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 (Contact)

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
KIARA FOWLER

FOOD AND DRUG ADMINISTRATION
Kiara.Fowler@fda.hhs.gov
2404023099

10. Program Official Contact Information
Laurie Keppley

FOOD AND DRUG ADMINISTRATION
Laurie.Keppley@fda.hhs.gov

Federal Award Information

11. Award Number
5U19FD007096-04

12. Unique Federal Award Identification Number (FAIN)
U19FD007096

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

14. Federal Award Project Title
Laboratory Flexible Funding Model

15. Assistance Listing Number
93.103

16. Assistance Listing Program Title
Food and Drug Administration Research

17. Award Action Type
Non-Competing Continuation

18. Is the Award R&D?
Yes

Summary Federal Award Financial Information

19. Budget Period Start Date 07/01/2023 **– End Date** 06/30/2024	
20. Total Amount of Federal Funds Obligated by this Action	$766,329
20 a. Direct Cost Amount	$820,000
20 b. Indirect Cost Amount	$0
21. Authorized Carryover	$0
22. Offset	$53,671
23. Total Amount of Federal Funds Obligated this budget period	$766,329
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$820,000
26. Project Period Start Date 09/01/2020 **– End Date** 06/30/2025	
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$2,947,965

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 – 5U19FD007096-04

Award Calculation (U.S. Dollars)

Federal Direct Costs	$820,000
Approved Budget	$820,000
Federal Share	$766,329
Less Unobligated Balance	$53,671
TOTAL FEDERAL AWARD AMOUNT	$766,329
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$766,329

SUMMARY TOTALS FOR ALL YEARS		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
4	$766,329	$766,329
5	$1,090,000	$1,090,000

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

Fiscal Information:

Document Number: UFD007096A
PMS AccountType: P(Subaccount)
Fiscal Year: 2023

IC	CAN	2023	2024
FD	6990914	$766,329	$1,090,000

* 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**: Pendleton, Kimberly 06/30/2023

SECTION II – PAYMENT/HOTLINE INFORMATION – 5U19FD007096-04

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 – 5U19FD007096-04

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) U19FD007096. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Expanded Authorities:
This award is not covered under Expanded Authorities. Carry over of an unobligated balance into the next budget period requires Grants Management Officer prior approval. All no cost extension requests require prior approval. Please see section Prior

Approval on Prior Approval requirements.

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 – 5U19FD007096-04

6/29/2023 - PLEASE SUBMIT A REVISED BUDGET IN THE AMOUNT OF $732,734 ON OR BEFORE JULY 29, 2023 TO KIMBERLY PENDLETON, CGMO AT KIMBERLY.PENDLETON@FDA.HHS.GOV.

Please note: This grant will be partially funded based on the grantee's unobligated balance of $53,671 from year 03, which will be used as an authorized offset for fiscal year 2023. $766,329 of new FY2023 funds will be awarded for this grant. The total approved budget including the offset for grant 5 U19FD007095 - 04 will be $820,000. In the event that the estimated unobligated balance from year 03 is less than the estimated amount provided by the grantee, no additional Federal Funds will be made available to offset a deficit.

The amounts listed in the Year 4 table reflect the new funds only. Authorized offsets may be applied to any of the approved projects.

The Projects listed below **are** approved and funded at the following total cost for the budget period 07/01/2023 - 06/30/2024:

Administration	$63,873
Microbiology Human Food Product Testing	$193,004
Microbiology Whole Genome Sequencing	$31,996
Chemistry Human Food Product Testing	$211,127
Radiochemistry Food Defense	$250,000
Special Projects Sample Collection	$35,000
Special Projects Method Development and Method Validation	$35,000

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 reporting requirements as outlined below.

***Programmatic Reports*:**

a. Quarterly Summary Reports (Human and Animal Food Product Testing Tracks Only)

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:

- the laboratory name;
- sample number;
- applicable LFFM track
- commodity (from commodity hazard pair);
- target species and form of feed (animal food only);
- product description;
- the manufacturer/brand of the product;
- any codes listed on the product (e.g., lot codes, etc.);
- product expiration date;
- country of origin, if available;
- collecting entity name;
- collection location
- date collected;
- lab receipt date;
- turnaround time;
- analytical method used
- screening results;
- Confirmatory results;
- final results (including value and units);
- completion date;
- method limits of detection (mLOD) and method limits quantitation (mLOQ) and;
- comments.

2. Spot check data packages (Human and Animal Food Product Testing Tracks Only) – At least 1 data package, assembled following the LFFM Sample Guide, must be submitted per analytical testing type per year for Technical

Advisor review.

