Notice of Grant Award

RESEARCH DEMONSTRATION COOPERATIVE AGREEMENTS

Issue Date: 08/31/2017

Department of Health and Human Services

FOOD AND DRUG ADMINISTRATION

Grant Number: 1U18FD006239-01
FAIN: U18FD006239

Principal Investigator:
Leon Luebbering, BS

Project Title: Maintenance and Enhancement of ISO/IEC 17025 Accreditation and Whole Genome Sequencing for State Food Testing Laboratories RFA-FD-17-010

Mr. Fischer, Bret
Director, Division of Administration
920 Wildwood Drive
PO Box 570
Jefferson City, MO 651020570

Budget Period: 09/05/2017 – 06/30/2018
Project Period: 09/05/2017 – 06/30/2019

Dear Business Official:

The Food and Drug Administration hereby awards a grant in the amount of $145,000 (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to MISSOURI STATE DEPT/ HEALTH & SENIOR SRV in support of the above referenced project. This award is pursuant to the authority of PHS Act,Sec 1706,42 USC 300u-5,as amended;Sec2(d),PL 98-551 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.

If you have any questions about this award, please contact the Grants Management Specialist and the Project Officer listed in the terms and conditions.

Sincerely yours,

Kimberly Pendleton
Grants Management Officer
Office of Acquisitions & Grants Services
Division of Acquisition Support and Grants
Grants & Assistance Team
FOOD AND DRUG ADMINISTRATION

See additional information below

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SECTION I – AWARD DATA – 1U18FD006239-01

Award Calculation (U.S. Dollars)

Salaries and Wages	$49,982
Fringe Benefits	$26,492
Personnel Costs (Subtotal)	$76,474
Supplies	$24,885
Travel Costs	$6,200
Other Costs	$21,074
Federal Direct Costs	$128,633
Federal F&A Costs	$16,367
Approved Budget	$145,000
Federal Share	$145,000
TOTAL FEDERAL AWARD AMOUNT	$145,000
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$145,000

SUMMARY TOTALS FOR ALL YEARS		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
1	$145,000	$145,000
2	$145,000	$145,000

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

Fiscal Information:

CFDA Number:	93.103
EIN:	[redacted]
Document Number:	UFD006239A
PMS AccountType	P(Subaccount)
Fiscal Year:	2017

IC	CAN	2017	2018
FD	6990928	$145,000	$145,000

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

FDA Administrative Data:
PCC: ORA19 / **OC**: 4141 / **Processed**: ERAAPPS 08/31/2017

SECTION II – PAYMENT/HOTLINE INFORMATION – 1U18FD006239-01

Grant payments will be made available through the DHHS Payment Management System (PMS). PMS is administered by the Division of Payment Management, Program Support Center (PSC), DHHS, Office of the Deputy Assistant Secretary, Finance. Requests for downloadable forms and inquiries regarding payment should be directed to:

Regular Mailing Address:
Division of Payment Management
P.O. Box 6021
Rockville, MD 20852
Telephone: (301) 443-1660

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Included are the following Links & Instructions for drawing down funds, reporting expenditures, required forms, and the help desk info:

Homepage: http://www.dpm.psc.gov/Default.aspx

Grant Recipient Information:
http://www.dpm.psc.gov/grant_recipient/grant_recipient.aspx?explorer.event=true

Grant Recipient Forms:
http://www.dpm.psc.gov/grant_recipient/grantee_forms.aspx?explorer.event=true

PMS Help Desk: http://www.dpm.psc.gov/help/help.aspx?explorer.event=true

The ONE-DHHS Help Desk for PMS Support is now available Monday – Friday from 7 a.m. to 9 p.m. EST (except Federal Holidays). Phone (877) 614-5533; Email PMSSupport@psc.gov

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SECTION III – TERMS AND CONDITIONS – 1U18FD006239-01

