal agencies). NIH will close the awards using the last recorded cash drawdown level in PMS for awards that do not require a final FFR on expenditures or quarterly federal cash transaction reporting. It is important to note that for financial closeout, if a grantee fails to submit a required final expenditure FFR, NIH will close the grant using the last recorded cash drawdown level. If the grantee submits a final expenditure FFR but does not reconcile any discrepancies between expenditures reported on the final expenditure FFR and the last cash report to PMS, NIH will close the award at the lower amount. This could be considered a debt or result in disallowed costs.

A Final Invention Statement and Certification form (HHS 568), (not applicable to training, construction, conference or cancer education grants) must be submitted within 120 days of the

expiration date. The HHS 568 form may be downloaded at: <http://grants.nih.gov/grants/forms.htm>. This paragraph does not apply to Training grants, Fellowships, and certain other programs—i.e., activity codes C06, D42, D43, D71, DP7, G07, G08, G11, K12, K16, K30, P09, P40, P41, P51, R13, R25, R28, R30, R90, RL5, RL9, S10, S14, S15, U13, U14, U41, U42, U45, UC6, UC7, UR2, X01, X02.

Unless an application for competitive renewal is submitted, a Final Research Performance Progress Report (Final RPPR) must also be submitted within 120 days of the period of performance end date. If a competitive renewal application is submitted prior to that date, then an Interim RPPR must be submitted by that date as well. Instructions for preparing an Interim or Final RPPR are at: [https://grants.nih.gov/grants/rppr/rppr\\_instruction\\_guide.pdf](https://grants.nih.gov/grants/rppr/rppr_instruction_guide.pdf). Any other specific requirements set forth in the terms and conditions of the award must also be addressed in the Interim or Final RPPR. *Note that data reported within Section I of the Interim and Final RPPR forms will be made public and should be written for a lay person audience.*

NIH strongly encourages electronic submission of the final invention statement through the Closeout feature in the Commons, but will accept an email or hard copy submission as indicated below.

Email: The final invention statement may be e-mailed as PDF attachments to: [NIHCloseoutCenter@mail.nih.gov](mailto:NIHCloseoutCenter@mail.nih.gov).

Hard copy: Paper submissions of the final invention statement may be faxed to the NIH Division of Central Grants Processing, Grants Closeout Center, at 301-480-2304, or mailed to:

National Institutes of Health  
Office of Extramural Research  
Division of Central Grants Processing  
Grants Closeout Center  
6705 Rockledge Drive  
Suite 5016, MSC 7986  
Bethesda, MD 20892-7986 (for regular or U.S. Postal Service Express mail)  
Bethesda, MD 20817 (for other courier/express deliveries only)

NOTE: If this is the final year of a competitive segment due to the transfer of the grant to another institution, then a Final RPPR is not required. However, a final expenditure FFR is required and should be submitted electronically as noted above. If not already submitted, the Final Invention Statement is required and should be sent directly to the assigned Grants Management Specialist.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than \$10,000,000 must report and maintain information in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently the Federal Awardee Performance and Integrity Information System (FAPIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75. This term does not apply to NIH fellowships.

**Treatment of Program Income:**  
Additional Costs

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## **SECTION IV – HD Special Terms and Conditions – 5R03HD091601-02**

Clinical Trial Indicator: No

This award does not support any NIH-defined Clinical Trials. See the NIH Grants Policy Statement Section 1.2 for NIH definition of Clinical Trial.

## **STAFF CONTACTS**

The Grants Management Specialist is responsible for the negotiation, award and administration of this project and for interpretation of Grants Administration policies and provisions. The Program Official is responsible for the scientific, programmatic and technical aspects of this project. These individuals work together in overall project administration. Prior approval requests (signed by an Authorized Organizational Representative) should be submitted in writing to the Grants Management Specialist. Requests may be made via e-mail.

