Department of Health and Human Services Food and Drug Administration

Notice of Award FAIN# U2FFD008064 Federal Award Date 08/30/2023

Recipient Information

1. Recipient Name

MISSOURI DEPARTMENT OF HEALTH & SENIOR SERVICES
920 WILDWOOD DR
JEFFERSON CITY, MO 65109

- 2. Congressional District of Recipient 03
- 3. Payment System Identifier (ID) 1446000987B7
- 4. Employer Identification Number (EIN) 446000987
- 5. Data Universal Numbering System (DUNS) 878092600
- 6. Recipient's Unique Entity Identifier
 UETLXV8NG8F4
- 7. Project Director or Principal Investigator
 Eric Hueste, BS

grants@health.mo.gov 573-751-6087

8. Authorized Official

Eric R Hueste

Federal Agency Information

9. Awarding Agency Contact InformationJanelle Fundersburg

FOOD AND DRUG ADMINISTRATION janelle.fundersburg@fda.hhs.gov

10. Program Official Contact Information

Laurie Keppley

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

Federal Award Information

11. Award Number

1U2FFD008064-01

12. Unique Federal Award Identification Number (FAIN)

U2FFD008064

13. Statutory Authority

FSMA, Section 210 FSMA, Section 210

14. Federal Award Project Title

Development and Maintenance of Human and Animal Food Rapid Response Teams

15. Assistance Listing Number

93.103

16. Assistance Listing Program Title

Food and Drug Administration Research

17. Award Action Type

New Competing

18. Is the Award R&D?

Yes

Summary Federal Award Financial Information				
19. Budget Period Start Date 09/01/2023 - End Date 06/30/2024				
20. Total Amount of Federal Funds Obligated by this Action	\$225,000			
20 a. Direct Cost Amount	\$193,831			
20 b. Indirect Cost Amount	\$31,169			
21. Authorized Carryover				
22. Offset				
23. Total Amount of Federal Funds Obligated this budget period	\$225,000			
24. Total Approved Cost Sharing or Matching, where applicable \$6				
25. Total Federal and Non-Federal Approved this Budget Period	\$225,000			
26. Project Period Start Date 09/01/2023 – End Date 06/30/2026				
27. Total Amount of the Federal Award including Approved Cost	\$225,000			
Sharing or Matching this Project Period				

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 – 1U2FFD008064-01

Award Calculation (U.S. Dollars)

Other

Salaries and Wages	\$102,350
Fringe Benefits	\$69,854
Personnel Costs (Subtotal)	\$172,204
Materials & Supplies	\$4,784
Travel	\$7,293

\$9,550

Federal Direct Costs \$193,831
Federal F&A Costs \$31,169
Approved Budget \$225,000
Federal Share \$225,000
TOTAL FEDERAL AWARD AMOUNT \$225,000

AMOUNT OF THIS ACTION (FEDERAL SHARE) \$225,000

SUMMARY TOTALS FOR ALL YEARS				
YR	THIS AWARD	CUMULATIVE TOTALS		
1	\$225,000	\$225,000		
2	\$225,000	\$225,000		
3	\$225,000	\$225,000		

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

Fiscal Information:

Document Number:UFD008064APMS AccountType:P(Subaccount)Fiscal Year:2023

IC	CAN	2023	2024	2025
FD	6990914	\$225,000	\$225,000	\$225,000

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

FDA Administrative Data:

PCC: ORA7 / OC: 4141 / Processed: Pendleton, Kimberly 08/22/2023

SECTION II – PAYMENT/HOTLINE INFORMATION – 1U2FFD008064-01

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 - 1U2FFD008064-01

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) U2FFD008064. 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 30 th
April, May, June	September 30 th
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 <u>IS</u> 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 <u>not covered</u> 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:

- 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.

- 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 (I), (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/civilrights/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 - 1U2FFD008064-01

CONDITION OF AWARD: Please address the following no later than 10/02/2023:

1. Submit to your GMS your organization's unexpired Federally Negotiated Indirect Cost Rate Agreement to justify the 18.1% rate used.

ADDITIONAL PRIOR APPROVAL REQUIREMENTS:

Prior approval is required for significant rebudgeting of 10% or more of the total funds authorized under the current year's award.

Additional Terms and Conditions for RRT funding track (Development and Maintenance)

Awardees receiving funding under the RRT track must have in place a valid non-public information sharing agreement with FDA per 21 CFR 20.88

A minimum of two (2) key RRT personnel must attend an annual face-to -face RRT meeting (as determined by FDA OP) and at least one person representing the RRT must attend the biennial Integrated Foodborne Outbreak Response Management (InFORM) Conference and the Regional InForm meetings (held in non-InFORM annual meeting years) as a condition of the award.