3. A Mid-Year Report is required no later than fifteen (15) days after the six (6) month mark of each budget year, annually.

4. An Annual Report is required no later than May 1, annually.

All programmatic reports, including the mid-year and annual reports, must include detailed information about accomplishments from the reporting period. The mid-year report must be submitted via email to the listed Grants Management Specialist and Program Official. The annual report (RPPR) must be submitted in eRA Commons.

Specific report data includes but is not limited to that outlined below.

All Tracks:

- Activity(ies) from a previous budget period that you are completing in this period; include LFFM track, budget period funded, work remaining, and accomplishments completed this reporting period
- 20.88 Agreement: Confirm if you maintain a valid 20.88 agreement with FDA; if yes, include date of expiration, if no, explain why
- FERN Membership: Confirm if your lab is currently a FERN member; if not, list the date of planned application to FERN
- ISO Accreditation: Confirm the current ISO 17025 status of your laboratory, if your laboratory will be accredited to ISO/IEC 17025:2017, any changes to Accreditation since last reporting and if not accredited to ISO 17025 explain how you maintain a quality system that ensures quality assurance and quality control of laboratory testing (provide the scope of accreditation as an email attachment).
- ORA DX: Confirm if you have successfully submitted data to FDA this budget period via the ORA DX (any workflow) and provide the workflow, number of samples submitted, and type of sampling.
- Facilities: Confirm you have the facilities needed and that you have maintained the facilities needed to operate under this CAP or explain if not.
- Positions/Hiring: Confirm if all needed positions are filled, if not, explain how and when you will fill the vacant positions.
- Instrumentation: Confirm if you have obtained or replaced instrumentation/equipment in order to operative under this CAP in this budget period; if yes confirm the following information:

    - Description of item
    - Common name
    - Make/model
    - New/replaced
    - Status
    - Total number of operational instruments used for CAPs
    - LFFM track(s) this instrumentation supported
- Training Received:
    - Training title
    - Training provider
    - Number of people trained
    - LFFM tracks this training supported
- Meetings:
    - Meeting name
    - Meeting start and end dates
    - Meeting format (i.e. face to face, or teleconference)
    - How many people attended
    - LFFM tracks this meeting supported
- Presentations and Publications:
    - Title
    - Author/Presenter(s)
    - Journal/Meeting
    - Link to presentation or publication
    - Status
    - Date presented or published

Provide the following information separately by LFFM track

- Key personnel include all personnel that work on this Track, even if they are not funded under the award. Laboratories may also list names of key personnel from the State Regulatory Program (SRP) who handle LFFM Sample collection planning and positive sample follow-up – this will allow those staff to receive the LFFM weekly email (they will not be added to the meeting invites or FERNlab.org workgroup for the analytical track):
    - Last name, first name

    - CAP role
    - Email
    - Phone
    - Confirm if this person should be included on distribution list for this LFFM track
    - Total expected CAP funded calendar months for this role
- Training/Mentorship Administered:
    - Describe Mentorship/Training Topic
    - Laboratories Mentored/Trained
    - Number of People Trained
- Training Needed:
    - Confirm if your laboratory needs a LFFM track specific training(s); if yes, describe the training need(s).
- Mentorship Needed:
    - Confirm if your laboratory needs a LFFM track specific mentor(s); if yes, describe the mentoring need(s) and if you have a particular laboratory associated with this CAP you would like to assist you list those as well.

Provide the following additional information separately by LFFM track if you are participating in the Microbiology and Chemistry Human and Animal Food (M-HF, M-AF, C-HF, C-AF) tracks

- Small-scale projects should include the following 1) FDA-requested special assignments (testing events) above and beyond the approved sampling plan for the budget period; 2) Method development/validation/other work required during an emergency/outbreak situation, where FDA approved re-direction of approved sampling plan; 3) Participation in FDA-directed matrix extension/method development/method validation work outside of the project formally assigned for the MDV track; 4) Work required as part of a Capability/Capacity development effort:
    - Project name
    - Scope
    - Description
- Proficiency Testing (Only report PTs/Competency Exercises related to commodity/hazard pairs on your approved sampling plan for the Budget Period):
    - PT/Exercise Description (Include analyte(s) and matrices)
    - PT/Exercise Provider
    - Laboratory Performance

- If unacceptable, explain

- FDA Form 431 or e431: Confirm if you are using the FDA Form 431 or e431; if no, confirm if the documents you are using cover all the items within the 431 and explain your answer.
- State Regulatory Action on LFFM track specific samples:
  - Sample number
  - Matrix
  - List contaminant found
  - Date analytical package sent to SRP/FDA
  - Describe any State regulatory actions such as recalls taken as a result of laboratory findings (including dates)
  - Describe any joint response with FDA as a result of laboratory findings (including dates)