**Grants Management Specialist:** Ryan Talesnik  
**Email:** talesnikr@mail.nih.gov **Phone:** (301)435-6976

**Program Official:** Deborah B. Henken  
**Email:** henkend@mail.nih.gov **Phone:** 301-496-5541 **Fax:** 301-480-0303

**SPREADSHEET SUMMARY**  
**GRANT NUMBER:** 5R03HD091601-02

**INSTITUTION:** Regents of the University of California

Budget	Year 2
TOTAL FEDERAL DC	\$50,000
TOTAL FEDERAL F&A	\$28,500
TOTAL COST	\$78,500

Facilities and Administrative Costs	Year 2
F&A Cost Rate 1	57%
F&A Cost Base 1	\$50,000
F&A Costs 1	\$28,500



# NOTICE OF GRANT AWARD – RFA 14-02: CIRM Preclinical Development Awards California Institute for Regenerative Medicine

**Issue Date:** September 8, 2015

Grant Number: PC1-08103 Project Period Start: 09/01/2015  
 Grantee Name: University of California, Davis Project Period End: 02/28/2018  
 Grantee ID: NE-A0002A-ST  
 Principal Investigator: Diana L. Farmer Total Award Amount: \$2,182,146  
 Co-Principal Investigator: Aijun Wang  
 Project Title: Placental Stem Cells for the In Utero Treatment of Spina Bifida

**Authorized Organizational Official and Address:** Robert Pattison  
 Contract and Grant officer  
 Office of Research - Sponsored Programs 1850  
 Research Park Drive, Suite 300  
 Davis, CA 95618

**Official and Address to Receive Payments:** Cashier's Office University of California,  
 Davis  
 P.O. Box 989062  
 West Sacramento, CA 95798-9062

The California Institute for Regenerative Medicine (CIRM) hereby awards a grant in the amount of \$2,182,146 to be disbursed over a total period of 3 years (30 months) to University of California, Davis (Grantee ID: NE-A0002A-ST) in support of the above referenced project. This award is pursuant to the California Stem Cell Research and Cures Act (Health and Safety Code section 125290.10 *et. seq.*) and is subject to terms and conditions referenced below. (Capitalized terms are defined in the *CIRM Grants Administration Policy for Academic and Non-Profit Institutions (GAP)*, a copy of which may be found on the CIRM website at: [https://www.cirm.ca.gov/sites/default/files/files/funding\\_page/NPGAP\\_03012015.pdf](https://www.cirm.ca.gov/sites/default/files/files/funding_page/NPGAP_03012015.pdf)

In accepting this Grant, the Grantee warrants to CIRM that any funds expended under the Award will be for the purposes set forth in the approved Application and agrees to comply with all applicable CIRM regulations and standards.

To accept this Grant, the Principal Investigator and Authorized Organizational Official must sign and return this Notice of Grant Award (NGA) to CIRM within 45 days of the issue date. Payment will be issued only after the fully signed NGA is received by CIRM. Grant funds will be sent to the organization's address listed above under *Official and Address to Receive Payments* unless an updated address is provided in the box below. If the Applicant cannot accept the award, including the legal obligation to perform in accordance with the provisions of this NGA, it should notify CIRM immediately.

If you have any questions about this award, please contact the CIRM staff referenced on page 4.

Updated Address to Receive Payments:

Ramona Doyle, M.D.  
 Vice President, Therapeutics  
 California Institute for Regenerative Medicine

**AWARD ACCEPTANCE:** The Principal Investigator and Authorized Organizational Official must sign below and return the entire NGA to CIRM to accept the Grant award.

	Principal Investigator	Authorized Organizational Official
Name	Diana L. Farmer	Robert Pattison
Signature		
Date		

