



NATIONAL INSTITUTE OF NEUROLOGICAL DISORDERS AND STROKE

**Grant Number:** 1R01NS115860-01A1  
**FAIN:** R01NS115860

**Principal Investigator(s):**  
Diana Lee Farmer (contact), MD  
Aijun Wang, PHD

**Project Title:** Engineered neuroprotective stem-cell exosomes for in utero spina bifida therapy

Celarbo, Saojane  
Contracts and Grants Analyst  
1850 Research Park Drive  
Davis, CA 956186153

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

**Period Of Performance:**

**Budget Period:** 09/30/2020 – 08/31/2021

**Project Period:** 09/30/2020 – 08/31/2025

Dear Business Official:

The National Institutes of Health hereby awards a grant in the amount of \$499,899 (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 R01NS115860. 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 – 1R01NS115860-01A1****Award Calculation (U.S. Dollars)**

Salaries and Wages	\$137,665
Fringe Benefits	\$39,058
Personnel Costs (Subtotal)	\$176,723
Materials & Supplies	\$56,100
Travel	\$4,125
Other	\$83,566
Publication Costs	\$2,475

Federal Direct Costs	\$322,989
Federal F&A Costs	\$176,910
Approved Budget	\$499,899
Total Amount of Federal Funds Obligated (Federal Share)	\$499,899
<b>TOTAL FEDERAL AWARD AMOUNT</b>	<b>\$499,899</b>

**AMOUNT OF THIS ACTION (FEDERAL SHARE)** **\$499,899**

SUMMARY TOTALS FOR ALL YEARS		
YR	THIS AWARD	CUMULATIVE TOTALS
1	\$499,899	\$499,899
2	\$489,939	\$489,939
3	\$492,615	\$492,615
4	\$507,395	\$507,395
5	\$497,031	\$497,031

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

**Fiscal Information:**

**CFDA Name:** Extramural Research Programs in the Neurosciences and Neurological Disorders  
**CFDA Number:** 93.853  
**EIN:** 1946036494A1  
**Document Number:** RNS115860A  
**PMS Account Type:** P (Subaccount)  
**Fiscal Year:** 2020

IC	CAN	2020	2021	2022	2023	2024
NS	8472428	\$499,899	\$489,939	\$492,615	\$507,395	\$497,031

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

**NIH Administrative Data:**

**PCC:** MORRIJNG / **OC:** 41021 / **Released:** CONKLINE 09/25/2020

**Award Processed:** 09/26/2020 12:04:38 AM

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**SECTION II – PAYMENT/HOTLINE INFORMATION – 1R01NS115860-01A1**

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 – 1R01NS115860-01A1**

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.
- c. 45 CFR Part 75.
- d. 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.
- e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
- f. 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) R01NS115860. 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

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**SECTION IV – NS Special Terms and Conditions – 1R01NS115860-01A1**

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.

**COMPETING AWARDS ADMINISTRATIVE REDUCTION (FY2020)**

In order to meet Institute program objectives within Fiscal Year 2020 budget constraints, the recommended levels for this grant have been reduced. Future year recommended levels of support have also been reduced.

Per the NINDS funding strategy: [http://www.ninds.nih.gov/funding/ninds\\_funding\\_strategy.htm](http://www.ninds.nih.gov/funding/ninds_funding_strategy.htm)

**START DATE IN MIDDLE OF MONTH**

This award includes funds for twelve months of support. The competing budget period is awarded for less than 12 months. Future year budget periods will start on September 1. Allowable preaward costs may be charged to this award, in accordance with the conditions outlined in the NIH Grants Policy Statement and with institutional requirements for prior approval. The NIH Grants Policy Statement can be found at <http://grants.nih.gov/grants/policy/nihgps/index.htm>

**ESCALATION FACTOR IN FUTURE YEARS**

Inflationary increases for future year commitments are not allowable. See NIH Guide Notice: NOT-OD-13-064-<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-13-064.html>

**MODEL ORGANISMS DATA AND SHARING PLAN**

The grantee is required to follow the model organism sharing plan included in the grant application and may not implement any changes in the plan without NINDS staff approval.

**GRADUATE STUDENT COMPENSATION**

In accordance with the Notice: NOT-OD-20-070, published on February 7, 2020 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-20-070.html>

**STANDARD TERM**

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 \(RPPR\)](http://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-014.html) 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 (\$197,300) per year effective January 5, 2020. See NIH Guide Notice: NOT-OD-20-065 <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-065.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](mailto:talleyy@mail.nih.gov) **Phone:** 301-496-7432 **Fax:** 301-451-5635

**Program Official:** Jill A Morris  
**Email:** [morrisja2@mail.nih.gov](mailto:morrisja2@mail.nih.gov) **Phone:** 301-496-5745

