Grant Number: 5U01FD005780-04 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: 09/01/2019 – 02/28/2021
Project Period: 09/01/2016 – 02/28/2021

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,

Lisa Ko
Grants Management Officer

FOOD AND DRUG ADMINISTRATION

Additional information follows

SECTION I – AWARD DATA – 5U01FD005780-04 REVISED

Award Calculation (U.S. Dollars)	
Salaries and Wages	$54,432
Fringe Benefits	$32,659
Personnel Costs (Subtotal)	$87,091
Equipment	$8,500
Supplies	$31,700
Travel Costs	$888
Other Costs	$3,184
Federal Direct Costs	$131,363
Federal F&A Costs	$18,637
Approved Budget	$150,000
Federal Share	$150,000
TOTAL FEDERAL AWARD AMOUNT	$150,000
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$0

SUMMARY TOTALS FOR ALL YEARS		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
4	$150,000	$150,000

* 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:	[redacted]
Document Number:	UFD005780A
PMS AccountType	P(Subaccount)
Fiscal Year:	2019

IC	CAN	2019
FD	6999DMY	$150,000

* 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**: FDAKO1 09/29/2020

SECTION II – PAYMENT/HOTLINE INFORMATION – 5U01FD005780-04 REVISED

Grant payments will be made available through the DHHS Payment Management System (PMS). Please go to https://pms.psc.gov/ to find more information on user access, payment, reporting and FAQs.

Inquiries should be directed to:

ONE-DHHS—the PMS Help Desk, providing assistance to all system users. Support is available Monday - Friday from 7 a.m. to 9 p.m. ET (except Federal Holidays): 1-877-614-5533 or email PMSSupport@psc.gov.

The HHS Inspector General (IG) maintains a toll-free telephone number, 1-800-447-8477, for receiving information concerning fraud, waste, or abuse under grants and cooperative agreements. Such reports are kept confidential, and callers may decline to give their names if they choose to remain anonymous.

SECTION III – TERMS AND CONDITIONS – 5U01FD005780-04 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. The Funding Opportunity Announcement in which this award is issued under.
g. 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.

Expanded Authorities:
Unless otherwise stated in Section IV – Special Terms and Conditions, this award is not under expanded authorities.

Reporting Requirements:
All FDA grants require both Financial and Performance reporting.

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. All annual FFRs must 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 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.

Performance Progress Reporting:

When multiple years (more than one budget period) are involved, awardees will be required to submit the Research Performance Progress Report (RPPR) annually as required in the Notice of Award. Annual RPPRs must be submitted using the RPPR module in eRA Commons. The annual RPPR must include a detailed budget. Annual RPPRs are due no later than 60 days prior to the start of the next budget period.

Failure to submit timely reports may affect future funding. Additional Financial and Performance Progress reports may be required for this award. Any additional reporting requirements will be listed under Section IV – Special Terms and Condition of the Notice of Award.

Salary Caps:
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 Executive Level II of the Federal Executive Pay Scale.

Certificates of Confidentiality – 42 U.S.C. 241(d)
Awardees are responsible for complying with all requirements to protect the confidentiality of identifiable, sensitive information that is collected or used in biomedical, behavioral, clinical, or other research (including research on mental health and research on the use and effect of alcohol and other psychoactive drugs) funded wholly or in part by the Federal Government. See 42 U.S.C. 241(d). All research funded by FDA, in whole or in part, that is within the scope of these requirements is deemed to be issued a "Certificate of Confidentiality" through these Terms and Conditions. Certificates issued in this manner will not be issued as a separate document.

Awardees are expected to ensure that any investigator or institution not funded by FDA who receives a copy of identifiable, sensitive information protected by these requirements, understand they are also subject to the requirements of 42 U.S.C. 241(d). Awardees are also responsible for ensuring that any subrecipient that receives funds to carry out part of the FDA award involving a copy of identifiable, sensitive information protected by these requirements understand they are also subject to subsection 42 U.S.C. 241(d).

Acknowledgment of Federal Support:
When issuing statements, press releases, publications, requests for proposal, bid solicitations and other documents --such as tool-kits, resource guides, websites, and presentations (hereafter "statements")--describing the projects or programs funded in whole or in part with FDA federal funds, the recipient must clearly state:

1. the percentage and dollar amount of the total costs of the program or project funded with federal money; and,
2. the percentage and dollar amount of the total costs of the project or program funded by non-governmental sources.