**TERMS AND CONDITIONS:**

- A. This award is based on the application submitted to CIRM, and as approved by the Independent Citizens' Oversight Committee (ICOC) on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:
1. The *California Stem Cell Research and Cures Act* (Health and Safety Code Section 125290.10 *et. seq.*) and regulations adopted by the ICOC.
  2. The *CIRM Grants Administration Policy for Academic and Non-Profit Institutions* (Title 17, California Code of Regulations, Section 100500), *CIRM Intellectual Property Policy and Revenue Sharing Requirements for Non-Profit and For-Profit Grantees* (Title 17, California Code of Regulations, Sections 100600-100611), the *CIRM Medical and Ethical Standards Regulations* (Title 17, California Code of Regulations, Sections 100010-1000120), and any subsequently adopted applicable regulations.
  3. The terms and requirements detailed in RFA 14-02: CIRM Preclinical Development Awards.
  4. The Progress Milestones and Go/No Go Milestones set out in Appendix A to this NGA.
  5. Budget detail for the Principal Investigator and the Co-Principal Investigator(s) set out below.
- B. CIRM may suspend or permanently cease Disbursements if CIRM determines, in its sole discretion, that Grantee has not satisfied a Go/No Go Milestone.
- C. If CIRM determines, in its sole discretion, that Grantee has not satisfied a Progress Milestone, CIRM may suspend Disbursements until such time as Grantee satisfies the Progress Milestone. Upon suspending Disbursements, CIRM may convene its progress Evaluation Committee and may seek input from Grantee in order to evaluate the circumstances of the delay, including but not limited to, its cause, impact and any mitigating factors; provided, however, that CIRM may permanently cease Disbursements if Grantee does not satisfy the Progress Milestone within four (4) months of the date that the Progress Milestone was scheduled to have been satisfied, or if the delay is not addressed to CIRM's satisfaction, as determined by CIRM in its sole discretion.
- D. CIRM has the right to attend key FDA meetings regarding the funded project, including but not limited to any clinical milestone meeting, or clinical hold meeting (FDA Meetings). CIRM also has the right to review any data package(s) or other information, including confidential and/or proprietary information, provided by Awardee to the FDA in connection with such FDA Meetings, as well as any FDA Meeting minutes, and to share such information with CIRM's confidential advisers. To facilitate CIRM's participation in FDA Meetings, Awardee shall notify CIRM as soon as practicable after it has scheduled an FDA Meeting, and shall, upon request, provide CIRM a copy of any data package or other information it intends to provide or has provided to the FDA, as well as any FDA Meeting minutes.
- E. If CIRM determines, in its sole discretion, that Grantee has not complied with the terms and conditions of this award, CIRM may suspend or permanently cease Disbursements, or pursue other remedies as allowed by law.
- F. The timing of the distribution of funds pursuant to this Grant shall be contingent upon the availability of funds in the California Stem Cell Research and Cures Fund in the State Treasury, as determined by CIRM in its sole discretion.

Please check the following website for updated policy documents: <http://www.cirm.ca.gov/cirm-operations/Regulations>



**AWARD DETAIL (U.S. Dollars):**

	Year 1	Year 2	Year 3
Principal Investigator	\$642,336	\$480,300	\$259,886
Co-Principal Investigator (1)	\$368,364	\$275,165	\$156,095
<b>TOTAL APPROVED BUDGET</b>	<b>\$1,010,700</b>	<b>\$755,465</b>	<b>\$415,981</b>

Principal Investigator: Diana L. Farmer (University of California, Davis)

	Year 1	Year 2	Year 3
<b><u>Direct Project Costs</u></b>			
Personnel	\$2,575	\$3,301	\$1,699
Travel	\$7,500	\$7,500	\$7,500
Supplies	\$295,111	\$231,239	\$94,623
Equipment	\$71,579	\$0	\$0
Consultants/Subcontracts	\$113,140	\$113,753	\$96,001
<b>Total Direct Project Costs</b>	<b>\$489,905</b>	<b>\$355,793</b>	<b>\$199,823</b>
Facilities Costs	\$89,481	\$73,436	\$35,426
Indirect Costs	\$62,950	\$51,071	\$24,637
<b>TOTAL APPROVED BUDGET</b>	<b>\$642,336</b>	<b>\$480,300</b>	<b>\$259,886</b>

Co-Principal Investigator: Aijun Wang (University of California, Davis)

	Year 1	Year 2	Year 3
<b><u>Direct Project Costs</u></b>			
Personnel	\$52,575	\$54,086	\$27,728
Travel	\$7,500	\$7,500	\$7,500
Supplies	\$97,059	\$116,080	\$66,231
Equipment	\$124,073	\$0	\$0
Consultants/Subcontracts	\$10,000	\$10,000	\$5,000
<b>Total Direct Project Costs</b>	<b>\$291,207</b>	<b>\$187,666</b>	<b>\$106,459</b>
Facilities Costs	\$45,293	\$51,608	\$29,276
Indirect Costs	\$31,864	\$35,891	\$20,360
<b>TOTAL APPROVED BUDGET</b>	<b>\$368,364</b>	<b>\$275,165</b>	<b>\$156,095</b>
<b>Total Co-Funding</b>	<b>\$895,789</b>	<b>\$900,756</b>	<b>\$470,739</b>

\*Any interest accrued by the Grantee from the Grant payments must be used for the CIRM Preclinical Development Awards.