## SPREADSHEET SUMMARY

**GRANT NUMBER:** 1R01NS115860-01A1

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

Budget	Year 1	Year 2	Year 3	Year 4	Year 5
Salaries and Wages	\$137,665	\$137,665	\$137,665	\$137,665	\$137,665
Fringe Benefits	\$39,058	\$39,058	\$39,058	\$39,058	\$39,058
Personnel Costs (Subtotal)	\$176,723	\$176,723	\$176,723	\$176,723	\$176,723
Materials & Supplies	\$56,100	\$45,375	\$18,150	\$19,800	\$19,800
Travel	\$4,125	\$4,125	\$4,125	\$4,125	\$4,125
Other	\$83,566	\$87,947	\$116,876	\$124,640	\$118,039
Publication Costs	\$2,475	\$2,475	\$2,475	\$2,475	\$2,475
TOTAL FEDERAL DC	\$322,989	\$316,645	\$318,349	\$327,763	\$321,162
TOTAL FEDERAL F&A	\$176,910	\$173,294	\$174,266	\$179,632	\$175,869
TOTAL COST	\$499,899	\$489,939	\$492,615	\$507,395	\$497,031

Facilities and Administrative Costs	Year 1	Year 2	Year 3	Year 4	Year 5
F&A Cost Rate 1	57%	57%	57%	57%	57%
F&A Cost Base 1	\$310,369	\$304,025	\$305,729	\$315,143	\$308,542
F&A Costs 1	\$176,910	\$173,294	\$174,266	\$179,632	\$175,869



NATIONAL INSTITUTE OF NEUROLOGICAL DISORDERS AND STROKE

**Grant Number:** 5R01NS100761-04  
**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:** 05/01/2020 – 04/30/2021

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

Dear Business Official:

The National Institutes of Health hereby awards a grant in the amount of \$343,438 (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 – 5R01NS100761-04****Award Calculation (U.S. Dollars)**

Federal Direct Costs	\$218,750
Federal F&A Costs	\$124,688
Approved Budget	\$343,438
Total Amount of Federal Funds Obligated (Federal Share)	\$343,438
<b>TOTAL FEDERAL AWARD AMOUNT</b>	<b>\$343,438</b>

<b>AMOUNT OF THIS ACTION (FEDERAL SHARE)</b>	<b>\$343,438</b>
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SUMMARY TOTALS FOR ALL YEARS		
YR	THIS AWARD	CUMULATIVE TOTALS
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:**

**CFDA Name:** Extramural Research Programs in the Neurosciences and Neurological Disorders  
**CFDA Number:** 93.853  
**EIN:** 1946036494A1  
**Document Number:** RNS100761A  
**PMS Account Type:** P (Subaccount)  
**Fiscal Year:** 2020

IC	CAN	2020	2021
NS	8472428	\$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:** 41025 / **Released:** CONKLINE 03/30/2020

**Award Processed:** 04/01/2020 12:05:47 AM

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**SECTION II – PAYMENT/HOTLINE INFORMATION – 5R01NS100761-04**

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 – 5R01NS100761-04**

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

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## SECTION IV – NS Special Terms and Conditions – 5R01NS100761-04

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.

This non-competing award has been made at the full committed level- the level indicated on the most recent Notice of Grant Award for FY 2020 award.

The grantee is required to follow the model organism sharing plan included in the grant application and may not implement any changes in the plan without NINDS staff approval.

In accordance with the Notice: NOT-OD-20-070, published on February 7, 2020 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-20-070.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 (\$197,300) per year effective January 5, 2020. See NIH Guide Notice: NOT-OD-20-065 <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-065.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](mailto:talleyy@mail.nih.gov) **Phone:** 301-496-7432 **Fax:** 301-451-5635

**Program Official:** Jill A Morris

**SPREADSHEET SUMMARY**

**GRANT NUMBER:** 5R01NS100761-04

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

Facilities and Administrative Costs	Year 4	Year 5
F&A Cost Rate 1	57%	57%
F&A Cost Base 1	\$218,750	\$218,750
F&A Costs 1	\$124,688	\$124,688



**Shriners Hospitals**  
for Children®

**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', with a stylized flourish at the end.

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**

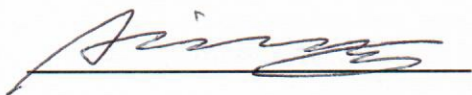
- Funding of studies involving animals is contingent upon approval of the local Animal Care and Usage Committee. Documentation of IACUC approval must be uploaded to *proposalCENTRAL* no later than February 14.

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

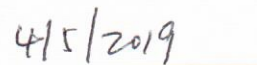
- Funding of studies involving human participants is contingent upon:
  - Protocol development
    - You are required to prepare and submit a new protocol (and informed consent, if applicable), which contains all the protocol elements required by Code of Federal Regulations and Good Clinical Practice 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. Singh", written over a horizontal line.