This award is based on the application submitted to, and as approved by, FDA on the above-title 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 Grant Award.
b. The restrictions on the expenditure of federal funds in appropriations acts to the extent those restrictions are pertinent to the award.
c. 45 CFR Part 75.
d. The HHS 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. A required Federal Financial Report (FFR) SF-425 must be submitted annually. FDA now requires all annual financial expenditure reports to be submitted electronically using the Federal Financial Report (FFR) system located in the eRA Commons. Annual FFRs must be submitted for each budget period no later than 90 days after the end of the calendar quarter in which the budget period ended. The reporting period for an annual FFR will be that of the budget period for the particular grant; however, the actual submission date is based on the calendar quarter. Failure to submit timely reports may affect future funding
g. Closeout Requirements (when applicable): A Final Program Progress Activity Report, Final Federal Financial Report SF-425, Final Invention Statement HHS-568 (if applicable), Tangible Personal Property Report SF-428, and Statement of Disposition of Equipment (if applicable) must be submitted within 90 days after the expiration date of the project period.
h. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

This award has been assigned the Federal Award Identification Number (FAIN) U18FD006239. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Treatment of Program Income:
Additional Costs

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.

SECTION IV – FD Special Terms and Condition – 1U18FD006239-01

SPECIAL PROGRAMMATIC TERMS AND CONDITIONS:

The following criteria shall be maintained to retain eligibility of future funding:

Competition A: ISO/IEC 17025 Accreditation Maintenance and Enhancement

1. Maintain ISO 17025 accreditation, including methods of interest to the FDA.
2. The State maintains a current food contract and is enrolled in MFRPS with FDA, and in good standing.
3. Remain the primary servicing laboratory for conducting microbiological and chemical food anaylses on behalf of the State agency enrolled in MFRPS.
4. Actively participate in the FERN, or enroll within 30 days of the award.
5. Maintain a current written agreement with the manufactured food program to participate in the Sample Collection and Analysis Project.
6. Enter surveillance and emergency response samples and share the results through eLEXNET.

Competition B: Whole Genome Sequencing

1. Maintain a Research Collaboration Agreement with FDA for the Genome Trackr network.
2. Sequence 400 or more isolates and deposit results, including metadata, in real-time to NCBI-NIH curated national database.

Failure to maintain any of the eligibility requirements at any stage in cooperative agreement project period may result in termination of the award.

A Mid-Year and End-of-Year/Annual Progress report are due annually for all competitions. The mid-year report shall be submitted to the Project Officer and Grants Management Specialist via email no later than Jan 30th in Year 1 and Feb 28th in Year 2. The annual progress report must be submitted through eRA commons, and is due no later than 60 days before the end of the budget period.

All progress reports shall contain certain elements as applicable to their approved competition and award. These elements include, but are not limited to, the following:

Competition A: ISO/IEC 17025 Accreditation Maintenance and Enhancement

1. An updated improvement plan for enhancing the scope of accreditation and maintaining accreditation within the established timeframes;
2. Hiring of new personnel and training of personnel in order to maintain and enhance ISO/IEC 17025 accreditation. The program shall include initial and ongoing training to ensure consistent quality and continuous improvement, including assisting laboratory personnel in maintaining current knowledge of scientific and technological advances in relevant areas;
3. Status report on the installation and operational readiness of any analytical equipment that is utilized in methods under scope of accreditation;

4. Summary of laboratory data shared with FDA and other regulatory agencies, including any regulatory actions taken by FDA or another regulatory agency or any significant laboratory findings that advanced the protection of public health;
5. Summary of samples collected and analyzed under the Sample Collection and Analysis Project. This should include the number of samples (including sub sizes), firm from which the sample was collected, matrices, analytes, and determinations;
6. Current funding level certification for the laboratory program from State funding appropriations (EOY report requirement only);
7. Budgetary status, to include the amount of funding expended to the date of the report and a detailed description of how this funding was utilized;
8. Summary of laboratory participation in FERN activities;
9. Evidence of samples submission into eLEXNET;
10. Current scope of ISO/IEC accreditation, and detailed information on the removal or addition of any methods;
11. Updated contact information on the key personnel working on the project; and
12. Summary of any programmatic issues and concerns.

