



FOOD AND DRUG ADMINISTRATION

Grant Number: 5U01FD005780-03 REVISED
FAIN: U01FD005780

Principal Investigator:
Leon Luebbering, BS

Project Title: National Antimicrobial Resistance Monitoring System (NARMS)- Surveillance in Retail Food Specimens in Missouri

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

Award e-mailed to: grants@health.mo.gov

Budget Period: 09/01/2018 – 08/31/2019
Project Period: 09/01/2016 – 08/31/2021

Dear Business Official:

The Food and Drug Administration hereby revises this award (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 42 USC 241 31 USC 6305 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.

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

SECTION I – AWARD DATA – 5U01FD005780-03 REVISED

Award Calculation (U.S. Dollars)

Salaries and Wages	\$49,836
Fringe Benefits	\$28,906
Personnel Costs (Subtotal)	\$78,742
Supplies	\$40,498
Travel Costs	\$888
Other Costs	\$2,817

Federal Direct Costs	\$122,945
Federal F&A Costs	\$16,772
Approved Budget	\$139,717
Federal Share	\$139,717
Less Unobligated Balance	\$18,680
TOTAL FEDERAL AWARD AMOUNT	\$121,037

AMOUNT OF THIS ACTION (FEDERAL SHARE) \$0

SUMMARY TOTALS FOR ALL YEARS			
YR	THIS AWARD	CUMULATIVE TOTALS	
3	\$121,037	\$121,037	
4	\$124,296	\$124,296	
5	\$124,296	\$124,296	

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

Fiscal Information:

CFDA Number: 93.876
 EIN: XXXXXXXXXX
 Document Number: UFD005780A
 PMS AccountType P(Subaccount)
 Fiscal Year: 2018

IC	CAN	2018	2019	2020
FD	6999DMY	\$121,037	\$124,296	\$124,296

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

FDA Administrative Data:

PCC: CVM4 / OC: 4141 / Processed: FDAKPU 11/26/2018

SECTION II – PAYMENT/HOTLINE INFORMATION – 5U01FD005780-03 REVISED

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

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

SECTION III – TERMS AND CONDITIONS – 5U01FD005780-03 REVISED

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) U01FD005780. 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 – 5U01FD005780-03 REVISED

11/26/2018: This award is being revised to reflect the submitted revised budget. Line items have been adjusted accordingly.

ALL PREVIOUS TERMS AND CONDITIONS REMAIN IN EFFECT

08/20/2018: This award has been issued with an \$18,680 offset to be applied to the FY18 award. Total new funds to be obligated will be \$121,037. Total award with offset will be \$139,717. A revised budget for \$139,717 to include the seafood pilot study will be required within 60 days of award.

This award is subject to the Special Requirements of the **PAR-16-099**, entitled, **NARMS Cooperative Agreement Program to Enhance and Strengthen Antibiotic Resistance Surveillance in Retail Food Specimens (U01)** 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.

SPECIAL TERMS AND CONDITIONS

The following conditions of the award will apply to all funded applicants and must be maintained throughout the cooperative agreement; these conditions include, but are not limited, to those listed below:

1. Actively participate in NARMS conference calls and working groups.
2. Implement NARMS sampling and laboratory protocols to ensure standardized methodologies.
3. Implement standardized data collection and isolate transmission protocols.
4. Provide FDA with a list of sampling areas that meet the NARMS sampling requirements.
5. Collect fresh retail meat at a minimum of 2 non-consecutive days per month from pre-selected retail locations.

6. Perform microbiological tests on retail meat samples according to the final application accepted by FDA.
7. Participate in NARMS pilot studies to examine novel fresh retail meat samples or to assess resistance in other organisms as specified in ad hoc pilot studies.
8. Provide serotype and/or species identifications for isolates when available.
9. Send isolates to the FDA on a monthly basis for antimicrobial susceptibility testing and other analyses.

Specific activities that are NOT supported by this cooperative agreement include but are not limited to those listed below:

1. Molecular testing of isolates cultured from fresh retail meat/food for the NARMS program.
2. Collection and testing of meats and/or food products not specified in the sampling assignment.
3. Isolation of organisms other than those agreed to or specified in pilot study programs.

FDA staff is substantially involved in the NARMS retail food surveillance program activities beyond routine grant monitoring which include but are not limited to the activities listed below:

1. Provide general coordination for all NARMS retail food surveillance sites and the overall NARMS network.
2. Develop, facilitate, and participate in collaborative multi-site relationships as needed to support the successful completion of the program activities.
3. Provide scientific consultation and technical assistance as necessary in the operation of the NARMS retail food surveillance program.
4. Facilitate the development of protocols, procedure manuals, and training of applicants.
5. Perform confirmatory bacterial identifications and antimicrobial susceptibility testing.
6. Perform whole genome sequencing and other molecular characterization of NARMS isolates.
7. Analyze, interpret, and disseminate surveillance results.
8. Any presentation of the results of testing must undergo FDA Office of Research and Center review and approval process. This process can take 30-90 days.
9. Coordinating and facilitating communications among NARMS retail food surveillance sites.

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 be 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#csid=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 **U01FD005780**. 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/CVM CONTACT INFORMATION:

Grants Management Contact:
Rene Vasquez
Grants Management Specialist
Phone: 301-796-3546
Email: rene.vasquez@fda.hhs.gov

Programmatic Contact:
Claudine Kabera
Project Officer
Phone: 240.402.5430
Email: Claudine.Kabera@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: Rene Vasquez
Email: rene.vasquez@fda.hhs.gov

Program Official: Claudine Kabera
Email: Claudine.Kabera@fda.hhs.gov

SPREADSHEET SUMMARY

GRANT NUMBER: 5U01FD005780-03 REVISED

INSTITUTION: MISSOURI STATE DEPT/ HEALTH & SENIOR SRV

Budget	Year 3	Year 4	Year 5
Salaries and Wages	\$49,836		
Fringe Benefits	\$28,906		
Personnel Costs (Subtotal)	\$78,742		
Supplies	\$40,498		
Travel Costs	\$888		
Other Costs	\$2,817	\$124,296	\$124,296
TOTAL FEDERAL DC	\$122,945	\$124,296	\$124,296
TOTAL FEDERAL F&A	\$16,772	\$0	\$0
TOTAL COST	\$121,037	\$124,296	\$124,296