Grant Number: 1U19FD007096-01
FAIN: U19FD007096

Principal Investigator:
Jessica Bauer
Leon Luebbering(contact), BS
Mindy Rustemeyer
Alan Schaffer

Project Title: Laboratory Flexible Funding Model

Mahaney, Marcia
Director, Division of Administration
920 Wildwood Drive
PO Box 570
Jefferson City, MO 651020570

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

Budget Period: 09/01/2020 – 06/30/2021
Project Period: 09/01/2020 – 06/30/2025

Dear Business Official:

The Food and Drug Administration hereby awards a grant in the amount of $970,000 (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 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

FOOD AND DRUG ADMINISTRATION

Additional information follows

SECTION I – AWARD DATA – 1U19FD007096-01

Award Calculation (U.S. Dollars)

Other Costs	$970,000
Federal Direct Costs	$970,000
Approved Budget	$970,000
Federal Share	$970,000
TOTAL FEDERAL AWARD AMOUNT	$970,000
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$970,000

SUMMARY TOTALS FOR ALL YEARS		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
1	$970,000	$970,000
2	$970,000	$970,000
3	$970,000	$970,000
4	$970,000	$970,000
5	$970,000	$970,000

* 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:	UFD007096A
PMS AccountType	P(Subaccount)
Fiscal Year:	2020

IC	CAN	2020	2021	2022	2023	2024
FD	6990914	$970,000	$970,000	$970,000	$970,000	$970,000

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

FDA Administrative Data:
PCC: ORA20 / **OC**: 4141 / **Processed**: FDAKPU 08/28/2020

SECTION II – PAYMENT/HOTLINE INFORMATION – 1U19FD007096-01

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 – 1U19FD007096-01

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. 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) U19FD007096. 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 – 1U19FD007096-01

NOTE: The grantee must submit revised project budgets within 30 days of award for the approved and funded projects listed below. Revised Project budgets must adhere to all project budget caps outlined in the FOA and the total overall award budget cannot exceed the total award amount of $970,000 in total costs.

NOTE: This Notice of Award has been issued with a shortened first budget period of 10 months from 09/01/2020 – 06/30/2021. All subsequent budget periods under this project will be for 12 months and will be on a 07/01 - 06/30 budget period cycle.

NOTE: This grant will be managed by the following Program Manager:

Erin Woodom-Coleman – Erin.Woodom-Coleman@fda.hhs.gov

The Projects listed below **are** approved and funded at the following total cost for the budget period 09/01/2020 - 06/30/2021:

Administration	$TBD
Microbiology Human Food Product Testing	$TBD
Microbiology Whole Genome Sequencing	$TBD
Chemistry Human Food Product Testing	$TBD
Radiochemistry Food Defense	$TBD
Radiochemistry Capability/Capacity Development	$TBD
Special Projects Sample Collection	$TBD

Special Projects Method Development and Method Validation	$TBD

The Projects listed below **are** approved, however will **not** be funded for the budget period 09/01/2020 - 06/30/2021:

Microbiology Food Defense
Microbiological Capability/Capacity Development
Chemistry Food Defense
Chemistry Capability/Capacity Development
Special Projects NFSDX Integration or ORAPP adoption

Restrictions:

FDA Records and FDA Directed Assignments

Any information received under this cooperative agreement or generated under an FDA directed assignment that 1) has been provided to the awardees by the FDA, or 2) was generated through sample analysis by the awardee shall not be released, published, disclosed or made known in any manner to any persons outside of the awardee organization or designated partner regulatory agency without prior authorization from the FDA. Examples of this information includes FDA assignment documents and laboratory results.

The awardee must notify the Project Manager (PM) and Program Official (PO) of any Freedom of Information Act (FOIA) requests received that would include any work performed or documents received under this cooperative agreement. FDA will determine if the requested records may be released at the awardee level or if the awardee must refer the requester to FDA's Division of Freedom of Information at https://www.fda.gov/regulatory-information/freedom-information/how-make-foia-request for access to the records.