Competition B: Whole Genome Sequencing

1. Summary of laboratory data shared with FDA and other regulatory agencies, including any regulatory actions taken by FDA or another regulatory agency or any significant laboratory findings that advanced the protection of public health;
2. Summary of foodborne pathogen isolates collected and sequenced under the Cooperative Agreement. This should include the number and type of isolates sequenced by each participating laboratory, including isolate metadata and NCBI BioProject and BioSample identifiers for isolates submitted to public databases;
3. Current funding level certification for the laboratory program from State funding appropriations (EOY report requirement only);
4. GenomeTrakr semi-monthly update call attendance;
5. GenomeTrakr semi-annual face-to-face meeting attendance;
6. Successful completion in the annual proficiency testing across the GenomeTrakr network;
7. Accept and sequence other network members' isolates as part of overflow assignments, at the request of FDA;
8. Budgetary status, to include the amount of funding expended to the date of the report and a detailed description of how this funding was utilized;
9. Updated contact information on the key personnel working on the project;
10. Summary of any programmatic issues and concerns

Competition C: ISO/IEC 17025 Accreditation and Whole Genome Sequencing Support Services

1. Development status and projected timeline of completion of any trainings, meetings, educational materials or resources for GenomeTrackr and ISO/IEC 17025 accreditation;
2. Overview of eLEXNET activities, to include trainings, marketing, and outreach. A summary of findings from any on-site trainings and any user submitted areas for improvement from the outreach and marketing activities shall also be included; and
3. Description of the support being provided to laboratories to obtain, maintain, and enhance ISO/IEC 17025 accreditation. This includes a summary of the monitoring activities and progress of the laboratories directly being supported through consultant services offered under this award;

The PD(s)/PI(s) shall retain the primary responsibility and dominant role for planning, directing, and
executing the proposed project. However, the cooperative agreement award mechanism will result in
substantial involvement by the FDA. Substantial involvement could include, but is not limited to (as
deemed necessary by FDA):

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1. Monitoring of progress through on-site visits, conference calls, emails, and other correspondence ;
2. Monitoring and approval of the Sample Collection and Analysis Projects;
3. Monitoring and approval of bacterial isolates to be sequenced by Whole Genome Sequencing;
4. Review and approval of training and workshop coursework, and meeting materials for the GenomeTrackr network; and
5. Technical and financial assistance to maintain and enhance laboratory accreditation, support the Sample Collection and Analysis Project, and GenomeTrackr activities.

This award is subject to the Special Requirements of the **RFA-FD-17-010**, entitled, **"Maintenance and Enhancement of ISO/IEC 17025 Accreditation and Whole Genome Sequencing for State Food Testing Laboratories"** is hereby incorporated by reference as special terms and conditions of this award. Copies of this announcement may be obtained from the Grants Management Contact referenced in the award.

This award is subject to the requirements of the HHS Grants Policy Statement (HHS GPS) that are applicable to you based on your recipient type and the purpose of this award. This includes any requirements in Parts I and II (available at http://www.hhs.gov/grantsnet/adminis/gpd/index.htm) of the HHS GPS that apply to an award.

Although consistent with the HHS GPS, any applicable statutory or regulatory requirements, including 45 CFR Part 75, directly apply to this award apart from any coverage in the HHS GPS that apply to an award.

Salary Cap: None of the funds in this award shall be used to pay the salary of an individual at a rate in excess of the current salary cap. Current salary cap level is $179,700.

STANDARD TERMS AND CONDITIONS:

2.A. Cooperative Agreement Terms and Conditions of Award

The following special terms of award are in addition to, and not in lieu of, otherwise applicable U.S. Office of Management and Budget (OMB) administrative guidelines, U.S. Department of Health and Human Services (HHS) grant administration regulations at 45 CFR Part 75, and other HHS, PHS, and FDA grant administration policies.