Program Specific Reporting:

In accordance with 5 CFR 1320.5(b), the approved OMB CONTROL NUMBER: 0910-0909 will be displayed on all forms provided to grantees to report information and data for this cooperative agreement program, including the RRT Cooperative Agreement Program Report Form (mid-year, annual, and final reporting). Grantees are strongly encouraged to use the reporting forms provided to ensure that all progress reporting

requirements are met.

The data elements that will be requested include, but are not limited to the following:

Yearly objectives for RRT Development:

- a. New RRTs have the option to enter into 3-year development track to establish and develop new team structure. Deliverables for year 1-3 of the development track are as follows: Hiring and placement of all proposed staff in the application by no later than the end of year.
- b. Actively participate in a web-based meeting organized by FDA OP introductory meeting, pre-progress report, and as needed or requested (in years 1 and 2)
- c. Complete the RRT Capacity Building Process and Mentorship Framework phases 1 and 2, including: developing the RRT structure (inclusive of human and animal food regulatory, epidemiology, and laboratory partners), holding quarterly meetings, training of team members, and development of standard operating procedures.
- d. Complete development of an RRT sustainability plan and provide updates in progress reports.
- e. Conduct at least one joint training addressing a common need among RRT member agencies/partners (e.g. Epi-Ready, Environmental Sampling, Tracebacks etc.).
 - f. Ensure RRT Coordinator's training level and needs are assessed at baseline assessment (refer to RRT Best Practices Manual RRT Coordinator Chapter for additional guidance).
- g. Use the RRT Coordinator Chapter in the RRT Best Practices Manual to understand roles, as well as internal and external responsibilities (in year 1; in years 2 and 3, as needed).
- h. Complete a capability assessment review each year and develop an improvement plan based on the results of the assessment.
- i. Participate in an RRT workgroup to improve capability assessments, when available.
- j. Conduct at least one presentation (oral or poster) about the development of the RRT or documenting a specific investigation (in years 2 and 3).
- k. Complete after-action reviews and summary reports in a timely way for exercises and responses to significant real incidents (for years 2 and 3). At least one afteraction report shall be shared with FDA each grant year.
- Attend an annual face-to-face meeting of the RRT States and FDA Headquarters and District Offices (a minimum of 2 key personnel), as well as the biennial Integrated Foodborne Outbreak Response Management (InFORM) Conference and Regional InFORM (at least 1 person representing RRT to the biennial InFORM and the Regional InFORM).
- m. Participate in initiatives supporting the RRT program, including FoodSHIELD workgroups, RRT monthly meetings, sharing best practices, and other RRT

Yearly objectives for RRT Maintenance:

Since the RRT maintenance funding is tiered, some goals are optional based on the state program funding tier as described below.

Maintenance and Continuous Program Improvement (All Sub-Parts Required)

- 1. Maintain the RRT: SOPs must be current and fit for use, execute the training plan, maintain the team, equip the team, complete at least one exercise each grant year, develop and maintain an improvement plan based on investigation findings.
- Conduct at least one planned, joint exercise with all RRT partners to focus on improving response capabilities identified as needing improvement (e.g. Tracebacks, Sampling, Environmental Assessments, Recalls etc.). The exercise must include ICS elements and standing up an Incident Management Team to manage the incident.
- 3. Work with federal, state, local government partners, and appropriate subject matter experts to effectively respond to human and animal food emergencies such as: foodborne illness outbreaks, intentional food contamination, natural disasters, and other food incidents. Federal partners may include but are not limited to: FDA Divisions, CORE, CVM, OEO, and USDA/FSIS. Describe multiagency responses in progress report narrative and/or incident summaries.
- 4. Conduct and document after-action reviews for RRT responses, activations, and exercises per RRT SOPs. Incorporate findings into the improvement plan.
- 5. Complete and submit a Capability Assessment Tool via FoodSHIELD.
- 6. Develop an Improvement Plan and submit for review based on CAT assessment results and AAR findings.
- 7. Ensure that state/local agencies who receive RRT funding from the primary awardee agency (pass through funding) will provide details of what was accomplished with the funding to the state RRT Coordinator or PI/PD to be shared with FDA via mid-year and end-of-year RRT Cooperative Agreement progress reports.
- 8. Contribute to the revision of the CAT by participating in the CAT revision workgroup, when applicable.
- 9. Complete and submit a Sustainability Assessment for the previous grant year by November 30th of each year. Reference phase 2 of the Capacity Building and Mentorship Framework describing the vision for sustainability including: 1) Resources critical to RRT operations and program maintenance; 2) Current funding source for each resource (State, Federal, etc.); 3) Approximate dollar value of each resource; 4) Contingency plans and impact on each resource

- should Federal RRT funds cease.
- 10. Diversify support for RRT operations/maintenance (ideally split across state and federal grant funds); in particular, ensuring key RRT personnel salaries are on partial state funds and O&M costs for IT systems and other technologies are on state, not federal, funds. Provide an update on diversification of funding (successful or unsuccessful) in progress reports.
- 11. Develop and track a training plan as outlined in the RRT Best Practices Manual to ensure RRT staff are competent in the Incident Command System (ICS), foodborne illness investigations, tracebacks, sampling, after-action reviews, and conducting environmental assessments/root cause investigations.

