Notice of Grant Award

RESEARCH DEMONSTRATION COOPERATIVE AGREEMENTS
Department of Health and Human Services

FOOD AND DRUG ADMINISTRATION

Grant Number: 1U18FD006422-01
FAIN: U18FD006422

Principal Investigator:
Eric Hueste, BS

Project Title: MFRPS-to achieve & maintain full conformance, RRT-Improve food safety in Missouri, FPTF-To organize Food Protection Task Force meetings.

Ms. Bedell, Pat
Deputy Director
920 Wildwood Drive
P.O. Box 570
Jefferson City, MO 651020570

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

Budget Period: 09/01/2018 – 06/30/2019
Project Period: 09/01/2018 – 06/30/2023

Dear Business Official:

The Food and Drug Administration hereby awards a grant in the amount of $460,000 (see “Award Calculation” in Section I and “Terms and Conditions” in Section III) to MISSOURI STATE DEPT/HEALTH & SENIOR SRV in support of the above referenced project. This award is pursuant to the authority of PHS Act, Sec 1706, 42 USC 300u-5, as amended; Sec 2(d), PL 98-551 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

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

If you have any questions about this award, please contact the Grants Management Specialist and the Project Officer listed in the terms and conditions.

Sincerely yours,

Kimberly Pendleton
Grants Management Officer
Office of Acquisitions & Grants Services
Division of Acquisition Support and Grants
Grants & Assistance Team
FOOD AND DRUG ADMINISTRATION

See additional information below
SECTION I – AWARD DATA – 1U18FD006422-01

Award Calculation (U.S. Dollars)

<table>
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<th>Item</th>
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<td>Salaries and Wages</td>
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Federal Direct Costs     $392,070
Federal F&A Costs        $67,930
Approved Budget          $460,000
Federal Share             $460,000
TOTAL FEDERAL AWARD AMOUNT $460,000

AMOUNT OF THIS ACTION (FEDERAL SHARE) $460,000

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

Fiscal Information:

CFDA Number: 93.367
EIN: [Redacted]
Document Number: UF006422A
PMS AccountType: P(Subaccount)
Fiscal Year: 2018

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FDA Administrative Data:
PCC: ORA20 / OC: 4141 / Processed: FDAKPU 08/23/2018

SECTION II – PAYMENT/HOTLINE INFORMATION – 1U18FD006422-01

Grant payments will be made available through the DHHS Payment Management System (PMS). PMS is administered by the Division of Payment Management, Program Support Center (PSC), DHHS, Office of the Deputy Assistant Secretary, Finance. Requests for downloadable forms and inquiries regarding payment should be directed to:

Regular Mailing Address:
Treatment of Program Income:

Additional Costs
In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than $10,000,000 must report and maintain information in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75.

SECTION IV – FD Special Terms and Condition – 1U18FD006422-01

Expanded Authorities do not apply to this award

Please note: The first year of this grant is included in the recycling process for administrative purposes, all future budget years will be funded for 12 months.

Pre-award costs incurred during August, 2018 are approved.

Terms and Conditions

The administrative and funding instrument used for this program is the cooperative agreement, an assistance instrument (rather than an acquisition instrument), in which substantial FDA programmatic involvement with the awardees is anticipated during the performance of the activities. Under the cooperative agreement, FDA’s objective is to support and stimulate the recipient’s activities by involvement in and otherwise working jointly with the award recipient in a partnership role; it is not to assume direction, prime responsibility, or a dominant role of activities. Consistent with this concept, the dominant role and prime responsibility resides with the awardee for the project although specific tasks and activities may be shared between the awardee and the FDA as defined below.

a) Cooperative Agreement–Project Director/Principal Investigator Rights and Responsibilities:
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 sufficient clearance and/or background checks 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.

b) Cooperative Agreement–FDA Responsibilities:
An FDA Project Officer (PO) will be assigned and named in the Notice of Award. The FDA PO is the official responsible for the programmatic, scientific, and/or technical aspects of assigned applications and cooperative agreements. The FDA PO will have substantial programmatic involvement that is above and beyond the normal stewardship role in awards as described below. The PO 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, direction, 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. 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.

