



Grant Number: 1K23DK082619-01A1 REVISED

Principal Investigator(s):

DANIEL A LEFFLER, MD

Project Title: Non-invasive markers of celiac disease activity during gluten challenge

DIR, OFC OF SPONSORED PROGRAMS
BETH ISRAEL DEACONESS MED CTR
330 BROOKLINE AVENUE, BR 264
BOSTON, MA 02115

Award e-mailed to: resadmin@bidmc.harvard.edu

Budget Period: 08/01/2009 – 07/31/2010

Project Period: 08/01/2009 – 07/31/2014

Dear Business Official:

The National Institutes of Health hereby revises this award (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to BETH ISRAEL DEACONESS MEDICAL CENTER 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 that cites results from NIH grant-supported research must include an acknowledgment of NIH grant support and disclaimer such as "The project described was supported by Award Number K23DK082619 from the National Institute Of Diabetes And Digestive And Kidney Diseases. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institute Of Diabetes And Digestive And Kidney Diseases or the National Institutes of Health."

Award recipients are required to comply with the NIH Public Access Policy. This includes submission to PubMed Central (PMC), upon acceptance for publication, an electronic version of a final peer-reviewed, manuscript resulting from research supported in whole or in part, with direct costs from National Institutes of Health. The author's final peer-reviewed manuscript is defined as the final version accepted for journal publication, and includes all modifications from the publishing peer review process. For additional information, please visit <http://publicaccess.nih.gov/>.

Award recipients must promote objectivity in research by establishing standards to ensure that the design, conduct and reporting of research funded under NIH-funded awards are not biased by a conflicting financial interest of an Investigator. Investigator is defined as the Principal Investigator and any other person who is responsible for the design, conduct, or reporting of NIH-funded research or proposed research, including the Investigator's spouse and dependent children. Awardees must have a written administrative process to identify and manage financial conflict of interest and must inform Investigators of the conflict of interest policy and of the Investigators' responsibilities. Prior to expenditure of these awarded funds, the Awardee must report to the NIH Awarding Component the existence of a conflicting interest and within 60 days of any new conflicting interests identified after the initial report. Awardees must comply with these and all other aspects of 42 CFR Part 50, Subpart F. These requirements also apply to subgrantees, contractors, or collaborators engaged by the Awardee under this award. The NIH website <http://grants.nih.gov/grants/policy/coi/index.htm> provides additional information.

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

Sincerely yours,

SHARON BOURQUE
Grants Management Officer
NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES

Additional information follows

SECTION I – AWARD DATA – 1K23DK082619-01A1 REVISED**Award Calculation (U.S. Dollars)**

Salaries and Wages	\$107,197
Fringe Benefits	\$28,393
Personnel Costs (Subtotal)	\$135,590
Supplies	\$16,673
Travel Costs	\$3,439
Other Costs	\$8,599

Federal Direct Costs	\$164,301
Federal F&A Costs	\$13,144
Approved Budget	\$177,445
Federal Share	\$177,445
TOTAL FEDERAL AWARD AMOUNT	\$177,445

AMOUNT OF THIS ACTION (FEDERAL SHARE) \$0

SUMMARY TOTALS FOR ALL YEARS		
YR	THIS AWARD	CUMULATIVE TOTALS
1	\$177,445	\$177,445
2	\$177,445	\$177,445
3	\$177,445	\$177,445
4	\$177,445	\$177,445
5	\$177,445	\$177,445

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

Fiscal Information:

CFDA Number: 93.847
 EIN: 1042103881A1
 Document Number: KDK082619A
 Fiscal Year: 2009

IC	CAN	2009	2010	2011	2012	2013
DK	8475349	\$177,445	\$177,445	\$177,445	\$177,445	\$177,445

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

NIH Administrative Data:

PCC: NJP DDTR / OC: 415L / Processed: BOURQUES 08/05/2009

SECTION II – PAYMENT/HOTLINE INFORMATION – 1K23DK082619-01A1 REVISED

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 – 1K23DK082619-01A1 REVISED

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 74 or 45 CFR Part 92 as applicable.
- The NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
- 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.)