## PROGRESS & FINANCIAL REPORTS SCHEDULE

Report Type	Due Date	Report Period
Progress Report	03/01/2016	Year 1 Q2
Semi-Annual Financial Report	04/01/2016	Year 1 Q2
Annual Progress Report	09/01/2016	Year 1
Annual Financial Report	12/01/2016	Year 1
Progress Report	03/01/2017	Year 2 Q2
Semi-Annual Financial Report	04/01/2017	Year 2 Q2
Annual Progress Report	09/01/2017	Year 2
Annual Financial Report	12/01/2017	Year 2
Annual Progress Report	03/01/2018	Year 3 Q2
Annual Financial Report	04/01/2018	Year 3 Q2

### CIRM CONTACTS:

Ryan Wells, Grants Management Specialist

Phone: 415-396-9124

Email: [rwells@cirm.ca.gov](mailto:rwells@cirm.ca.gov)

Fax: (415) 396-9274

Dr. Mani Vessal, Scientific Officer

Phone: 415-396-9308

Email: [mvessal@cirm.ca.gov](mailto:mvessal@cirm.ca.gov)

Fax: (415) 396-9141

The CIRM home page is at <http://www.cirm.ca.gov>

### CIRM Mailing Address:

California Institute for Regenerative Medicine

Attn: Ryan Wells, Grants Management Specialist

210 King Street

San Francisco, CA 94107

CIRM USE ONLY: 6445-601-6047001/H&S Code 125291.20 Statutes 2004



## NOTICE OF GRANT AWARD – RFA 14-02: CIRM Preclinical Development Awards California Institute for Regenerative Medicine

**Issue Date:** September 8, 2015

Grant Number:	PC1-08103	Project Period Start:	09/01/2015
Grantee Name:	University of California, Davis	Project Period End:	02/28/2018
Grantee ID:	NE-A0002A-ST		
Principal Investigator:	Diana L. Farmer	Total Award Amount:	\$2,182,146
Co-Principal Investigator:	Aijun Wang		
Project Title:	Placental Stem Cells for the In Utero Treatment of Spina Bifida		

Milestone achievement is an important indicator of progress and is a major factor in review of progress reports. Insufficient progress through Milestones may result in loss of further funding. The Milestones summarized below replace the Milestones proposed in the original Application. These Milestones will be used as a basis for review in the progress reports and progress Evaluation Meetings unless further modified with Prior Approval from CIRM.

### **Milestone 1: (CMC) Establish cGMP-compliant master and working cell banks for placental mesenchymal stem cells (PMSCs)**

**Initiate Y1Q1, complete by Y1Q3; months 1 – 9**

#### **Go/No Go Milestone**

- 1) Establish independent Master Cell Banks (MCBs) from three different donors. Cells from each donor will be cryopreserved at P2 to give a MCB of 20 vials with  $1 \times 10^6$  cells/vial.
- 2) Establish a MSC Working Cell Bank (WCB) from each MCB. Using cGMP-compliant reagents and SOPs expand cells to P4-5 and cryopreserve (per WCB, 100 vials of  $1 \times 10^6$  cells per vial).
- 3) Assess karyotype, expression of pluripotency markers, sterility, mycoplasma, endotoxin and VEGF secretion of MCB.
- 4) Assess stability (viability) of frozen cGMP cells, every 6 months.

Success Criteria for Go/No Go milestone 1 will be met if:

- a) PMSCs in the MCB are at least 90% positive for markers CD29, CD44, CD73, CD90 and CD105 and negative for CD31, CD34, and CD45 upon expansion to P3 for flow analysis prior to cryopreserving for WCB.
- b) Cell viability for the MCBs and WCB are at least 85% prior to freezing and at least 70% after thawing.
- c) Karyotype analyses are normal in 20/20 spreads for each MCB line, prior to incorporation into the WCB. Cells are sterile and free of mycoplasma and endotoxin.
- d) MCB cells have detectable VEGF secretion at 24 hours post seeding on plastic culture dishes. Positive VEGF detection is a prerequisite for establishment of the WCB.

### **Milestone 2: Determine maximum effective cell concentration for the clinical construct Initiate Y1Q1, complete by Y1Q2; months 1 – 6**

#### **Go/No Go Milestone**

- 1) Determine maximum loading density of PMSCs within the FDA approved collagen-based extracellular matrix (ECM) intended for use as part of this combination product by MTT colorimetric assay.
- 2) Utilize ELISA assays to assess secretion of BDNF, VEGF and HGF from PMSCs grown in the ECM clinical vehicle as compared to those grown under standard conditions.