RRT Innovation, Integration, and National Capacity/Capability Development (Level 3 RRTs: Must Have 2 Distinct Projects Per Year; Level 2 RRTs: Must Have 1 Project Per Year; Level 1 RRTs: No Requirement). Collaborative projects with external groups aligned with the project areas in Program Objective 2 below may be added as an optional goal with FDA/OP approval.

- 1. Mentor a voluntary RRT (must be assigned by FDA Office of Partnerships (OP)) in RRT development.
- 2. Develop and execute an inter-RRT project/collaboration, aimed at any RRT-related topic of mutual interest. Examples include: Regional RRT meetings, District-wide RRT collaboration, multi-RRT After Action Reports (AAR)/improvement plans, identifying and proposing solutions to regional/national needs/gaps (surveillance, response or prevention; training; exercise; data sharing), and working with relevant partners to propose outreach, education, legislative and other activities to prevent incident/contamination recurrence.
- 3. Pilot, implement, and evaluate newly established best practices. This includes a written evaluation of the effectiveness of implementing the best practices and any recommendations for improvement.
- 4. Assist non-RRT states in developing advanced response capabilities (e.g. training on the RRT Best Practices Manual, the Capacity Building and Mentorship Framework, and/or procedures used for RRT responses and activations).
- 5. Develop and execute a specific project aimed at enhancing/improving collaboration with local health departments during RRT responses and activations, or with another RRT partner or non-RRT state that historically has not been involved in your RRT (e.g., FSIS, a new food/feed commodity area, law enforcement, emergency management; which partners meet this criteria will largely depend on how your RRT is structured).
- 6. Develop and execute a training-related project.
- 7. Participate in individual, multi-state or national initiatives to undertake innovative approaches to response and/or create and provide tools and resources to help others enhance their ability to effectively respond to human

and animal food contamination incidents.

8. Additional projects the RRT is working on related to Program Objective 2 may be submitted to FDA/OP for review and approval to be added as optional goals.

Gathering and Sharing Data to Support Prevention (Number 3 is Required for all RRTs; Level 3 RRTs: Must Have 1 Project Per Year Selected from Other Sub-Parts; Level 1 & 2 RRTs: No Requirement)

- 1. Conduct environmental assessments for food contamination events occurring in the state and share data in the appropriate reporting systems.
- 2. Address gaps in procedures or training necessary to support conducting environmental assessments/root cause investigations (assessments geared at identifying contributing factors and environmental antecedents that led to a human or animal food contamination event).
- 3. Use the Environmental Assessment chapter of the RRT Best Practices Manual to document EA findings. Share results of EAs via the capability assessment tool, National Environmental Assessment Reporting System (NEARS), and National Outbreak Reporting System (NORS). Root cause or innovative findings are shared in a written report, during RRT monthly teleconference updates, or at the annual meeting.
- 4. Share investigation findings with industry, or work with relevant partners to propose recommendations for industry or other preventive measures based on findings from environmental assessments. Examples include: organizing/hosting workshop or trainings for industry, developing and providing written guidelines/best practices/handouts or other resources to industry, publishing articles in trade journals, leveraging State Food Protection Task Force events, and speaking at industry events.
- 5. May develop the capability to conduct Dead End Ultra-Filtration (DEUF)/high volume water sampling to enhance ability to investigate outbreaks where non-public water is a suspected contamination source. Share the results of DEUF sampling with FDA through email or progress reports to document findings and build a better data set of DEUF sampling results.
- 6. Proactively monitor complaint systems or Reportable Food Registry (RFR) notifications for trends and respond to investigate. A written report or presentation of findings and recommendations for improvement must be completed. This can be accomplished by uploading a report to FoodSHIELD or sharing a copy via email with RRT Program staff.
- 7. Work with RRT member agencies/partners to capture and report environmental assessment data to national reporting systems, such as: FDA's Farm Investigation Questionnaire for on-farm/produce related microbiological contamination events, and CDC's NORS for any human foodborne illness outbreak. Use of the FDA Environmental Assessment Process Overview in conducting environmental