Other Information Generated under the Cooperative Agreement

Any other information generated under this cooperative agreement that has been collected by the awardee or designated partner regulatory agency, or generated through sample analysis by the awardee under their own state authority (and not related to an FDA directed assignment) will not be released, published, disclosed or made known in any manner to any persons outside of the awardee organization or designated partner regulatory agency without prior timely advance notification to the FDA. Examples of this information includes sample collection reports, and laboratory results.

The awardee agrees to the timely notification the Project Manager (PM) and Program Official (PO) in advance of any disclosure.

The following are non-allowable costs under this project:

1. Facilities and work reimbursed under the FDA human or animal food safety inspection contract or other funding mechanisms must remain distinct and separate from the cooperative agreement.
2. Vehicle purchases are not permitted.
3. Cooperative agreement funds may not be utilized for new building construction; however, remodeling of existing facilities is allowed, provided that remodeling costs do not exceed 10% of the grant award amount.
4. Clothing and uniforms with the exception of personal protective equipment (PPE). PPE is defined as protective clothing or other outerwear required to mitigate a defined workplace hazard.
5. Other items listed in the HHS Grants Policy Statement or Notice of Award.

Additional Reporting Requirements:

All FDA grants require annual financial and performance progress as stated in Section III. This award has additional financial and performance reporting requirements as outlined below.

Financial

A Budget Resolution Report is required no later than thirty (30) days after the end of each budget period, annually. This report must include the amount of the total funding spent in each of the following categories:

a. Salary/wages
b. Fringe benefits
c. Consultant services
d. Equipment
e. Supplies
f. Travel costs
g. Other costs
h. Federal facilities and administrative costs

This report must also disclose any additional resources provided to the laboratory through other FDA funding mechanisms, including but not limited to other cooperative agreements (e.g. Flexible Funding Model, AFRPS, Produce, etc.) and contracts.

Performance

A detailed quarterly summary of all samples collected and analyzed must be submitted through the FERN website, or other FDA approved system. This summary must include, at a minimum:

a. the laboratory name;
b. sample number;
c. product description;
d. the manufacturer/brand of the product;
e. any codes listed on the product (e.g. lot codes, etc);
f. product expiration date;
g. country of origin, if available;
h. collecting entity name;
i. date collected;
j. lab receipt date;
k. analytical method used
l. screening results;
m. confirmatory results;
n. final results (including value and units);
0. completion date; and
p. comments.

A Mid-Year Progress Report is required no later than fifteen (15) days after the six (6) month mark of each budget year, annually. The interim performance progress reports should be submitted via email to the listed Grants Management Specialist and Program Official.

The interim performance progress report should include:

1. A completed copy of the most recent version of the LFFM Reporting Document (FDA provided)
2. A pdf version of samples submitted in the FERN website during the reporting period, or other format, as requested by FDA
3. A summary of the following must include the following, and any additional reporting elements, as requested by FDA:

a. All work completed under each analytical track, including but not limited to:
    i. Samples analyzed through proposed plan, or FDA-approved
    ii. Status and results of any small-scale, short-term method development, method validation, and matrix extension projects
    iii. Status of publications, research projects, or other special projects funded under this project
b. Any hiring of new personnel, and training or existing personnel, working on this project
c. Status on the installation and operational readiness of any analytical equipment utilized for this project
d. Any regulatory actions taken by FDA or another regulatory agency, or any other significant laboratory findings

e. Participation, including attendance, in any professional meetings or conferences supporting work related to this project
f. Details of any completed proficiency testing for work done under this project
g. Changes in ISO 17025 accreditation status, or quality management system
h. Contact information for the key personnel working on each analytical track, including name, title, phone number, and email address
a. Any programmatic issues or concerns

Prior Approval:
The following additional situations require prior approval:

1. Annual sample plans, including the sample load and hazard/commodity pair must be reviewed and approved prior to plan execution. In order to change the hazard/commodity pair after the initial plan approval, a request must be submitted to the Project Manager for approval.

Cooperative Agreement Terms and Conditions:
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 (DHHS) 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, the FDA 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 the FDA as defined below.

The PD(s)/PI(s) will have the primary responsibility for:
The Project Director/Principal Investigator (PD/PI) retains the primary responsibility and dominant role for planning, directing, and executing the proposed project, with FDA/ORA staff being substantially involved as a partner with the PD/PI, as described below.
The PD/PI will maintain general oversight for ensuring compliance with the financial and administrative aspects of the award, as well as ensuring that all staff have the necessary training and clearance to work on this project. This individual will work closely with designated officials within the recipient organization and with partner organizations 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, regulatory, and organizational requirements.

