Department of Health and Human Services
Food and Drug Administration

Notice of Award
FAIN# U01FD007224
Federal Award Date
08/07/2023

Recipient Information

1. Recipient Name
MISSOURI DEPARTMENT OF HEALTH & SENIOR SERVICES
920 WILDWOOD DR
JEFFERSON CITY, MO 65109

2. Congressional District of Recipient
03

3. Payment System Identifier (ID)
1446000987B7

4. Employer Identification Number (EIN)
446000987

5. Data Universal Numbering System (DUNS)
878092600

6. Recipient's Unique Entity Identifier
UETLXV8NG8F4

7. Project Director or Principal Investigator
Leon Luebbering, BS

leon.luebbering@health.mo.gov
573-751-3334

8. Authorized Official
Marcia Mahaney
grants@health.mo.gov
5737516014

Federal Agency Information

9. Awarding Agency Contact Information
Rene Vasquez
Grants Management Specialist
FOOD AND DRUG ADMINISTRATION
rene.vasquez@fda.hhs.gov
301-796-3546

10. Program Official Contact Information
Claudine Kabera

FOOD AND DRUG ADMINISTRATION
Claudine.Kabera@fda.hhs.gov
240-402-5430

Federal Award Information

11. Award Number
5U01FD007224-04

12. Unique Federal Award Identification Number (FAIN)
U01FD007224

13. Statutory Authority
42 USC 241 31 USC 6305 42 CFR 52

14. Federal Award Project Title
FDA NARMS Cooperative Agreement Program to Strengthen Antibiotic Resistance Surveillance in Retail Food Specimans

15. Assistance Listing Number
93.876

16. Assistance Listing Program Title
Antimicrobial Resistance Surveillance in Retail Food Specimens

17. Award Action Type
Non-Competing Continuation

18. Is the Award R&D?
Yes

Summary Federal Award Financial Information

19. Budget Period Start Date 09/01/2023 – **End Date** 08/31/2024	
20. Total Amount of Federal Funds Obligated by this Action	$165,000
20 a. Direct Cost Amount	$143,559
20 b. Indirect Cost Amount	$21,441
21. Authorized Carryover	
22. Offset	
23. Total Amount of Federal Funds Obligated this budget period	$165,000
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$165,000
26. Project Period Start Date 09/01/2020 – **End Date** 08/31/2025	
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$629,000

28. Authorized Treatment of Program Income
Additional Costs

29. Grants Management Officer - Signature
Kimberly Pendleton

30. Remarks

PLEASE REVIEW ALL TERMS AND CONDITIONS IN SECTIONS III AND IV. "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

SECTION I – AWARD DATA – 5U01FD007224-04

Award Calculation (U.S. Dollars)	
Salaries and Wages	$62,899
Fringe Benefits	$40,186
Personnel Costs (Subtotal)	$103,085
Materials & Supplies	$32,240
Travel	$888
Alterations and Renovations	$7,346
Federal Direct Costs	$143,559
Federal F&A Costs	$21,441
Approved Budget	$165,000
Federal Share	$165,000
TOTAL FEDERAL AWARD AMOUNT	$165,000
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$165,000

SUMMARY TOTALS FOR ALL YEARS		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
4	$165,000	$165,000
5	$200,000	$200,000

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

Fiscal Information:

Document Number:	UFD007224A
PMS AccountType:	P(Subaccount)
Fiscal Year:	2023

IC	CAN	2023	2024
FD	6999DMY	$165,000	$200,000

* 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**: Pendleton, Kimberly 08/07/2023

SECTION II – PAYMENT/HOTLINE INFORMATION – 5U01FD007224-04

Acceptance of this award including the "Terms and Conditions" is acknowledged by the recipient when funds are drawn down or otherwise obtained from the grant payment system.

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 – 5U01FD007224-04

Acceptance of this award including the "Terms and Conditions" is acknowledged by the recipient when funds are drawn down or otherwise obtained from the grant payment system.

Failure to adhere and comply with the terms and conditions of award, may result in disallowances, enforcement actions such suspension, termination, withholding of support and/or conversion to a reimbursement payment method.

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. 2 CFR Part 200 and 45 CFR Part 75, currently in effect or implemented during the period of the award.
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) U01FD007224. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Expanded Authorities:
This award is covered under Expanded Authorities. An unobligated balance (carryover) may be carried over from one budget period to any subsequent budget period for allowable costs within the original scope of the project without Grants Management Officer prior approval. The recipient is required to indicate as part of the grant's annual progress report (RPPR), whether any estimated unobligated balance (including prior-year carryover) is expected (regardless of whether the percentage of unobligated funds is over or under 25% of the current year's total approved budget) and indicate the carryover amount in the Remarks section of the annual FFR. Carryover from one competitive segment to a new competitive segment will not be allowed under expanded authorities. A recipient may perform a one-time no cost extension (NCE) of the expiration date of the award (Project Period) of up to 12 months in eRA Commons without prior approval. The NCE request must be made prior to the end of the current project period end date but preferably no later than 30 days before the expiration date. The one-time extension may not be exercised to extend Budget Periods, or merely for the purpose of using unobligated balances, nor may recipients extend project periods previously extended by the FDA awarding office. If a second NCE is required beyond the initial Expanded Authority extension, a prior approval request must be submitted to FDA's Grants Management Office.

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

Financial Reporting:

A. Financial Expenditure Reports

A required Federal Financial Report (FFR) must be submitted annually. All annual FFRs must be submitted electronically using the Payment Management System (PMS). 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. If a grant is under expanded authorities, the recipient must indicate the carryover amount in Section 12. Remarks of the annual FFR.