When issuing statements resulting from activities supported by FDA financial assistance, the recipient entity must include an acknowledgement of federal assistance using one of the following statements.

If the FDA Grant or Cooperative Agreement is NOT funded with other non-governmental sources:

> This [project/publication/program/website, etc.] [is/was] supported by the Food and Drug Administration (FDA) of the U.S. Department of Health and Human Services (HHS) as part of a financial assistance award [FAIN] totaling $XX with 100 percent funded by FDA]/HHS. The contents are those of the author(s) and do not necessarily represent the official views of, nor an endorsement, by FDA/HHS, or the U.S. Government.

If the FDA Grant or Cooperative Agreement IS partially funded with other nongovernmental sources:

This [project/publication/program/website, etc.] [is/was] supported by the Food and Drug Administration (FDA) of the U.S. Department of Health and Human Services (HHS) as part of a financial assistance award [FAIN] totaling $XX with XX percentage funded by FDA/HHS and $XX amount and XX percentage funded by non-government source(s). The contents are those of the author(s) and do not necessarily represent the official views of, nor an endorsement, by FDA/HHS, or the U.S. Government.

The federal award total must reflect total costs (direct and indirect) for all authorized funds (including supplements and carryover) for the total competitive segment up to the time of the public statement. Any amendments by the recipient to the acknowledgement statement must be coordinated with FDA. If the recipient plans to issue a press release concerning the outcome of activities supported by FDA financial assistance, it should notify FDA in advance to allow for coordination.

Additional prior approval requirements pertaining to Acknowledgement of Federal Support, publications, press statements, etc. may be required, and if applicable, will be listed under Section IV – Special Terms and Condition of the Notice of Award.

Prior Approval:
All prior approval requests must be submitted using the Prior Approval module in eRA Commons. Any requests involving budgetary issues must include a new proposed budget and a narrative justification of the requested changes. If there are any questions regarding the need or requirement for prior approval for any activity or cost, the grantee is to contact the assigned Grants Management Specialist prior to expenditure of funds. The following activities require prior approval from FDA:

1. Carryover of Unobligated Balances
2. No Cost Extensions
3. Change in Grantee Organization
4. Significant Rebudgeting
5. Change in Scope or Objectives
6. Deviation from Terms and Conditions of Award
7. Change in Key Personnel which includes replacement of the PD/PI or other key personnel as specified on the NoA.
8. Disengagement from the project for more than three months, or a 25 percent reduction in time devoted to the project, by the approved PD/PI. No individual may be committed to more than 100% professional time and effort. In the event that an individual's commitment exceeds 100%, the grantee must make adjustments to reduce effort. For FDA-sponsored projects, significant reductions in effort (i.e., in excess of 25% of the originally proposed level of effort) for the PD/PI and key personnel named on named on this Notice of Award must receive written prior approval from FDA.

Additional prior approval requirements may be required for this award, and if applicable, will be listed under Section IV – Special Terms and Condition of the Notice of Award.

Audits and Monitoring:

Audit Requirements:

1. Recipients of Federal funds are subject to annual audit requirements as specified in 45 CFR 75.501 (https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&SID=8040c4036b962cc9d75c3638dedce240&ty=HTML&h=L&r=PART&n=pt45.1.75#se45.1.75_1501). Grantees should refer to this regulation for the current annual Federal fund expenditure threshold level which requires audit.
2. Foreign recipients are subject to the same audit requirements as for-profit organizations (specified in 45 CFR 75.501(h) through 75.501(k).
3. For-profit and foreign entities can email their audit reports to AuditResolution@hhs.gov or mail them to the following address:

U.S. Department of Health and Human Services
Audit Resolution Division, Room 549D
Attention: Robin Aldridge, Director
200 Independence Avenue, SW
Washington, DC 20201

Monitoring:

Recipients are responsible for managing the day-to-day operations of grant-supported activities using their established controls and policies, as long as they are consistent with Federal, DHHS and FDA requirements. However, to fulfill their role in regard to the stewardship of Federal funds, FDA monitors our grants to identify potential problems and areas where technical assistance might be necessary. This active monitoring is accomplished through review of reports and correspondence from the recipient, audit reports, site visits, and other information available to FDA.