Provide the following additional information separately by LFFM track if you are participating in the Microbiology, Chemistry and Radiology Food Defense (M-FD, C-FD and R-FD) LFFM tracks

- Expansions of Capabilities/Capacities for Food Defense testing:
  - Describe increases or expansions in capabilities or capacities for food Defense testing (increases in trained personnel, new capabilities developed, etc.)
  - If your lab utilized funding to implement a new method under the Food Defense Track
    - Was equipment purchased? If no, explain
    - Were supplies, reagents, media, standards, etc. purchased? If no, explain
    - Training received? Describe training or explain if no training was received
    - Competency demonstrated? If not, explain
- Maintenance of Key Food Defense Capabilities/Methods:
  - Methods
  - Methods comments
  - Confirm if equipment is in house and operational; if no, explain
  - Confirm if supplies, reagents, media are in house and within date; if no, explain
  - Provide the name(s) of PT/Competency exercise
  - Provider

- Date of last competency determination
- Laboratory performance comments (required for unacceptable performance)
- Summary of next step to maintain capability, increase capacity or document needs

- Food Defense Activities i.e. FDA-assigned samples, exercises, responses:
  - provide a list of activities with a corresponding description of activity and highlights.
  - For the M-FD track only:
    - Is your laboratory registered for Select Agents or Toxins (include what level)?
    - Does your lab have an APHIS permit for controlled materials transport?
    - Do you have laboratory staff that can package and ship Category A?
    - Do you have laboratory staff that can package and ship Select Agents?
    - Does your laboratory have BSL2 facilities in which BSL-2+ work can be completed?
    - Does your laboratory have BSL3 facilities (if so are they operational)?
    - Can you accept food samples for testing?

Provide the following additional information for the Microbiology – Whole Genome Sequencing (M-WGS) track:

- Proficiency Testing (Only report PTs/Competency Exercises related to commodity/hazard pairs on your approved sampling plan for the Budget Period):
  - PT/Exercise Description (Include analyte(s) and matrices)
  - PT/Exercise Provider
  - Laboratory Performance
  - If unacceptable, explain
- Collaborations:
  - Specific Projects (sets of Isolates) the Lab is Sequencing
  - Confirm all collaboration types that apply (i.e. FDA directed project, academia collaboration, international collaboration, other historical isolate sets)

Provide the following additional information for the Microbiology, Chemistry, Radiochemistry – Capability/Capacity Development track:

- Capability/Capacity Development:
    - Describe the highlights as they align with the Capability/Capacity Development track
    - If your lab was funded to implement a new method under the Capability/Capacity Development Track please provide:
        - Confirm if equipment purchased; if no, explain
        - Confirm if supplies reagents, media, standards, etc. purchased; if no, explain
        - Confirm if training was received; if yes, describe, if no, explain
        - Confirm if competency was demonstrated, explain if not
- Proficiency Testing (Only report PTs/Competency Exercises related to commodity/hazard pairs on your approved sampling plan for the Budget Period):
    - PT/Exercise Description (Include analyte(s) and matrices)
    - PT/Exercise Provider
    - Laboratory Performance
    - If unacceptable, explain

Provide the following additional information for the Special Projects – Sample Collection (SP-SC) track:

- Competency Verification Exercises
    - Exercise description
    - Exercise organizer
    - Collector performance
    - If unacceptable, explain

Provide the following additional information for the Special Projects – IT (SP-IT) track:

- ORA Data exchange (ORA DX) Adoption:
    - Confirm if you are participating in NSFDX
    - Confirm if you are participating in ORAPP
    - Confirm if you are participating in DX Client

- Confirm if you participated in an onboarding session and complete the FDA questionnaire for the overview of NFSDX, ORAPP, and DX
- NSFDX only
  - Confirm if you have entered into a Memorandum of Understanding with FDA
  - Confirm if you have entered into an interconnection security agreement with FDA
- Confirm if you assessed the current IT capabilities of your laboratory as it pertains to sample collection and analytical data, including conducting an analysis of which fields can be mapped to FDA data elements, system changes needed to capture missing data, and any that would need to be developed; if no, confirm the date you plan to complete this activity.