**Monitoring Activities**

Periodic program monitoring will be conducted by FDA on an ongoing basis which may include telephone conversations between the Principal Investigator and the Project Officer/Grants Management Officer/Grants Management Specialist, site visits and the review of written reports. The Annual Progress Report will be due as part of the Research Performance Progress Report (RPPR) and is due no later than 60 days prior to the start date of the next budget period start date.

Grants with Multiple Years: In order to receive future funding, the grantee is required to submit the Research Performance Progress Report (RPPR). The Annual Progress Report will be due as part of the Research Performance Progress Report (RPPR) and is due no later than 60 days prior to the start date of the next budget period start date. This report should cover all activities/work that took place during the current budget performance period noted in your Notice of Grant Award (NGA).

**Financial Reporting:**

A. Cash Transaction Reports

The Federal Financial Report (FFR) has a dedicated section to report Federal cash receipts and disbursements. For recipients this information must be submitted quarterly directly to the Payment Management System (PMS) using the web-based tool. Quarterly reports are due 30 days following the end of each calendar quarter. The reporting period for this report continues to be based on the calendar quarter. Questions concerning the requirements for this quarterly financial report should be directed to the PMS.

B. Financial Expenditure Reports

A required Federal Financial Report (FFR) must be submitted annually. FDA now requires all annual financial expenditure reports to be submitted electronically using the Federal Financial Report (FFR) system located in the eRA Commons. This includes all initial FFRs being prepared for submission and any revised FSR/FFRs being submitted or re-submitted to FDA. Paper expenditure/FFR reports will not accepted.

Annual FFRs must be submitted for each budget period no later than 90 days after the end of the calendar quarter in which the budget period ended. The reporting period for an annual FFR will be that of the budget period for the particular grant; however, the actual submission date is based on the calendar quarter. Failure to submit timely reports may affect future funding.

4. Closeout Requirements (when applicable): A Final Program Progress Activity Report, Final Federal Financial Report SF-425, Final Invention Statement HHS-568 (if applicable), Tangible Personal Property Report SF-428, and Statement of Disposition of Equipment (if applicable) must be submitted within 90 days after the expiration date of the project period.

5. A non-Federal entity that expends $750,000 or more during the non-Federal entity's fiscal year in Federal awards must have a single or program-specific audit conducted for that year in accordance with the provisions of 45 CFR 75, Subpart F-Audit Requirements. Audits must be completed and submitted electronically to the Federal Audit Clearinghouse (FAC) within 30 days after receipt of the auditor's report(s), or 9 months after the end of the audit period, i.e., the end of the organization's fiscal year, whichever is earlier. If you need information on your organization's obligations, please visit the following website: [http://harvester.census.gov/sac/](http://harvester.census.gov/sac/). Valuable information is included under the “Frequently Asked Questions” section of that website. The grantee organization must comply with all special terms and conditions of the cooperative agreement. Future funding will be dependent on recommendations from the Project Officer. The scope of the recommendation will confirm an acceptable level of performance and continued compliance with all FDA regulatory requirements and conditions of the award. Specific project milestones, reporting requirements, and other project deliverables may be included as a condition.
of your award. If FDA determines that the state is unable to make adequate progress, FDA may place them in special condition status and may require a corrective action plan. Grantees developing their MFRPS program will achieve and maintain conformance with the MFRPS (most recent version) within five years. Grantees who have already developed their MFRPS program will maintain conformance by demonstrating implementation of a strategic improvement plan when non-conformance is identified by the State program or FDA. The grantee must maintain a food safety inspection contract in satisfactory standing with the FDA throughout the cooperative agreement.

If a recipient of multiple FDA awards (cooperative agreements, grants, contracts), the State must be able to account separately for fund expenditures, including employee salaries, wages, and benefits, under those funding mechanisms and this cooperative agreement.

A rebudgeting request covers reallocation of cooperative agreement funds and change of planned expenditures (compared to the existing budget on record for the grantee) either between budget categories (personnel, equipment, supplies, etc.) or within a single budget category. All rebudgeting requests that involve moving cooperative agreement funds between budget categories in excess of 10% of the total track award must be submitted and approved by OP/OAGS. A new NGA will only be issued when rebudgeting requests reach a cumulative total (during a single budget period) of 25% of the total award or more. Rebudgeting requests within a single budget category must be submitted and approved by OP/OAGS when they reach a cumulative (during a single budget period) total of $10,000 or more.