Success Criteria for Go/No Go milestone 2 will be met if a maximum loading density is determined that meets all the following criteria:

- a) a minimum density of 42K cells/cm<sup>2</sup>.
  - i. Our in-vivo preclinical studies determined that 42K cells/cm<sup>2</sup> was needed in order to be efficacious. Thus, 42K cells/cm<sup>2</sup> will be used as the minimum acceptable density
- b) No evidence of acute cytotoxicity (>30%) of PMSCs at the time of seeding and at 24 hours post seeding on the clinical grade ECM.
- c) PMSC-ECM cytokine secretion at 24hr post ECM seeding meets the following minimum release criterion:
  - i. BDNF: >30pg/ml/5x10<sup>5</sup> cells

- ii. HGF: >750pg/ml/5x10<sup>5</sup> cells
- iii. VEGF: >90pg/ml/5x10<sup>5</sup> cells

### **Milestone 3: (CMC) Develop an *in vitro* neuroprotection assay for use as a potency assay**

**Initiate Y1Q2, complete by Y1Q4; months 4-12**

#### **Progress milestone**

- 1) Develop and test a neuroprotection assay using three different GMP compliant cell lines seeded on ECM at three different loading densities (42,000 cells/cm<sup>2</sup>, half max density and max density as determined in milestone 2.1) for use as an activity assay and potentially a potency assay.

Success Criteria for Progress milestone 3 will be met if:

- a) Demonstrate PMSC-ECM mediated neuroprotection by decrease in neuron damage/apoptosis in vitro by at least 10% compared to ECM only controls.

### **Milestone 4: (Pharm/Tox) Rodent Dose Optimization Studies**

**Initiate Y1Q1, complete by Y2Q1; months 3-15**

#### **Go/No-go Milestone.**

- 1) Determine clinical grade PMSC-ECM dose in fetal rat SB defect model (SD cyclosporine treated rats).
  - i. A low dose of 5x10<sup>4</sup> cells/cm<sup>2</sup>, medium dose of 10<sup>5</sup> cells/cm<sup>2</sup>, high dose of 2x10<sup>5</sup> cells/cm<sup>2</sup> and the maximum possible dose will be transplanted in the fetal rats to determine the optimal dose category. The maximum dose will be equal to the maximum loading capacity as determined in milestone 2. An ECM only control group will be used for comparison.
- 2) Histopathology analysis of rat tissue to assess efficacy of each dose.

Success Criteria for Go/No Go milestone 4 will be met if all of the following results are obtained:

- a) Identification of a single dose (PMSC-ECM) that produces the following:
  - i. Lowest number of damaged neurons by TUNEL assay
  - ii. Highest density of neurons in the rat spinal cord

### **Milestone 5: (Pharm/Tox) Large Animal Dose Optimization/Efficacy Studies**

**Initiate Y1Q1, complete by Y3Q2, months 3-28 of the award**

#### **Go/No-Go Milestones**

- 1) Establish dose and efficacy of cGMP compliant PMSC-ECM in the fetal lamb spina bifida defect model in the following 2 studies:
  - i. **Study 1: Efficacy verification study. Initiate Y1Q1, complete Y1Q4, months 3-12. Go/No Go milestone**
    - i. Verify known efficacious PMSC-ECM dose (42,000 cells/cm<sup>2</sup>) from prior studies using research grade materials is true for cGMP compliant PMSC-ECM. Arms to include cGMP compliant PMSC-ECM and FDA-approved ECM
  - ii. **Study 2: Dose Optimization. Initiate Y2Q1, complete Y3Q2, months 15-28. Go/No Go milestone**
    - i. Test two optimal doses of cGMP compliant PMSC-ECM determined from the rat dosing studies, as well as the maximum dose of PMSC-ECM as determined by the maximum loading capacity in Milestone 2
- 2) For both studies, conduct locomotor assessment after birth.
- 3) For both studies, conduct histopathological analysis on recovered lamb tissue to assess dose efficacy and therapeutic effects of PMSC-ECM.