- List planned activities for adoption of ORA DX workflow and highlights, specific to this budget period:
  - Activity(ies)
  - Description(s)

Provide the following additional information for the Special Projects – Method Development and Method Validation (SP-MD/V) track

- Method Development and Method Validation Summary:
  - Name of MDV Project
  - Type of Project
  - Multi or Single Lab
  - Confirm intended outcome of the project (i.e. New or Revised Method to be Submitted to FDA or FERN Methods Coordination Committee, In-house Implementation of the Method, Response/Emergency use to Support State or Local Regulatory Programs)
  - What reference materials or known samples were used in this track to complete the MDV project
  - If the MDV Project is related to response/emergency activities describe below
- Method Development and Method Validation Planned Activities and Highlights (list planned activities for this MDV project and highlights, specific to this budget period)

Provide the following additional information for the Special Projects – SARS-CoV-2 in

Wastewater (SP-CoV2) track

- Proficiency Testing (Only report PTs/Competency Exercises related to commodity/hazard pairs on your approved sampling plan for the Budget Period):
    - PT/Exercise Description (Include analyte(s) and matrices)
    - PT/Exercise Provider
    - Laboratory Performance
    - If unacceptable, explain

Further, germane information may be requested and required by FDA.

Prior Approval:

The following additional situations require prior approval:

1. Annual Sample Plans

   Annual sample plans must be reviewed and approved prior to plan execution. To change the hazard/commodity pair after the initial plan approval, a request must be submitted to the Grants Management Specialist and Program Official for approval.

   The sample plan includes, but is not limited to, the following:

   - Recipient (Laboratory) name
   - State
   - LFFM Track
   - Commodity
   - Analyte
   - Confirm if this is a back-up commodity-hazard pair for the applicable budget period for this plan
   - Confirm FDA or State proposed Commodity-Hazard pair
   - Characterization to be performed and name of laboratory performing characterization - Serotyping, Enumeration, WGS
   - Derivation of Screening Method(s)
   - Derivation of Confirmatory Method(s)
   - Do your screening/confirmatory method(s) include modifications (describe)

- Confirm if you already use this method for testing foods in your lab
- Do you need to develop/validate/verify the method for this matrix prior to beginning collections?
- Is the Method on your ISO Scope of Accreditation?
- Date and Source of most recent PT covering analyte
- Number of Samples – Annually
- Number of unique analyses
- Count towards Sample Load
- Collection Organization/Program
- Collection Location(s) - list all that apply
- Collection Details

The sample plan must be accompanied by an SRP-laboratory agreement, which includes:

- States that the state regulatory program (SRP) and laboratory have reviewed, discussed and jointly submit the sample plan.
- Sample collection and follow-up agreement: SRP (or laboratory if laboratory is collecting) agrees to collect the samples outlined in the approved LFFM sampling plan, in accordance with the sample collection and documentation requirements laid out in the current version of the LFFM Sample Guide. SRP agrees to lead the response, in coordination with FDA and following the current version of the LFFM Sample Guide, for any state-collected LFFM samples (whether collected by SRP or laboratory). This includes inter-agency and multi-state coordination, including: notifying another SRP with jurisdiction over the responsible firm of laboratory findings if product was grown/manufactured/distributed in another state and found violative; coordinating with another SRP, if referral had occurred, to ensure violative findings are communicated with the responsible firm by one of the SRPs; and conducting follow-up activities per [SRP] policies, procedures, and regulatory authority.
- Points of contact for the laboratory and SRP
- For each commodity-hazard pair on the Sample Plan:
    - Entity collecting
    - Sample Collection location
    - Number of Samples
    - Name of SRP with jurisdiction or providing support for follow-up on potentially violative samples

- Does SRP have regulatory limits, action levels, other compliance threshold related to this commodity-hazard pair?
- Types of actions the SRP can take under their regulatory authority (specific to the commodity-hazard pair and the type of firm associated with sampling). If a retail collection, please indicate ability to collect traceback records (documents) and actions that could be taken at distributor or manufacturer, if located within the state. If commodity/hazard pair requires consultation with FDA prior to conducting follow-up (referring to another state for follow-up, notifying responsible firm), include statement confirming awareness.

Sample plans must be submitted via email to the representatives identified in the annual submission instructions document, in addition to the Grants Management Specialist and Program Official.

2. Ad-Hoc Capability Inquiry Requests

There are special situations where a capacity and capability assessment is needed to evaluate ability of LFFM laboratories to respond to outbreaks or other national or emerging events or needs.