Additional Terms and Conditions for MFRPS Funding track (as applicable)

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

State manufactured food regulatory programs in the MFRPS Development funding track are expected to achieve conformance with the MFRPS before Year 5 of the cooperative agreement. State manufactured food regulatory programs in the MFRPS Maintenance funding track are expected to maintain conformance with the MFRPS throughout the duration of the award.

Additional Terms and Conditions for RRT funding track (as applicable)

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 (held in odd number years) and the Regional PulseNet/OutbreakNet meetings (held in non-InFORM years) as a condition of the award.

Additional Terms and Conditions for FPTF funding track (as applicable)

All conference material (promotional materials, agenda, publications and internet sites) related to this project must include an acknowledgement of FDA grant support and a disclaimer stating the following: "Funding for this conference was made possible [in part] by [insert grant number] from [insert FDA name]. The views expressed in written conference materials or publications and by speakers and moderators do not necessarily reflect the official policies of the Department of Health and Human Services; nor does mention of trade names, commercial practices, or organizations imply endorsement by the U.S. Government."

Additional Terms and Conditions for Special Project funding track (as applicable)

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.

Reporting

When multiple years are involved, awardees will be required to submit the Research Performance Progress Report (RPPR) annually and financial statements as required in the Notice of Award. For all years of the cooperative agreement except the 2018-2019 funding year, mid-year reports and an end of year program progress report are required. In 2018-2019, only the RPPR through eRA Commons is required. For continuation years, the RPPR will be considered the end of year progress report. Reporting requirements may be adjusted for individual grantees in the Notice of Award.

Mid-year and end of year 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.

Summary of grant expenditures and obligations during the current budget period. The report must include detail of spending by funding track if more than one option is funded under this award.

**Additional requirements for the mid-year progress report:** Submission of the following documents in the most current version of the MFRPS reviewed and updated within the current budget period (see below list). State programs enrolling in MFRPS for the first time under this cooperative agreement do not need to submit these appendices until the mid-year progress report of Year 2 of the cooperative agreement. These documents may be found in the 2016 version of the MFRPS available at [https://www.fda.gov/downloads/ForFederalStateandLocalOfficials/ProgramsInitiatives/RegulatoryPrgmStnds/UCM523944.pdf](https://www.fda.gov/downloads/ForFederalStateandLocalOfficials/ProgramsInitiatives/RegulatoryPrgmStnds/UCM523944.pdf).

Appendix 1 or alternate form that is equivalent
Appendix 2.1 or alternate form that is equivalent
Appendix 3.1 or alternate form that is equivalent
Appendices 4.1 or alternate form that is equivalent
Appendix 5.1 or alternate form that is equivalent
Appendices 6.1 or alternate form that is equivalent
Appendix 7.1 or alternate form that is equivalent
Appendices 8.1 or alternate form that is equivalent
Appendix 9.1 or alternate form that is equivalent
Appendix 10.1 or alternate form that is equivalent

Submission of a strategic improvement plan, as defined in the current version of the MFRPS, updated within the current budget period to demonstrate program advancement in achieving conformance with the MFRPS.

**Additional requirements for the end of year progress report:**

?Summary of grant expenditures and obligations during the current budget period and those anticipated to occur during the budget period. The grantee is required to indicate if a carryover request will be submitted for any remaining funds in the current budget period and the anticipated use of the funds in the upcoming budget period. The grantee is strongly encouraged to submit the carryover request with the continuation application.

For each funding track and option selected under this cooperative agreement (i.e., MFRPS Development or MFRPS Maintenance, RRT Development or RRT Maintenance, FPTF and Special Project), the grantee must clearly and separately describe all the associated costs in the narrative budget justification.

The grantee must provide an estimate (in total dollars) of in-kind contributions toward accomplishing the goals of the cooperative agreement during the reporting period. A separate estimate should be provided for each funding option selected under this cooperative agreement (i.e., MFRPS Development or MFRPS Maintenance, RRT Development or RRT Maintenance, FPTF and Special Project).