The administrative and funding instrument used for this program will be the cooperative agreement, an "assistance" mechanism (rather than an "acquisition" mechanism), in which substantial FDA programmatic involvement with the awardees is anticipated during the performance of the activities. Under the cooperative agreement, FDA's purpose is to support and stimulate the recipients' activities by involvement in and otherwise working jointly with the award recipients in a partnership role; it is not to assume direction, prime responsibility, or a dominant role in the activities. Consistent with this concept, the dominant role and prime responsibility resides with the awardees for the project as a whole, although specific tasks and activities may be shared among the awardees and FDA as defined below.

2.A.1. Principal Investigator Rights and Responsibilities

The PD(s)/PI(s) will have the primary responsibility for the scientific, technical, or programmatic aspects of the cooperative agreement and for day-to-day management of the project or program. The PD(s)/PI(s) will maintain general oversight for ensuring compliance with the financial and administrative aspects of the award, as well as ensuring that all staff have sufficient clearance and/or background checks to work on this project or program. This individual will work closely with designated officials within the recipient organization to create and maintain necessary documentation, including both technical and administrative reports; prepare justifications;

appropriately acknowledge Federal support in publications, announcements, news programs, and other media; and ensure compliance with other Federal and organizational requirements.

Awardees will retain custody of and have primary rights to the data and software developed under these awards, subject to Government rights of access consistent with current HHS, PHS, and FDA policies.

Additionally PD/PIs will:

1. Participate in site visits or attend meetings as requested by the FDA. A portion of the budget should be reserved for such travel.

2. FDA may also request data be made available through speaking engagements and publications, presentations at scientific symposia and seminars, while making sure that confidentiality and privacy of the data is protected.

3. The awardees will provide FDA any data obtained from investigations if requested by FDA.

4. Any publication or oral presentation of regarding outcomes of this grant must undergo FDA Office of Research and Center review and approval process. This process can take 30-90 days.

2. A.2. FDA Responsibilities

An FDA Project Officer (PO) will have substantial programmatic involvement as described below. The PO is the official responsible for the programmatic, scientific, and/or technical aspects of assigned applications and grants. The PO's responsibilities include, but are not limited to, post-award monitoring of project/program performance, including review of progress reports and making site visits; and other activities complementary to those of the Grants Management Officer (GMO). The PO and the GMO work as a team in many of these activities.

Additionally, an agency program official will be responsible for the scientific and programmatic stewardship of the award and will be named in the award notice.

FDA will provide technical monitoring and/or direction of the work, including monitoring of data analysis, interpretation of analytical findings and their significance.

FDA will assist and approve (as deemed appropriate) the substance of publications, co-authorship of publications and data release.

Financial Reporting:

A. Cash Transaction Reports

The Federal Financial Report (FFR) has a dedicated section to report Federal cash receipts and disbursements. For recipients this information must be submitted quarterly directly to the Payment Management System (PMS) using the web-based tool. Quarterly reports are due 30 days following the end of each calendar quarter. The reporting period for this report continues to be based on the calendar quarter. Questions concerning the requirements for this quarterly financial report should be directed to the PMS.

B. Financial Expenditure Reports

A required Federal Financial Report (FFR) must be submitted annually. FDA now requires all annual financial expenditure reports to be submitted electronically using the Federal Financial Report (FFR) system located in the eRA Commons. This includes all initial FFRs being prepared for submission and any revised FSR/FFRs being submitted or re-submitted to FDA. Paper expenditure/FFR reports will not accepted.

Annual FFRs must be submitted for each budget period no later than 90 days after the end of the calendar quarter in which the budget period ended. The reporting period for an annual FFR will be that of the budget period for the particular grant; however, the actual submission date is based on the calendar quarter. Failure to submit timely reports may affect future funding.

Performance Progress Reporting:

1. Annual progress reports are required. The Annual Progress Report will be due as part of the Research Performance Progress Report (RPPR).

2. Grants with Multiple Years: When multiple years are involved, awardees will be required to submit the Research Performance Progress Report (RPPR).

Information regarding submitting the RPPR is available at
https://era.nih.gov/erahelp/commons/default.htm#cshid=1020

PROGRAM INCOME:

1. The grantee is required to report any Program Income generated during the Project Period of this grant. Except for royalty income generated from patents and inventions, the amount and disposition of Program Income must be identified on lines 10 (l), (m), (n), and (o) of the grantee's Federal Financial Report (FFR) SF-425.