1. **Desk review:** FDA grants monitoring specialists will periodically reach out to recipients to request information for the completion of desk reviews. Requested information may include:
    - Policies and procedures
    - List of grant expenditures
    - Accounting records
    - Supporting documents (e.g., invoices, receipts, paystubs, timesheets, contracts, etc.)
    - Financial statements
    - Audit reports
    - Other related documentation
2. **Site visits:** FDA will conduct site visits when necessary and will notify the recipient with reasonable advance notice of any such visit(s).
3. **Foreign entities:** All Foreign entities are subject to the same monitoring requirements as domestic entities. Foreign entities covered under immunity Executive Orders will provide supporting documents for monitoring requirements unless such an action is a violation of the Executive Orders. Recipients may discuss with the FDA to come up with an alternate approach to satisfy the award monitoring requirements.

All recipients will make reasonable efforts to resolve issues found, including audit findings. Successful resolutions to issues are important as they are part of the grant performance review. All recipients are responsible for submitting all requested information in an expeditious manner. **Failure to submit timely reports and/or respond to inquiries from FDA may affect future funding or enforcement actions, including withholding, or conversion to a reimbursement payment method.**

Financial Conflict of Interest (FCOI):
This award is subject to the Financial Conflict of Interest (FCOI) regulation at 42 CFR Part 50 Subpart F.

Closeout Requirements (when applicable):
A Final Research Performance Progress Report (FRPPR), Final Federal Financial Report SF-425, Final Invention Statement HHS-568 (if applicable), Tangible Personal Property Report SF-428 (if applicable), and Statement of Disposition of Equipment (if applicable) must be submitted within 90 days after the expiration date of the project period. All closeout documents must be submitted electronically in eRA Commons.

The Final FFR must indicate the exact balance of unobligated funds and may not reflect unliquidated obligations. There must be no discrepancies between the Final FFR expenditure data and FFR cash transaction data in the Payment Management System (PMS). It is the recipient's responsibility to reconcile reports submitted to PMS and to the FDA.

Program Income:

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.

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.

Any Program Income generated during the Project Period of this grant by the grantee or sub-grantee will be treated as identified below.

Treatment of Program Income:
Additional Costs

Other:
This award is subject to the requirements of 2 CFR Part 25 for institutions to maintain an active registration in the System of Award Management (SAM). Should a consortium/subaward be issued under this award, a requirement for active registration in SAM must be included.

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 – 5U01FD005780-04 REVISED

09/28/2020: This award is being revised for a 6 months NCE with a new budget and project period end date of 02/28/2021. During the NCE the remainder unobligated funds in the amount of $10,811.90 will be used.

ALL PREVIOUS TERMS AND CONDITIONS REMAIN IN EFFECT

09/01/2020: This award is being revised to update the project period end date to 08/31/2020. Grantee with existing award (U01FD005780) under PAR-16-099 and who received a new award under PAR-20-124 (1U01FD007224-01).

08/31/2020-This award reflects rebudgetting of $8,500 from supplied to equipment. Line items have been adjusted accordingly.

ALL PREVIOUS TERMS AND CONDITIONS REMAIN IN EFFECT

08/15/2019: This award reflects the submitted revised budget. Line items have been adjusted accordingly.

ALL PREVIOUS TERMS AND CONDITIONS REMAIN IN EFFECT

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: Direct salaries for individuals under FDA grant and cooperative agreement awards cannot exceed the Executive Level II of the Federal Executive pay scale.

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 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 **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.*

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, technical and programmatic issues to the program official listed below.

Direct inquiries regarding fiscal, grants policy, procedures 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: 5U01FD005780-04 REVISED

INSTITUTION: MISSOURI STATE DEPT/ HEALTH & SENIOR SRV

Budget	Year 4
Salaries and Wages	**$54,432**
Fringe Benefits	**$32,659**
Personnel Costs (Subtotal)	**$87,091**
Equipment	**$8,500**
Supplies	**$31,700**
Travel Costs	**$888**
Other Costs	**$3,184**
TOTAL FEDERAL DC	**$131,363**
TOTAL FEDERAL F&A	**$18,637**
TOTAL COST	**$150,000**