Success Criteria for Go/No Go milestones 5-1 and 5-2 (each study):

- a) PMSC-ECM treated lambs show a mean increase of 1 point in the SLR score over ECM only treated control lambs. This increase of 1 SLR point can translate to the following:
  - i. The ability of a lamb to walk
  - ii. The ability of a lamb to stand and bear weight independently
- b) There is at least a 20% increase in density of large neurons in the spinal cords of lambs treated with PMSC-ECM in comparison to ECM only controls.



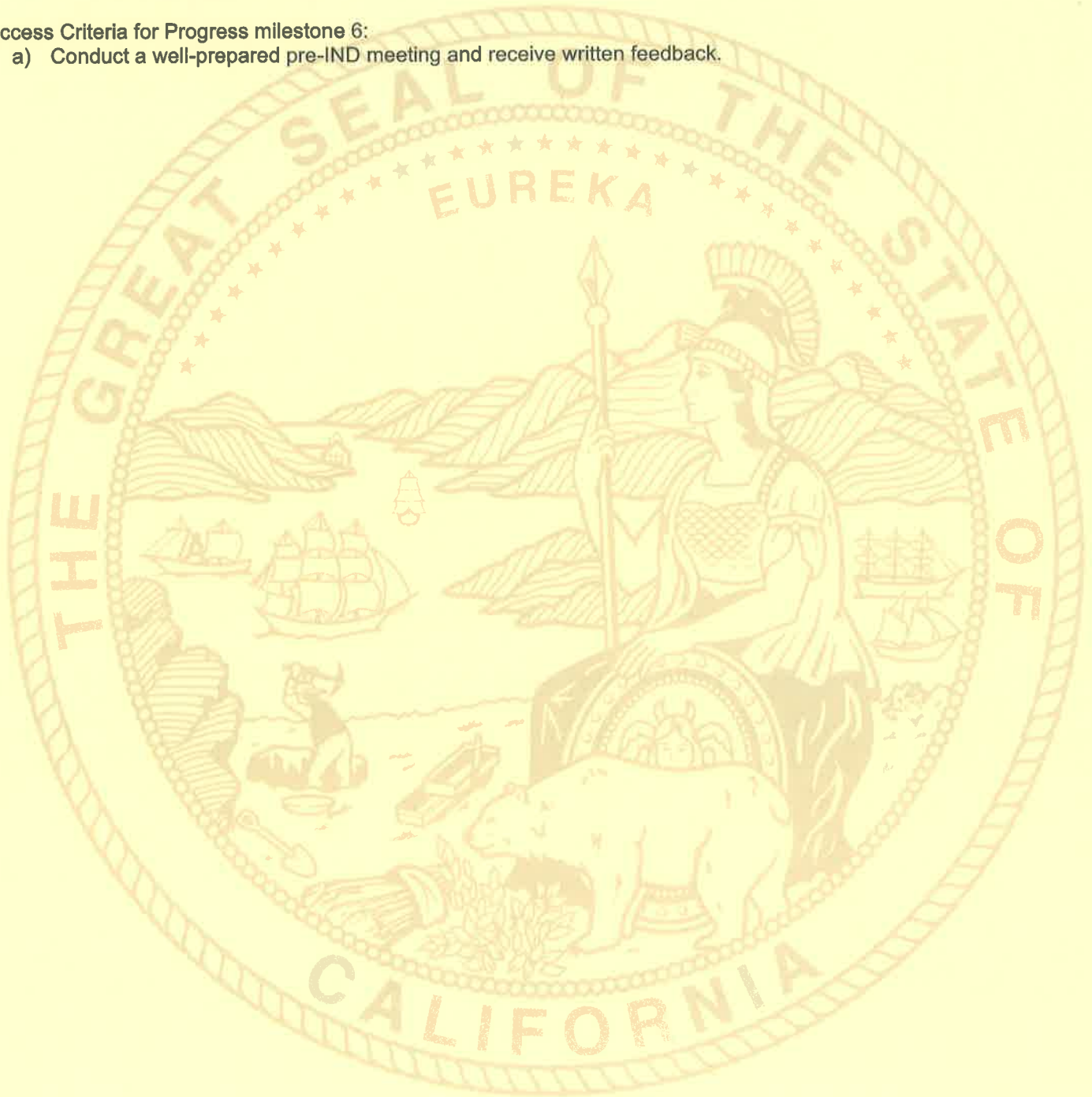
**Milestone 6: (Regulatory) Prepare and submit Pre-IND Package to FDA, hold pre-IND meeting  
Initiate Y2Q1, complete by Y3Q2; months 24–30 of award**

**Progress Milestone**

- 1) Prepare draft outline of pre-IND document
- 2) Outline pivotal safety study for submission to FDA for comment
- 3) Compile documents for pre-IND, submit pre-IND package, and schedule a pre-IND meeting discussion with FDA
- 4) Receive written feedback from FDA

**Success Criteria for Progress milestone 6:**

- a) Conduct a well-prepared pre-IND meeting and receive written feedback.