2. Examples of Program Income include (but are not limited to): fees for services performed during the grant or sub-grant period, proceeds from sale of tangible personal or real property, usage or rental fees, patent or copyright royalties, and proceeds from the sale of products and technology developed under the grant.

3. Any Program Income generated during the Project Period of this grant by the grantee or sub-grantee is subject to the Addition Alternative for Program Income and, therefore, must only be used to further the goals of the project for which this grant was awarded.

PRIOR APPROVAL:

All requests that require prior approval must include the award number and bear the signature of an authorized official of the grantee business office as well as that of the PI/PD. Any requests involving funding issues must include a new proposed budget and a narrative justification of the requested changes. If a grantee questions whether prior approval is required for an activity or cost, they should contact the assigned Grants Management Specialist prior to expenditure of funds for clarification. Below are activities that require prior approval from FDA:

1. CHANGE IN SCOPE OR OBJECTIVES
2. CHANGE IN KEY PERSONNEL
3. CHANGE IN GRANTEE ORGANIZATION
4. DEVIATION FROM TERMS AND CONDITIONS OF THE AWARD
5. CARRYOVER OF UNOBLIGATED BALANCES
6. NO COST EXTENSIONS
7. SIGNIFICANT REBUDGETING

ACKNOWLEDGEMENT OF FEDERAL SUPPORT:

When issuing statements, press releases, publications and other documents describing projects or programs funded in whole or in part with Federal money, all awardees receiving Federal funds, including and not limited to State and local governments and recipients of Federal research grants, shall clearly state:

*Funding for this statement, publication, press release, etc. was made possible, in part, by the Food and Drug Administration through grant **U18FD006239.** Views expressed in written materials or publications and by speakers and moderators do not necessarily reflect the official policies of

the Department of Health and Human Services; nor does any mention of trade names, commercial practices, or organization imply endorsement by the United States Government.*

FDA/ORA CONTACT INFORMATION:

Grants Management Contact:
Kiara Fowler
Grants Management Specialist
Food and Drug Administration, MSC HFA-500
5630 Fishers Lane, Rockville, MD 20857
Phone: 240.402.0399
Email: kiara.fowler@fda.hhs.gov

Programmatic Contact:
Erin Woodom-Coleman
Project Officer
12420 Parklawn Drive
Rockville, MD 20857
Phone: (240) 402-4617
Email: erin.woodom-coleman@fda.hhs.gov

FAILURE TO COMPLY WITH THE ABOVE STATED TERMS AND CONDITIONS COULD RESULT IN THE SUSPENSION OR TERMINATION OF THIS COOPERATIVE AGREEMENT.

All formal correspondence/reports regarding the grant should be signed by an authorized institutional official and the Principal Investigator and should be sent to the attention of the grants management specialist, unless otherwise directed.

Direct inquiries regarding scientific programmatic issues to the official listed below.

Direct inquiries regarding fiscal and/or administrative matters to the grants management specialist listed below.

All formal correspondence/reports regarding the grant should be signed by an authorized institutional official and the Principal Investigator and should be sent to the attention of the grants management specialist, unless otherwise explicitly directed.

STAFF CONTACTS
Grants Management Specialist: Kiara Fowler
Email: Kiara.Fowler@fda.hhs.gov

SPREADSHEET SUMMARY
GRANT NUMBER: 1U18FD006239-01

INSTITUTION: MISSOURI STATE DEPT/ HEALTH & SENIOR SRV

Budget	Year 1	Year 2
Salaries and Wages	$49,982	$49,982
Fringe Benefits	$26,492	$26,492
Personnel Costs (Subtotal)	$76,474	$76,474
Supplies	$24,885	$24,885
Travel Costs	$6,200	$6,200
Other Costs	$21,074	$21,074

TOTAL FEDERAL DC	**$128,633**	**$128,633**
TOTAL FEDERAL F&A	**$16,367**	**$16,367**
TOTAL COST	**$145,000**	**$145,000**