



NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES

Grant Number: 5R01DK067071-13
FAIN: R01DK067071

Principal Investigator(s):
MICHAEL L. CAMILLERI, MD

Project Title: Effects of Liraglutide on Gastric Functions and their Relationship to Weight Loss in Obesity

Janice Grace
Institutional Official
200 First Street SW
Rochester, MN 559050001

Award e-mailed to: researchadmin@mayo.edu

Period Of Performance:

Budget Period: 09/01/2018 – 08/31/2019

Project Period: 09/30/2004 – 08/31/2021

Dear Business Official:

The National Institutes of Health hereby awards a grant in the amount of \$514,059 (see “Award Calculation” in Section I and “Terms and Conditions” in Section III) to Mayo Clinic 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 Diabetes And Digestive And Kidney Diseases of the National Institutes of Health under Award Number R01DK067071. 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,

Charmaine Parsad
Grants Management Officer
NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES

Additional information follows

SECTION I – AWARD DATA – 5R01DK067071-13**Award Calculation (U.S. Dollars)**

Salaries and Wages	\$113,501
Fringe Benefits	\$38,495
Personnel Costs (Subtotal)	\$151,996
Materials & Supplies	\$118,775
Other	\$54,229

Federal Direct Costs	\$325,000
Federal F&A Costs	\$189,059
Approved Budget	\$514,059
Total Amount of Federal Funds Obligated (Federal Share)	\$514,059
TOTAL FEDERAL AWARD AMOUNT	\$514,059

AMOUNT OF THIS ACTION (FEDERAL SHARE) \$514,059

SUMMARY TOTALS FOR ALL YEARS		
YR	THIS AWARD	CUMULATIVE TOTALS
13	\$514,059	\$514,059
14	\$514,059	\$514,059
15	\$317,078	\$317,078

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

Fiscal Information:

CFDA Name: Diabetes, Digestive, and Kidney Diseases Extramural Research
CFDA Number: 93.847
EIN: 1416011702A1
Document Number: RDK067071D
PMS Account Type: P (Subaccount)
Fiscal Year: 2018

IC	CAN	2018	2019	2020
DK	8472277	\$514,059	\$514,059	\$317,078

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

NIH Administrative Data:

PCC: NPM CONP / **OC:** 414E / **Released:** PARSADC 07/24/2018
Award Processed: 07/27/2018 12:09:52 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 5R01DK067071-13

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

SECTION III – TERMS AND CONDITIONS – 5R01DK067071-13

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:

- a. The grant program legislation and program regulation cited in this Notice of Award.
- b. 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).

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) R01DK067071. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

This award is not subject to the Transparency Act subaward and executive compensation reporting requirement of 2 CFR Part 170.

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 provides support for one or more clinical trials. By law (Title VIII, Section 801 of [Public Law 110-85](#)), the “responsible party” must register “applicable clinical trials” on the [ClinicalTrials.gov Protocol Registration System Information Website](#). NIH encourages registration of all trials whether required under the law or not. For more information, see http://grants.nih.gov/ClinicalTrials_fdaaa/

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: Yes

This award supports one or more NIH-defined Clinical Trials. See the NIH Grants Policy Statement Section 1.2 for NIH definition of Clinical Trial.

In accordance with NIH Guide Notice [NOT-OD-18-137](#), Notice of Salary Limitation on Grants, Cooperative Agreements, and Contracts, none of the funds in this award shall be used to pay the salary of an individual at a rate in excess of the applicable salary cap. Therefore, this award and/or future years are adjusted accordingly, if applicable. See the [Salary Cap Summary](#) for a historical record of the salary cap, including effective dates.

Plan for the Dissemination of NIH-funded Clinical Trial Information:

1. The clinical trial(s) supported by this award is subject to the plan dated July 2018 submitted to NIH and the NIH policy on *Dissemination of NIH-Funded Clinical Trial Information*. The plan states that the clinical trial(s) funded by this award will be registered in ClinicalTrials.gov not later than 21 calendar days after enrollment of the first participant and primary summary results reported in ClinicalTrials.gov, not later than one year after the completion date. The reporting of summary results is required by this term of award even if the primary completion date occurs after the period of performance.
2. This award is subject to additional certification requirements with each submission of the Annual, Interim, and Final Research Performance Progress Report (RPPR). The recipient must agree to the following annual certification when submitting each RPPR. By submitting the RPPR, the AOR signifies compliance, as follows:

In submitting this RPPR, the SO (or PD/PI with delegated authority), certifies to the best of his/her knowledge that, for all clinical trials funded under this NIH award, the recipient and all investigators conducting NIH-funded clinical trials are in compliance with the recipient's plan addressing compliance with the NIH Policy on Dissemination of NIH-Funded Clinical Trial Information. Any clinical trial funded in whole or in part under this award has been registered in ClinicalTrials.gov or will be registered not later than 21 calendar days after enrollment of the first participant. Summary results have been submitted to ClinicalTrials.gov or will be submitted not later than one year after the completion date, even if the completion date occurs after the period of performance.

Inclusion Monitoring

The NIH is mandated by law (Public Health Service Act sec. 492B, 42 U.S.C. sec. 289a-2) to ensure the inclusion of women and minority groups in clinical research. The goal is to ensure that individuals are included in clinical research in a manner that is appropriate to the scientific question under study.

Investigators must report sex/gender, race, and ethnicity information using the Inclusion Management System (IMS) module in the eRA Commons. For more information see the NIH Guide Notice [NOT-OD-15-005](#).

See the budget information below for additional information.

Grantees can determine which progress reports are due through the website located at <https://public.era.nih.gov/chl/public/search/index.jsp>, and should periodically check the site, which is updated on or around the 30th of each month. Progress report due dates are also available in the eRA Commons Status system. In addition, automatic e-mail notifications are sent to the PD/PI prior to due date.

As of October 17, 2014, the National Institutes of Health (NIH) requires grantees to submit all type 5 progress reports using the eRA [Research Performance Progress Report \(RPPR\)](#) module. Annual progress reports submitted in any format other than the RPPR will not be processed by the NIH and will require resubmission through the RPPR module in accordance with NIH Guide Notice [NOT-OD-15-014](#) released October 16, 2014.

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: Charmaine Parsad
Email: parsadrc@mail.nih.gov **Phone:** 301-451-0152 **Fax:** 301-451-5462

Program Official: Padma Maruvada
Email: maruvadp@mail.nih.gov **Phone:** 301-594-8884 **Fax:** 301-480-8300

SPREADSHEET SUMMARY

GRANT NUMBER: 5R01DK067071-13

INSTITUTION: Mayo Clinic

Budget	Year 13	Year 14	Year 15
Salaries and Wages	\$113,501	\$113,462	\$104,537
Fringe Benefits	\$38,495	\$38,534	\$35,333
Personnel Costs (Subtotal)	\$151,996	\$151,996	\$139,870
Materials & Supplies	\$118,775	\$118,775	\$38,580
Other	\$54,229	\$54,229	\$21,550
TOTAL FEDERAL DC	\$325,000	\$325,000	\$200,000
TOTAL FEDERAL F&A	\$189,059	\$189,059	\$117,078
TOTAL COST	\$514,059	\$514,059	\$317,078

Facilities and Administrative Costs	Year 13	Year 14	Year 15
F&A Cost Rate 1	59%	59%	59%
F&A Cost Base 1	\$320,439	\$320,439	\$198,438
F&A Costs 1	\$189,059	\$189,059	\$117,078