Signature of Principal Investigator

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

Date





CHARLES DECARLI  
DEPARTMENT OF NEUROLOGY  
4860 Y STREET  
SUITE 3700  
SACRAMENTO, CALIFORNIA 95817  
TELEPHONE: (916) 734-6280  
FAX: (916) 734-6526  
EMAIL: cdecarli@ucdavis.edu

SCHOOL OF MEDICINE

August 25, 2020

Dr. Aijun Wang  
University of California, Davis  
Department of Surgery  
4625 2<sup>nd</sup> Avenue, 3<sup>rd</sup> Floor  
Sacramento, CA 95817

Dear Dr. Wang:

Thank you for your application to the UC Davis Alzheimer's Disease Pilot Project Program. After careful internal and external review, I am pleased to inform you that your application was approved for funding by the ADC Executive Committee and the National Institute on Aging in the amount of \$32,000 direct costs.

Please review the Terms and Conditions document following this letter and return a signed copy to Jayne La Grande via email to [jmlagrande@ucdavis.edu](mailto:jmlagrande@ucdavis.edu) no later than **August 31, 2020**. This document outlines our expectations and support to ensure your success with this award.

The Alzheimer's Disease Center encourages collaborative research and we are available to support your research study and discuss your progress during the funding cycle at your convenience. Lee-Way Jin will serve as the mentor for your project.

Congratulations on being selected to receive one of our pilot awards. Please do not hesitate to contact me directly at 916-734-8413 with any questions you might have. We look forward to working with you.

Sincerely,

A handwritten signature in black ink, appearing to read "Charles DeCarli".

Charles DeCarli, MD  
Professor of Neurology  
Director, Alzheimer's Disease Center &  
Imaging of Dementia and Aging (IDeA) Laboratory  
Department of Neurology and Center for Neuroscience  
University of California at Davis  
4860 Y Street, Suite 3700  
Sacramento, CA 95817

UC Davis Alzheimer's Disease Center Pilot Program  
Terms and Conditions  
July 1, 2020 – June 30, 2021

As principal investigator of the pilot application, "Developing a stem cell-based multifaceted treatment for Alzheimer's disease," I agree to the following terms and conditions in exchange for receipt of \$32,000 from the ADC pilot program.

1. If applicable, obtain approval from the appropriate regulatory body when using human subjects or animals for biomedical research within two months of acceptance of this award. Please send the approval letter and protocol to Charles DeCarli MD. The funds will be awarded once the full approval has been received.
2. Establish an account through your institution for recording income and expenses associated with this project for the period July 1, 2020 – June 30, 2021. Contact your department grants management staff to advise them of this award. Jayne La Grande (916-734-5728) is available to assist with any needed information.
3. Discuss study design with ADC biostatistical experts within three weeks of acceptance. You may contact either Bharat Rajan (530-752-2042) or Danielle Harvey (530-752-8036).
4. Present proposed pilot study application at an upcoming ADC Research meeting no later than October 31, 2020. Meetings are generally held twice monthly on Thursdays between 9-11 a.m. Contact Shelly Allocco at [saalloccocdavis.edu](mailto:saalloccocdavis.edu) to arrange a date and time.
5. Promote the ADC Pilot program by presenting your pilot project at the UC Davis Alzheimer's Research Forum and/or the Northern California Alzheimer's Research Symposium (usually held in the fall). You will be advised of the specific dates.
6. Meet with your mentor, Lee-Way Jin, on a quarterly basis beginning in October 2020 to review your progress.
7. Complete a Progress Report Summary and associated enrollment form, if applicable, to be filed with the parent grant progress report (RPPR format). This report should be reviewed with your mentor prior to submitting to Jayne La Grande at [jmlagrande@ucdavis.edu](mailto:jmlagrande@ucdavis.edu) no later than April 1, 2021.
8. Present your pilot study and findings at an April 2021 ADC Research meeting. Experts will be available to discuss subsequent funding opportunities and publication plans. Please contact Shelly Allocco to schedule.
9. 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 on Aging of the National Institutes of Health under Award Number P30AG010129. 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 and Carole Gan in UCDH Public Affairs (916-734-9047).

10. Each publication citing ADC award number P30AG010129 must comply with the NIH public access policy for peer reviewed journal manuscripts upon acceptance for publication. *A PMCID number will be required in order to report publications in the annual ADC progress report.*
11. On April 1 of each year, provide a report outlining your publication activity and acquisition of new research funding resulting from the pilot award to the ADC Center Director and Administrator. We report this information annually to our NIH program officials.

**Accept**



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**Date**

8/26/2020

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**Shriners Hospitals**  
for Children®

**International Headquarters**  
Pediatric Specialty Care

May 30, 2019

Dake Hao, 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. Hao,

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

84705 **Dake Hao, Ph.D.**

RF Engineering the developmental milieu to repair spina bifida bony defect in utero

~~\$34,456.00~~

7/1/2019

12/31/2019

Year 1 (6 mos) of 2

**\$35,456.00** According to proposal central.

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.
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- 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**

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### **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.
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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.**
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- Western Institutional Review Board (WIRB) approval of the protocol and informed consent form.
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  - 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".
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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.

#84705 / Engineering the developmental milieu to repair spina bifida bony defect in utero

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

Dale H. O.

Signature of Principal Investigator

6/10/2019

Date