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).

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/>.

Treatment of Program Income:

Additional Costs

SECTION IV – DK Special Terms and Conditions – 1K23DK082619-01A1 REVISED

Revision #1

Revised award issued to remove previous restriction on human subjects research due to concerns about a monitoring board. The Office of Extramural Programs, NIH has concurred that the human subjects issues have been appropriately addressed and the prior restrictions are removed.

NOGA issued 7/23/2009

Mentored career development awards (K awards) recipients please be aware of the following notice regarding concurrent support on a research grant <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-065.html>.

Salary and Fringe Benefits support for the principal investigator must be in accordance with guidelines for this mechanism of support. These funds are restricted and may not be used for any other purpose without prior approval of the awarding office.

The amount requested exceeds the maximum allowed by guidelines and has been reduced accordingly.

Grantees must access a website to determine which progress reports are due. The Office of Policy for Extramural Research Administration, OER, National Institutes of Health (NIH) hosts the website located at: http://era.nih.gov/userreports/pr_due.cfm. Grantees are responsible for periodically checking the list, which is updated on/around the 30th of each month. In addition to this website, e-mail reminders are sent to the Principal Investigator.

Effective October 1, 2004, NIH centralized receipt and initial processing of all NIH non-competing progress reports. The new centralized mailing address for all NIH Institutes/Centers (IC) is now:

Division of Extramural Activities Support, OER
National Institutes of Health
6705 Rockledge Drive, Room 2207, MSC 7987
Bethesda, MD 20892-7987 (for regular or US Postal Service Express mail)
Bethesda, MD 20817 (for other courier/express mail delivery only)
Phone Number: (301) 594-6584

RESTRICTION: This award is issued subject to the following special condition: Only activities that do not directly involve human subjects (i.e., are clearly severable and independent from those activities that do involve human subjects) may be conducted under this award until the following issues are resolved: reviewers concerns about the use of a DSMP as opposed to a DSMB, have been resolved to the satisfaction of the NIH, NIDDK.

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: Sharon Bourque
Email: bourques@extra.niddk.nih.gov **Phone:** (301) 594-8846 **Fax:** (301) 594-9523

Program Official: Judith M. Podskalny
Email: podskalnyj@extra.niddk.nih.gov **Phone:** (301) 594-8876 **Fax:** (301) 480-8300

SPREADSHEET SUMMARY

GRANT NUMBER: 1K23DK082619-01A1 REVISED

INSTITUTION: BETH ISRAEL DEACONESS MEDICAL CENTER

Budget	Year 1	Year 2	Year 3	Year 4	Year 5
Salaries and Wages	\$107,197	\$107,197	\$107,197	\$107,197	\$107,197
Fringe Benefits	\$28,393	\$28,393	\$28,393	\$28,393	\$28,393
Personnel Costs (Subtotal)	\$135,590	\$135,590	\$135,590	\$135,590	\$135,590
Supplies	\$16,673	\$16,673	\$16,673	\$16,673	\$16,673
Travel Costs	\$3,439	\$3,439	\$3,439	\$3,439	\$3,439
Other Costs	\$8,599	\$8,599	\$8,599	\$8,599	\$8,599
TOTAL FEDERAL DC	\$164,301	\$164,301	\$164,301	\$164,301	\$164,301
TOTAL FEDERAL F&A	\$13,144	\$13,144	\$13,144	\$13,144	\$13,144
TOTAL COST	\$177,445	\$177,445	\$177,445	\$177,445	\$177,445

Facilities and Administrative Costs	Year 1	Year 2	Year 3	Year 4	Year 5
F&A Cost Rate 1	8%	8%	8%	8%	8%
F&A Cost Base 1	\$164,301	\$164,301	\$164,301	\$164,301	\$164,301
F&A Costs 1	\$13,144	\$13,144	\$13,144	\$13,144	\$13,144



NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES

Grant Number: 5T32DK007760-20
FAIN: T32DK007760

Principal Investigator(s):
Ciaran P Kelly, MB

Project Title: Research Training in Gastroenterology

Ms. Jennifer Sabbagh
Research Administrative Director
Beth Israel Deaconess Medical Center
Office of Sponsored Programs
330 Brookline Avenue, BR-0216
Boston, MA 02215

Award e-mailed to: resadmin@bidmc.harvard.edu

Period Of Performance:
Budget Period: 05/01/2019 – 04/30/2020
Project Period: 07/01/1999 – 04/30/2020

Dear Business Official:

The National Institutes of Health hereby awards a grant in the amount of \$301,821 (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to BETH ISRAEL DEACONESS MEDICAL CENTER in support of the above referenced project. This award is pursuant to the authority of 42 USC 288 42 CFR 66 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 T32DK007760. 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,

Mitchell D. Curling
Grants Management Officer
NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES

Additional information follows

SECTION I – AWARD DATA – 5T32DK007760-20**Award Calculation (U.S. Dollars)**

Stipends	\$232,128
Tuition & Fees	\$29,500
Trainee Travel	\$4,000
Training related Expenses	\$43,400
Federal Direct Costs	\$309,028
Federal F&A Costs	\$22,362
Approved Budget	\$331,390
Total Amount of Federal Funds Obligated (Federal Share)	\$331,390
Less Unobligated Balance	\$29,569
TOTAL FEDERAL AWARD AMOUNT	\$301,821
AMOUNT OF THIS ACTION (FEDERAL SHARE)	\$301,821

SUMMARY TOTALS FOR ALL YEARS								
YR	THIS AWARD				CUMULATIVE TOTALS			
	Total	Pre	Post	Short Term	Cumulative Total	Pre	Post	Short Term
20	\$301,821		4		\$301,821		4	

Fiscal Information:

CFDA Name: Diabetes, Digestive, and Kidney Diseases Extramural Research
CFDA Number: 93.847
EIN: 1042103881A1
Document Number: TDK007760D
PMS Account Type: P (Subaccount)
Fiscal Year: 2019

IC	CAN	2019
DK	8472292	\$301,821

NIH Administrative Data:

PCC: NCD DDTR / **OC:** 412R / **Released:** CURLINGM0 04/08/2019
Award Processed:4/9/2019 12:05:29 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 5T32DK007760-20

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 – 5T32DK007760-20

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.

- 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).

Carry over of an unobligated balance into the next budget period requires Grants Management Officer prior approval.

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) T32DK007760. 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 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 expenditure 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. 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.

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. 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.*

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.

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:

Other Research (Add/Deduct Option)

SECTION IV – DK Special Terms and Conditions – 5T32DK007760-20

This award is issued in accordance with the NIH 2019 fiscal policies described in the NIH Guide Notice [NOT-OD-19-036](#).

This award uses as an offset the unobligated balance of \$29,569 from the year 18 Federal Financial Report.

This award represents the final year of the competitive segment for this grant. If the grant is no-cost extended, only trainees currently supported may be reappointed during the extension period. No new trainees may be appointed during this period.

Postdoctoral trainees with no clinical responsibilities (e.g. Ph.D. degree, M.D. degree with no U.S. board certification) and more than 5 years of postdoctoral research experience (i.e. stipend level 6 or higher) must receive prior approval from the NIDDK before being appointed to an NIDDK training grant. Only in unusual cases will such approval be given. Advanced postdoctoral scientists working in NIDDK-relevant research areas should consider applying for the NIDDK Mentored Research Scientist Development Award (K01).

Grantees must seek prior approval for the addition of new training program faculty. An authorized institutional business official should submit the request to the Program Official and Grants Management Specialist identified in the Commons for this award. A current biosketch of the proposed mentor should be included in the request.

Appointed trainees are required to engage in research relevant to the mission of the NIDDK. For information on relevant research topics, please refer to <http://www.niddk.nih.gov/about->

niddk/research-areas/pages/research-areas.aspx. The Program Official identified in the Commons for this award should be contacted for any questions.