- assessments is encouraged.
- 8. Work with RRT member agencies/partners to capture and report environmental assessment data to CDC's NEARS for outbreaks linked to food service establishments
- 9. Work with laboratory partners to support Laboratory Flexible Funding Model (LFFM) goals. This includes coordination between the food regulatory program and lab on sampling initiatives and pivoting to prioritize and redirect sampling during an outbreak or other food incident. Support the laboratory by coordinating with regulatory program partners within the state to develop the LFFM sample plan proposal, develop the sample collection schedule, coordinate and lead the response to potentially violative samples etc. Evaluate responses and sampling from the previous year and recommend pathogen/commodity pairs to proactively target and support early detection and prevention.
- 10. Collaborate with non-RRT regulatory partners to suggest and implement prevention-focused improvements in routine inspection and sampling activities based on lessons learned and findings from past environmental assessments and investigations. Examples include: revision of inspection/investigation questionnaires or protocols, implementation of or changes to surveillance sampling schedules, revision of sampling protocols, and changes in risk classification of firm inventory, working with laboratory partners to develop a joint sampling project considering pathogen commodity pairs to proactively target prevention sampling in alignment with both RRT and LFFM goals. Implementing Good Samples training strategies and incorporating into sampling procedures.

Communicating RRT Impact (All Sub-Parts Required)

- Conduct at least two presentations per year (oral or poster) documenting a specific RRT investigation or other activity and share a copy of the presentation within the RRT Program Workgroup in FoodSHIELD. At least one of these two presentations must be at a regional or national meeting (a RRT Face to Face (F2F) Meeting presentation cannot count as your regional/national meeting presentation).
- 2. Present at least once per year on the national RRT monthly teleconference and present a poster at the national RRT F2F meeting to share investigation or project outcomes, as well as emerging or nascent stage lessons learned and best practices with other RRTs.
- 3. Prepare and post at least one report per year of a significant investigation, successful prevention effort, or other RRT action taken to protect public health on a Food Protection Task Force webpage, a state agency webpage or other public webpage and notify RRT Program Coordinators to allow cross-linking from the FDA RRT webpage. RRT authorship on a peer reviewed journal article is acceptable for this goal.

4. For each revision cycle of the RRT Manual, participate in at least one aspect of RRT Manual revision. Options include: review chapters to verify content or identify content requiring revision (at least 3 chapters), participate in the national review (review at least 3 chapters), and participate in a chapter committee (at least 1 committee/workgroup). This goal may not be applicable during each year of the cooperative agreement.

Grantees must review and achieve these yearly RRT milestones/objectives each grant year. Grantees must provide mid-year and annual progress report updates each grant year.

Performance

Mid-year interim progress reports are required for this award describing the status of completing each milestone/objective described above. The mid-year progress reports should be submitted via email to the listed Grants Management Specialist, Program Official and Program Managers by January 30, 2024.

Progress updates on subaward funded activities must be included in the mid-year and annual progress reports. RRT partner recipients of subawards must agree to document how the subawards are used to assist the RRT in meeting program milestones/objectives. This includes information related to the overall RRT budget and Capability Assessment submissions.

An annual progress report and final progress report are required for this award describing the status of completing each milestone/objective described above. These reports should be submitted via eRA Commons.

Grantees are strongly encouraged to use the reporting forms provided to ensure that all progress reporting requirements are met.

Additional programmatic report requirements:

Mid-year, annual, and final progress reports must contain the elements below:

- Detailed progress report on the grantee meeting the project milestones detailed in the cooperative agreement, proposal, strategic plan, conditions of the award, etc. Goals and objectives should be outlined in detail and specific progress reported.
- Status report on the hiring and training of cooperative agreement funded personnel and other manufactured food program personnel.

- Status report on the purchasing, development, and operational readiness of any equipment, computers, or software purchased.
- Identify any pending issues or concerns that may affect accomplishing the objectives and goals of the cooperative agreement.
- A corrective action plan must be submitted if the objectives and goals of the cooperative agreement are not being met. The corrective action plan must detail the tasks, responsible personnel, and updated timeframes to ensure satisfactory performance and meet the deliverables required under the grant.
- Points of Contacts and Project Key Personnel

Non-allowable costs:

- Facilities and work reimbursed under other FDA funding mechanisms must remain distinct and separate from the cooperative agreement.
- Vehicle purchases are not permitted.
- 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.
- Clothing and uniforms, with the exception of personal protective equipment (PPE). Other items listed in the HHS Grants Policy Statement Financial.

Financial

Mid-year interim financial reports are required for this award. The interim financial report should be submitted via email to the listed Grants Management Specialist, Program Official and Program Managers by January 30, 2024. The Federal Financial Report (SF-425) which can be downloaded at

https://grants.nih.gov/grants/forms/report on grant/federal financial report ffr.htm should be used to submit interim financial reports via email to the Grants Management Specialist and Program Official.

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

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

All formal correspondence/reports regarding the grant should be signed by an authorized institutional official and the Principal Investigator and should be sent to the attention of the grants management specialist, unless otherwise explicitly directed.