FDA staff have substantial programmatic involvement that is above and beyond the normal stewardship role in awards, as described below:
The Grants Project Team may consist of a Grants Management Specialist, Program Official (PO), Project Manager (PM) and Technical Advisor. The Grants Project Team collaborates to review the progress of the grantee. The Grants Project Team may utilize the grantee's progress reports, site visits, audit reports and other supporting documentation to determine if the condition of the award was met and satisfactory progress is being made. Each team member works in consultation with each other, as needed, throughout the duration of the project. A description of each team member involved with the program are described below.

An FDA Grants Management Specialist (GMS) will be assigned and named in the Notice of Award. The GMS oversees the administrative, financial, business and other non-programmatic aspects of the program. These activities include, but are not limited to the following:

- Provides guidance on administrative, business, fiscal aspects of grants management to grantees and FDA program staff
- Monitors and manages applications and required reports on eRA Commons

- Monitors administrative and financial aspects of grantee activities
- Maintains the official grantee file

An FDA Program Official (PO) will be assigned and named in the Notice of Award. The PO is accountable for the programmatic oversight of the grant to include coordination, with the Project Manager, on the technical aspects of the grant. S/he ensures the budget of grantees are reasonable and costs are allowable and allocable. The PO reviews the progress reports to verify the budget proposed includes only allowable expenses that support the project goals and objectives. The PO also assists with post-award monitoring and establishing a corrective action plan, if necessary.

An FDA Project Manager (PM) will be assigned to the program. The FDA PM is the responsible official for the programmatic, scientific, and/or technical aspects of assigned applications and cooperative agreements. The FDA PM will have substantial programmatic involvement that is above and beyond the normal stewardship role in awards as described below.

The PM will have substantial involvement in the design, implementation, and evaluation of program activities, and dissemination of program results and outcomes, above and beyond routine grant monitoring. Substantial involvement by FDA/ORA includes, but is not limited to, the following:

- Provide guidance, and technical assistance in project planning, implementation, and evaluation;
- Provide subject matter expertise, programmatic assistance, and evaluation services to support program studies and activities;
- Actively monitor the supported program via telephone conversations, webinars, e-mails, written correspondence, or periodic site visits;
- Evaluate the supported program, including development of program-level performance measures, consistent data collection, and reporting procedures and protocols;
- Convene trainings, meetings, conference calls, and site visits with grantee to facilitate collaboration and information sharing;
- Participate in data analysis, interpretation of findings, and where appropriate, co-authorship of publications;
- Development of programs to meet the FDA mission;
- Provision of programmatic technical assistance;
- Post-award monitoring of project/program performance, including review of progress reports and making site visits; and other activities complementary to those of the FDA.

An FDA Technical Advisor(s) will be assigned to each enrolled program. The Advisor will work cooperatively with the PO to help monitor and report grantee status/progress including sharing of information and historical backgrounds. The FDA Technical Advisor will have programmatic involvement

- Provide guidance, and technical assistance in project planning, implementation, and evaluation;
- Convene trainings, meetings, conference calls, and site visits with grantee to facilitate collaboration and information sharing;
- Provide subject matter expertise, programmatic assistance, and evaluation services to support program studies and activities;
- Provision of programmatic technical assistance;
- Post-award monitoring of project/program performance, including review of progress reports and making site visits; and other activities complementary to those of the FDA.
- Unless another governance structure is mutually agreed upon, the PO will serve as the primary point of contact for the dissemination of FDA policy and milestones/objectives work planning.

Other:

For Year 1, the NOA does not constitute approval of the proposed sample plan. Grantees will be contacted by FDA regarding the proposed sample plan within 30 days of award.

For the purpose of this cooperative agreement, a sample is defined as one that:

1. Has been taken from a lot of which federal jurisdiction can be established (e.g proof of interstate movement)
2. Is representative of the lot from which collected
3. Is a physical sample, large enough to permit proper laboratory examination and retain a reserve portion
4. Handled, identified, and sealed in such a manner as to maintain its integrity and with a clear record of its chain of custody

Samples must consist of sufficient units, size, etc., necessary for the official laboratory methodology to be used. Samples must be collected in accordance with current food testing methodologies and techniques, as specified by the FDA.