March of Dimes Foundation

National Office  
1275 Mamaroneck Avenue  
White Plains, NY 10605  
Telephone (914) 997-4504  
Fax (914) 428-0537  
Email: [jhowse@marchofdimes.com](mailto:jhowse@marchofdimes.com)

[marchofdimes.com](http://marchofdimes.com)

Dr. Jennifer L. Howse  
President

January 15, 2016

Aijun Wang, PhD  
Assistant Professor  
Department of Surgery  
University of California at Davis  
Room 3005, Research II  
4625 2nd Avenue  
Sacramento, CA 95817

Dear Dr. Wang:

Re: #5-FY16-82

I am pleased to inform you on behalf of the Board of Trustees that the March of Dimes Foundation has approved both the program content and funding for your Basil O'Connor Starter Scholar Research Award grant application entitled "In Utero Treatment of Spina Bifida via Autologous Fetal Stem Cell Mediated Neuroprotection." The approved amount is \$150,000 for the two-year period, February 1, 2016 through January 31, 2018.


Questions concerning budget and other administrative details should be directed to Mrs. Debbi Bailey-Graff, Director of Grant Management.

From time to time, you may receive a request from a local March of Dimes Chapter to participate in a Chapter event. We will extend those invitations to keep you informed of the Foundation's activities and to express our appreciation to you for your work to support our mission; however, you are under no obligation to accept those invitations or attend the events.

All communications concerning the program content of this grant should be directed to Joe Leigh Simpson, M.D., FACOG, FACMG, Senior Vice President for Research and Global Programs.

A copy of our Policies Governing Research Grants is enclosed.

Sincerely yours,

  
Dr. Jennifer L. Howse

Enclosure

c: Joe Leigh Simpson, M.D., FACOG, FACMG, Senior Vice President for Research  
and Global Programs

Debbi Bailey-Graff, Director, Grant Management

Diana L. Farmer, MD, FACS, FRCS, Pearl Stamps Stewart Professor and Chair  
Robert Pattison, Contracts and Grants Officer

march  of dimes®



National Office  
1275 Mamaroneck Avenue  
White Plains, NY 10605  
Telephone (914) 428-7100  
Direct Line (914) 997-4553  
Fax (914) 997-4560  
Email: [dbaileygraff@marchofdimes.com](mailto:dbaileygraff@marchofdimes.com)

[marchofdimes.com](http://marchofdimes.com)

Debbi Bailey-Graff  
Director  
Grants Administration

January 15, 2016

Mr. Robert Pattison  
Contracts and Grants Officer  
Office of Research -Sponsored Programs  
University of California, Davis  
1850 Research Park Drive  
Suite 300  
Davis, CA 95618

Dear Mr. Pattison:

Re: #5-FY16-82

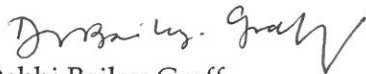
As you know from your copy of Dr. Howse's approval letter dated January 15, 2016, a Basil O'Connor Starter Scholar Research Award grant under the direction of Dr. Wang has been approved in the amount of \$150,000 for a two-year period, February 1, 2016 through January 31, 2018.

This grant is subject to the *March of Dimes Policies Governing Research Grants* (enclosed). The principal investigator and grantee institution's agreement to adhere to the *Policies* is indicated by acceptance of our grant.

We have not received the *Certificate of Approval By the Animal Care and Use Committee* form. We must receive it before making any payment. Please have the enclosed form completed and returned to us as soon as possible.

Also, enclosed is a copy of the approved budget upon which all further communications will be based. If you have any questions concerning administrative details, please contact Ms. Susan Rauh at (914) 997-4646.

Sincerely yours,



Debbi Bailey-Graff  
Director  
Grant Management

Enclosures

c: Joe Leigh Simpson, M.D., FACOG, FACMG, Senior Vice President for Research  
and Global Programs

Aijun Wang, PhD, Assistant Professor