The National Institutes of Health (NIH) requires the use of the xTrain Commons module to electronically prepare and submit the PHS 2271 Statement of Appointment form and PHS 416-7 Termination Notice for institutional research training grants. PHS 2271 Statement of Appointment forms must be submitted for each trainee, each year, prior to or at the time of appointment. Guidance regarding this policy requirement is communicated in the NIH Guide Notice [NOT-OD-10-072](#). Information on xTrain can be found at http://era.nih.gov/services_for_applicants/other/xTrain.cfm.

The [PHS 6031 Payback Agreement](#) must be submitted for all postdoctoral trainees beginning their initial NRSA appointment. The original executed [Payback Agreement](#) must be mailed to the Grants Management Specialist identified in the Commons at the below-referenced address.

Grants Management Branch, NIDDK
Two Democracy Plaza
6707 Democracy Boulevard
Suite 7300A, MSC 5456
Bethesda, MD 20892 (use 20817 for FedEx, UPS, Priority Mail))

Within 30 days of the end of the total support period for each trainee, the institution must submit a PHS Form 416-7 Termination Notice electronically using the eRA Commons xTrain application.

No stipend or other allowances may be paid until submission of the proper forms. Failure to submit these forms within 90 days of the start date of the appointment may result in an expenditure disallowance or a delay in continued funding.

It is understood that no trainee will be permitted to work on any project involving live vertebrate animals or human subjects that has not been approved by the IACUC and/or IRB, as appropriate.

In accordance with the NIH Guide Notice [NOT-OD-06-093](#) dated August 18, 2006, entitled "Revision: Notice of New NIH Policy for Funding of Tuition, Fees, and Health Insurance on Ruth L. Kirschstein National Research Service Awards," the Tuition and Fees category has been calculated using the following per trainee formula: the amount per predoctoral trainee equal to 60% of the level requested by the institution and up to \$16,000 per year (unless dual degree program); and for post-doctoral trainees an amount per trainee equal to 60% of level requested by institution and up to \$4,500 per year (unless the trainee is enrolled in a program that supports postdoctoral individuals in formal degree-granting training).

In accordance with Public Health Service Policy, trainee appointments of less than 9 months duration require written prior approval from the awarding office. The NIDDK has adopted a one person-one slot policy whereby a trainee whose appointment terminates prior to scheduled completion may not be replaced by a new appointee for the remaining number of months.

Trainee appointments may begin at any time during the budget period. When an appointment starts in a budget period, the entire stipend for that appointment must be charged to that same budget period. Trainee appointments may extend beyond the end date of the budget period to accommodate a normal 12-month appointment. That is, such appointments need not coincide with the end of the budget period.

FEDERAL FINANCIAL REPORT (FFR):

At the end of a competitive segment, NIH requires a Federal Financial Report (FFR) to be submitted through the eRA Commons within 120 days after the period of performance end date. The FFR must have no unliquidated obligations and must indicate the exact balance of unobligated funds. See [Administrative Requirements-Monitoring-Reporting-Financial Reports](#) and [Administrative Requirements-Closeout-Final Reports](#). The FFR is due whether or not a competing continuation is made. If no further award is made, it will serve as the final FFR.

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: Jayanthi (jay) Regunathan
Email: Jayanthi.regunathan@nih.gov **Phone:** 301-827-4380

Program Official: Christine L Densmore
Email: densmorec@extra.niddk.nih.gov **Phone:** (301) 402-8714 **Fax:** (301) 480-8300

SPREADSHEET SUMMARY

GRANT NUMBER: 5T32DK007760-20

INSTITUTION: BETH ISRAEL DEACONESS MEDICAL CENTER

Budget	Year 20
Stipends	\$232,128
Tuition & Fees	\$29,500
Trainee Travel	\$4,000
Training related Expenses	\$43,400
TOTAL FEDERAL DC	\$309,028
TOTAL FEDERAL F&A	\$22,362
TOTAL COST	\$301,821

Facilities and Administrative Costs	Year 20
F&A Cost Rate 1	8%
F&A Cost Base 1	\$279,528
F&A Costs 1	\$22,362



CENTER GRANT
Department of Health and Human Services
National Institutes of Health



NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES

Grant Number: 2P30DK034854-31

FAIN: P30DK034854

Principal Investigator(s):

WAYNE I LENCER, MD

Project Title: Integrated Epithelial and Mucosal Biology

Miss Trac, Tee
Senior Grant Officer
300 Longwood Avenue
Office of Sponsored Programs
Boston, MA 021155724

Award e-mailed to: osp@childrens.harvard.edu

Period Of Performance:

Budget Period: 04/01/2016 – 11/30/2016

Project Period: 09/01/1997 – 11/30/2020

Dear Business Official:

The National Institutes of Health hereby awards a grant in the amount of \$1,384,348 (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to CHILDREN'S HOSPITAL CORPORATION 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 P30DK034854. 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,

SHARON BOURQUE
Grants Management Officer
NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES

Additional information follows

SECTION I – AWARD DATA – 2P30DK034854-31**Award Calculation (U.S. Dollars)**

Salaries and Wages	\$169,408
Fringe Benefits	\$49,551
Personnel Costs (Subtotal)	\$218,959
Materials & Supplies	\$3,000
Travel	\$4,000
Other	\$193,121
Subawards/Consortium/Contractual Costs	\$565,576

Federal Direct Costs	\$984,656
Federal F&A Costs	\$399,692
Approved Budget	\$1,384,348
Total Amount of Federal Funds Obligated (Federal Share)	\$1,384,348
TOTAL FEDERAL AWARD AMOUNT	\$1,384,348

AMOUNT OF THIS ACTION (FEDERAL SHARE) \$1,384,348

SUMMARY TOTALS FOR ALL YEARS		
YR	THIS AWARD	CUMULATIVE TOTALS
31	\$1,384,348	\$1,384,348
32	\$1,307,347	\$1,307,347
33	\$1,307,347	\$1,307,347
34	\$1,297,304	\$1,297,304
35	\$1,297,304	\$1,297,304

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: 1042774441A1
Document Number: PDK034854G
PMS Account Type: P (Subaccount)
Fiscal Year: 2016

IC	CAN	2016	2017	2018	2019	2020
DK	8472282	\$1,384,348	\$1,307,347	\$1,307,347	\$1,297,304	\$1,297,304

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

NIH Administrative Data:

PCC: NPP DDRC / OC: 414B / Released: BOURQUES 03/16/2016
Award Processed: 03/22/2016 06:01:46 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 2P30DK034854-31

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 – 2P30DK034854-31

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 excluded from 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) P30DK034854. 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/>.

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

SECTION IV – DK Special Terms and Conditions – 2P30DK034854-31

This grant is in response to DK14-012. Acceptance of this award requires compliance with this solicitation. See the NIH Guide at <http://grants.nih.gov/grants/guide/index.html> for copy of the RFA/PA that includes administrative and programmatic requirements specific to this award.

This award is issued in accordance with the NIH 2016 fiscal policies described in the NIH Guide Notice [NOT-OD-16-046](#).

The award is based on the IRG recommendations as noted on the Summary Statement and no further administrative reductions have been taken.

See the spreadsheet below for additional information.

Pre-award Costs

Although the initial budget period for this award is 04/01/2016 – 11/30/2016, the award includes funds for 12 months of support. Future year budget periods will cycle on 12/01. Allowable preaward costs may be charged to this award in accordance with the conditions outlined in the [NIH Grants Policy Statement \(revised November 2015\)](#) and with institutional requirements for prior approval.

Effort Over Commitment

A review of other support information provided in Just in Time for this project indicates that with the award of this project, Dr. Wayne Lencer's effort commitment may exceed 100%. If applicable, the awardee is responsible for both eliminating this overcommitment (and any other overcommitment of effort or budgetary overlap) and for obtaining appropriate prior approval(s) in accordance with NIH and institutional policy requirements.

The grantee institution must submit documents certifying resolution of this overcommitment to the grants management specialist named in Notice of Grant Award in writing within 30 days of the issue date of this notice of grant award.