If the budget period end date falls within:	then annual FFR is due by:
January, February, March	June 30th

April, May, June	September 30th
July, August, September	December 31st
October, November, December	March 31st

Performance Progress Reporting:

When multiple years (more than one budget period) are involved, recipients 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)
Recipients 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.

Recipients 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). Recipients 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 recipient is to contact the assigned Grants Management Specialist prior to expenditure of funds.

For grant awards not covered under Expanded Authorities, Carryover and No Cost Extension (NCE) requests will require prior approval. All Carryover and NCE requests should be submitted using the Prior Approval module in eRA Commons. ****Please review the section on Expanded Authorities to determine if this award is covered/not covered under Expanded Authorities and whether prior approval is needed for carryover and no cost extension requests.****

The following activities require prior approval from FDA on all awards:

1. Change in Recipient Organization
2. Significant Rebudgeting
3. Change in Scope or Objectives
4. Deviation from Terms and Conditions of Award
5. Change in Key Personnel which includes replacement of the PD/PI or other key personnel as specified on the NoA.
6. 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 recipient 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). Recipients 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 Invention Statement (FIS) HHS-568 (if applicable), Tangible Personal Property Report SF-428 (if applicable), and Statement of Disposition of Equipment (if applicable) must be submitted within 120 days after the expiration date of the project period. All closeout documents must be submitted electronically in eRA Commons.

The Final Federal Financial Report (FFFR) SF-425 must be submitted in the Payment Management System (PMS) within 120 days after the expiration date of the project period. Recipients have 90 days after the project period end date to liquidate all obligations in PMS. All obligations must be liquidated prior to the submission of the Final FFR. 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). The expended funds reported on the Final FFR must exactly match the disbursements and the charge advances in PMS. It is the recipient's responsibility to reconcile reports submitted to PMS and to the FDA.

Program Income:
The recipient 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 recipient'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 recipient or sub-recipient will be treated as identified below.

Treatment of Program Income:
Additional Costs

Prohibition on certain telecommunications and video surveillance services or equipment:

(a) As described in CFR 200.216, recipients and subrecipients are prohibited to obligate or spend grant funds (to include direct and indirect expenditures as well as cost share and program) to:

(1) Procure or obtain,

(2) Extend or renew a contract to procure or obtain; or

(3) Enter into contract (or extend or renew contract) to procure or obtain equipment, services, or systems that use covered telecommunications equipment or services as a substantial or essential component of any system, or as critical technology as part of any system. As described in Pub. L. 115-232, section 889, covered telecommunications equipment is telecommunications equipment produced by Huawei Technologies Company or ZTE Corporation (or any subsidiary or affiliate of such entities).

i. For the purpose of public safety, security of government facilities, physical security surveillance of critical infrastructure, and other national security purposes, video surveillance and telecommunications equipment produced by Hytera Communications Corporation, Hangzhou Hikvision Digital Technology Company, or Dahua Technology Company (or any subsidiary or affiliate of such entities).

ii. Telecommunications or video surveillance services provided by such entities or using such equipment.

iii. Telecommunications or video surveillance equipment or services produced or provided by an entity that the Secretary of Defense, in consultation with the Director of the National Intelligence or the Director of the Federal Bureau of Investigation, reasonably believes to be an entity owned or controlled by, or otherwise, connected to the government of a covered foreign country.

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.

You must administer your project in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age and, in some circumstances, religion, conscience, and sex (including gender identity, sexual orientation, and pregnancy). This includes taking reasonable steps to provide meaningful access to persons with limited English proficiency and providing programs that are accessible to and usable by persons with disabilities. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. Please see https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html and https://www.hhs.gov/civil-rights/for-individuals/nondiscrimination/index.html

- You must take reasonable steps to ensure that your project provides meaningful access to persons with limited English proficiency. For guidance on meeting your legal obligation to take reasonable steps to ensure meaningful access to your programs or activities by limited English proficient individuals, see https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html and https://www.lep.gov.
- For information on your specific legal obligations for serving qualified individuals with disabilities, including providing program access, reasonable modifications, and taking appropriate steps to provide effective communication, see http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html.
- HHS funded health and education programs must be administered in an environment free of sexual harassment, see https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html.
- For guidance on administering your project in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws, see https://www.hhs.gov/conscience/conscience-protections/index.html and https://www.hhs.gov/conscience/religious-freedom/index.html.

SECTION IV – FD Special Terms and Condition – 5U01FD007224-04

This award is subject to the Special Requirements of the **PAR-20-124,** entitled, **NARMS Cooperative Agreement Program to 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.

COOPERATIVE AGREEMENT 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. Fresh retail meat should be collected on a minimum of 7 non-consecutive days per month from pre-selected retail locations.
6. Perform whole genome sequencing on an agreed-upon number and type of isolate recovered from retail meat samples.
7. Participate in NARMS pilot studies to examine novel sample types 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. Collection and testing of food products or other samples types not specified in the assignment.
2. Isolation and characterization of organisms other than those agreed upon or specified in the cooperative agreement

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 on select NARMS isolates.
7. Analyze, interpret, and disseminate surveillance results.
8. Any presentation of the results of testing must be shared with the FDA Office of Research for review. This process can take 30-90 days.
9. Coordinating and facilitating communications among NARMS retail food surveillance sites

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

Direct inquiries regarding fiscal, grants policy, procedures and/or administrative matters to the grants management specialist listed on page one of the Notice of Award (NoA).

Direct inquiries regarding scientific, technical and programmatic issues to the program official listed on page one of the Notice of Award (NoA).

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.