This Capability Inquiry assessment includes, but is not limited to, the following:

- Lab Name
- Are you able to analyze any or all the matrices listed using the method(s) cited?
- Please list what matrices you could test.
- Has your lab analyzed these matrices using these methods in the past?
- Which methods do you use? Please list all methods available.
- Are the methods validated for the matrices?
- Please list matrix, method and validation status.
- Do you have trained staff proficient for this analysis?
- Are any or all of methods on your scope of accreditation?
- Please list which methods are on your accreditation scope.
- Are you willing to pivot current approved sampling plan to this activity?
- How many samples can you do in a week? (Estimate only)

- How many samples would you be willing test in total? (Estimate only)?
- Are you able to arrange collection of these samples in your state?
- Please Provide Any Additional Information to Explain Your Labs Capabilities

3. Re-budgeting

As stated in SECTION III – TERMS AND CONDITIONS, Prior Approval is required for significant rebudgeting. Under this cooperative agreement, significant is defined as 10% or more. Although Prior Approval is not required for rebudgeting of less than 10%, the PM and PO must be notified.

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, 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. The PO 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:

Grantees must follow the most current version of the Laboratory Flexible Funding Model (LFFM) Cooperative Agreement Program (CAP) Sample Process Guide provided to them. For the purpose of this cooperative agreement, a sample is defined as one that:

1. Is a physical sample, large enough to permit proper laboratory examination and retain a reserve portion
2. Handled, identified, and sealed in such a manner as to maintain its integrity and with a clear record of its chain of custody
3. For samples where FDA regulatory authority may be requested or required, the product must have been taken from a lot for which federal jurisdiction can be established (e.g proof of interstate movement)
4. Is representative of the lot from which collected (when collecting at manufacturer, producer, or other point in the supply chain where an entire lot is available for sampling)

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 physical sample may be counted under more than one discipline if separate and unique analyses occurred (e.g., analysis of poultry feed for Salmonella and aflatoxin), with prior approval by the FDA.

Special considerations when tabulating samples to meet annual sample load per Track: Some samples may require multiple analyses to complete (e.g., samples that require analysis of subsamples individually vs. compositing; or conducting multiple separate, distinct analyses on a single sample [screening vs. confirmatory testing does not apply]). In these cases, the LFFM lab and FDA can agree to count the individual analyses towards the annual sample load (i.e., a single sample may be counted as multiple for the purposes of LFFM activities). Laboratories cannot make this determination on their own, approval to count individual analyses towards the sample load must be done in consultation with the PM and the technical coordinator for the Track in question. This information will be included in the annual sample and project

plan options by track, sent out when requesting sampling proposals from grantees for the upcoming year.

An example could be as follows: 1 sample (20 subsamples) of avocados will be composited into two analyses of 10 subsamples each. This would count as two samples for the LFFM since two analyses were needed. Another example could be: 1 sample is analyzed by two distinct methods (toxic elements by ICP-MS and nutritional elements by ICP-OES). This would count as two samples towards the LFFM sample load since two analyses were needed. If any clarification on sampling and sample numbers is needed, please reach out to your PM and the Track technical coordinator for guidance.

A proposed sample plan for each upcoming year must be submitted by the annual pre-announced deadline and approved by FDA prior to the start of work.

Environmental swabs (from any type of facility, e.g., processor or retail), products produced 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 (unless designated as part of a national sampling project by FDA) 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.

Isolates resulting from LFFM Micro Human or Animal Food Product Testing Tracks must be sequenced. If a laboratory is also participating in the LFFM WGS Track, it is expected that the sequencing will be prioritized and supported by the WGS Track. Other laboratories may utilize existing partnerships to accomplish sequencing. If your laboratory does not have WGS capabilities and needs assistance sequencing isolates resulting from LFFM testing, contact the ORA Technical Leads for assistance; a LFFM WGS Track lab may be able to assist.

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 and the designated FDA Program Division email for your state. The State regulatory program with jurisdiction over the presumptive positive or CRO sample must also be notified.

Submit the completed laboratory package for confirmed positive or violative samples for which FDA will be joining the state in response activities to the State Regulatory Program and the FDA Program Division within three (3) business days of final determination. This would include any supplemental information, as requested. The FDA Program Division and the SRP will work together to discuss and plan the response efforts warranted by either agency.

Timely notification to the FDA, including the LFFM CAP Technical Leads, Project Managers, Program Division, and the SRP is a specific aim of the cooperative agreement and is included in the metrics used to evaluate recipient performance.

Key personnel (minimum of two) must attend an annual face-to-face meeting (as determined by FDA OP) as a condition of the award. One (1) of these attendees must be the PI/PD of the project.

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 participating in any Food Defense, Human Food Testing, or Animal Food Testing tracks 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. Those that 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 fiscal, grants policy, procedures and/or administrative matters to the grants management specialist listed below.

Kiara Farmer

Kiara.Farmer@fda.hhs.gov

Direct inquiries regarding scientific, technical, and programmatic issues to the program official listed below.

Laurie Keppley

Laurie.Keppley@fda.hhs.gov

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.

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).

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