Key Personnel

In addition to the PI, the following individuals are named as key personnel:

- Richard Blumber, M.D.
- Lynn Bry, M.D.
- Wolfram Goessling, M.D., Ph.D.
- Susan J. Hagen, Ph.D.
- Jonathan C. Kagan, Ph.D.
- Scott Snapper, M.D.

Written prior approval is required if any of the individual(s) named above withdraws from the project entirely, is absent from the project during any continuous period of 3 months or more, or reduces time devoted to the project by 25 percent or more from the level that was approved at the time of award.

Human Subjects

In accordance with NIH policy <http://grants.nih.gov/grants/policy/hs/index.htm> and the NIH Guide Notice [NOT-OD-15-078](#), the awardee institution is required to submit the following documentation in their annual progress report for any P&F projects selected in the prior year that involve human subjects: <http://grants.nih.gov/grants/funding/424/SupplementalInstructions.pdf>

- Institutional Review Board (IRB) approval,
- Protection of Human Subjects section,
- the Inclusion Table,
- Education in the Protection of Human Research Participants certifications,
- and a description of progress on previously awarded projects.

No funds may be drawn down from the payment management system and no obligations/expenditures may be made against Federal funds for research involving human subjects at any site engaged in such research for any period not covered by both an OHRP-approved Assurance and by an IRB approval consistent with 45 CFR Part 46.

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. Separate Inclusion Data Records should be created for each individual P&F project.

Consortium

This award includes funds awarded for consortium activity with Brigham and Women's Hospital in the amount of \$327,121 total costs, and Beth Israel Deaconess Medical Center in the amount of \$159,050 total costs. Consortia are to be established and administered as described in the NIH Grants Policy Statement (revised November 2015).

Pilot and Feasibility Studies

This award includes \$100,000 and associated F&A costs for pilot and feasibility studies. These funds are restricted and may not be used for any other purpose without the written prior approval of the Awarding Office.

Funds awarded for pilot and feasibility studies and/or for support of a New Investigator Award, though restricted and not available for expenditure for other purposes, may be carried over to the next budget period and used for the originally awarded purposes.

Future Years of Support: Each budget period will be individually negotiated based on study progress and availability of funds.

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: Karin Mastrangelo
Email: mastrangelokj@nidk.nih.gov **Phone:** 301-443-3603 **Fax:** 301- 594-9523

Program Official: Peter J Perrin
Email: Peter.Perrin@nih.hhs.gov **Phone:** 301 451-3759 **Fax:** 301 480-8300

SPREADSHEET SUMMARY

GRANT NUMBER: 2P30DK034854-31

INSTITUTION: CHILDREN'S HOSPITAL CORPORATION

Budget	Year 31	Year 32	Year 33	Year 34	Year 35
Salaries and Wages	\$169,408	\$169,408	\$169,408	\$165,017	\$165,017
Fringe Benefits	\$49,551	\$49,551	\$49,551	\$48,267	\$48,267

Personnel Costs (Subtotal)	\$218,959	\$218,959	\$218,959	\$213,284	\$213,284
Materials & Supplies	\$3,000	\$3,000	\$3,000	\$3,000	\$3,000
Travel	\$4,000	\$4,000	\$4,000	\$4,000	\$4,000
Other	\$193,121	\$193,120	\$193,120	\$193,120	\$193,120
Subawards/Consortium/Contractual Costs	\$565,576	\$565,577	\$565,577	\$565,579	\$565,579
TOTAL FEDERAL DC	\$984,656	\$984,656	\$984,656	\$978,983	\$978,983
TOTAL FEDERAL F&A	\$399,692	\$322,691	\$322,691	\$318,321	\$318,321
TOTAL COST	\$1,384,348	\$1,307,347	\$1,307,347	\$1,297,304	\$1,297,304

Facilities and Administrative Costs	Year 31	Year 32	Year 33	Year 34	Year 35
F&A Cost Rate 1	77%	77%	77%	77%	77%
F&A Cost Base 1	\$519,080	\$419,079	\$419,079	\$413,404	\$413,404
F&A Costs 1	\$399,692	\$322,691	\$322,691	\$318,321	\$318,321