Samples that arrive in the laboratory and are unable to be analyzed, for any reason, cannot be counted toward the sample load selected by the laboratory.

For laboratories awarded multiple tracks under this project, the same samples cannot be counted under more than one discipline.

A proposed sample plan for each upcoming year must be submitted with the Research Performance Progress Report (RPPR) and approved by FDA prior to the start of work.

Environmental swabs, products produced or environmental samples obtained in a retail setting (unless it is designated as part of a national sampling assignment assigned by the FDA, or in conjunction with a foodborne illness outbreak), municipal water (that is covered under the purview of the Environmental Protection Agency, and products regulated by the United States Department of Agriculture are not allowed under this project.

Samples analyzed under this cooperative agreement could derive from a variety of sources including but not limited to: an approved sample plan, emergency outbreak situations, national special security exercises, or an FDA assignment. Laboratories that agree to participate in national special security exercises and FDA assignments could receive samples that were not collected by their identified sampling organization.

When available, and if the capability exists in the laboratory, participate in at least one (1) FDA-requested assignment annually.

Follow best practices recommendations for proper sampling and laboratory data documentation and use FDA Form 431, or equivalent, as necessary for analytical worksheet packages.

Notify the FDA project manager and the technical lead within one (1) business day of any presumptive positive or “cannot rule out” (CRO) samples. Notification via email must be sent to ORA-LFFM-CAP@fda.hhs.gov. The State regulatory program with jurisdiction over the presumptive positive or CRO sample must also be notified.

Submit the full laboratory package for any confirmed positive or violative sample within three (3) business days of final determination. This would include any supplemental information, as requested. The State regulatory program and the FDA will work collaboratively to determine if regulatory action is warranted, and which organization will be the lead.

Key personnel (minimum of two) must attend an annual face-to-face meeting (as determined by FDA OP) as a condition of the award.

FDA reserves a royalty-free, nonexclusive, and irrevocable right to reproduce, publish, or otherwise use for federal purposes any copyrighted works that are outcomes from these funding tracks, including curriculum, course content, objectives, learning outcomes, presentations, manuals, scripts, exercises, handouts, reports, documents or other tangible materials produced by the awardee. FDA may authorize others to reproduce, publish, or otherwise use such works for Federal purposes.

Grantees are required to maintain a 20.88 agreement with the FDA.

It is preferred that the sample collection conducted under this cooperative agreement is done by the state manufactured food regulatory program and the animal food regulatory program. If the awardee is the primary servicing laboratory for MFRPS and/or AFRPS, it is required that the enrolled regulatory program collect a minimum of 15% of the proposed samples under the human and/or animal food testing tracks. Other acceptable organizations include:

1. State Government;
2. County Government;
3. City or Township Government;
4. Special District Government;
5. Indian/Native American Tribal Government;
6. U.S. Territory or Possession; or
7. have regulatory authority for human and/or animal food.

Any personnel performing the collection on behalf of the sampling organization must be trained and have demonstrated competency in sample collection, including but not limited to:

1. Maintaining sample integrity,
2. Aseptic sampling; and
3. Proper chain of custody.

Training records and other proof of competency for any personnel performing sampling collections must be made available upon request by FDA.

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: Kiara Fowler
Email: Kiara.Fowler@fda.hhs.gov

Program Official: Laurie Keppley
Email: Laurie.Keppley@fda.hhs.gov

SPREADSHEET SUMMARY
GRANT NUMBER: 1U19FD007096-01

INSTITUTION: MISSOURI STATE DEPT/ HEALTH & SENIOR SRV

Budget	Year 1	Year 2	Year 3	Year 4	Year 5
Other Costs	**$970,000**				
TOTAL FEDERAL DC	**$970,000**	**$970,000**	**$970,000**	**$970,000**	**$970,000**
TOTAL FEDERAL F&A	**$0**	**$0**	**$0**	**$0**	**$0**
TOTAL COST	**$970,000**	**$970,000**	**$970,000**	**$970,000**	**$970,000**