**Special consideration for programs in RRT Maintenance & Development**

All progress reports (mid-year, end of year and final) must contain, but are not limited to the following:

Progress & achievements for each yearly goal.

Progress & achievements for other projects, identified by the grantee in the application or subsequent to receiving funding.

Summary of significant RRT responses or other activities within the timeframe for the report, including status of AAR & lessons learned/recommendations for improvement

Point of Contact and Project Key Personnel

Pending Issues/Concerns and Proposed Solutions

The final End of Project RPPR report at the conclusion of the award must include an Exit Strategy of Sustainment (ESS), describing the recipient’s plan for continued maintenance of the regulatory infrastructure developed under this award.
Special consideration for programs in FPTF
Food Protection Task Forces must meet at least once annually with a formal agenda and/or evaluation of meeting.
The mid-year progress report submitted for the overall cooperative agreement (MFRPS Development or Maintenance Tracks) does not need to include a mid-year progress report for the FPTF funding option. The FPTF funding option must be included in the end of year and final progress reports.
FPTF progress reports must address the following:
- The FPTF official name, mission and annual goals and objectives
- A description of their FPTF structure, leadership and membership
- The number of meetings, trainings, and workshops supported with copies of agendas and supporting materials (handouts, slides, etc.)
- Copies of FPTF PPT, job aids, and other tools and resources developed by FPTF to meet their goals and objectives for sharing with other task forces and stakeholders
- A copy of the meeting, training, workshop etc. sign-in sheet that captures the names, emails, and affiliations of the attendees.
- Discussions and decisions resulting from these activities (reports, recommendations, questions etc.), including the replicability across other state task forces.
- Identification of an integration activity to address each year (see FOA Part 2, Section I, Subsection 3 (FPTF), objective 3, above) and provide an update on the activity in the annual report.
- Identification of any issues encountered during the implementation and/or adoption of FSMA or other rules/codes/ordinances.
- Recipients shall notify OP of any changes in key task force personnel and provide annually

Special consideration for programs in Special Projects:
Mid-year and end of year progress reports for the Special Projects funding option should describe progress made to date.
The final progress report (after the conclusion of the entire cooperative agreement) must include an evaluation/final report, including: lessons learned, results, and analysis of effectiveness and impact.
Final progress report: additional requirements (applies only after the conclusion of the entire cooperative agreement):
- Full written documentation of the project and summaries of accomplishments and goals, as described in the grant application. The documentation must be in a form and contain sufficient detail such that other State, local, and tribal governments could reproduce the final project.
- The most recent assessment by FDA should verify the program is maintaining conformance with the MFRPS.

Funding Restrictions
All FDA awards are subject to the terms and conditions, cost principles, and other considerations described in the HHS Grants Policy Statement.
Pre-award costs are allowable only as described in the HHS Grants Policy Statement.
Program funds may not be used for any purpose other than those directly tied to the goals of the cooperative agreement.
Non-allowable costs:
- Facilities and work reimbursed under the FDA human food safety inspection contract and other 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 or Notice of Award.

Additional Terms
The Federal Funding Accountability and Transparency Act of 2006 (Transparency Act), includes a requirement for awardees of Federal grants to report information about first-tier subawards and executive compensation under Federal assistance awards issued in FY2011 or later. All awardees of applicable FDA grants and cooperative agreements are required to report to the
At the conclusion of the multi-year cooperative agreement, a final progress report, invention statement, and the expenditure data portion of the Federal Financial Report are required for closeout of an award, as described in the HHS Grants Policy Statement, to be submitted within ninety (90) days of the expiration date as noted on the Notice of Grant Award. Alternatively, a final Progress Report is due when an award is relinquished, when a recipient changes institutions or when an award is terminated.

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 from all Federal awarding agencies with a cumulative total value greater than $10,000,000 for any period of time during the period of performance of a Federal award, must report and maintain the currency of information reported 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)). This is a statutory requirement under section 872 of Public Law 110-417, as amended (41 U.S.C. 2313). As required by section 3010 of Public Law 111-212, all information posted in the designated integrity and performance system on or after April 15, 2011, except past performance reviews required for Federal procurement contracts, will be publicly available. Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75 – Award Term and Conditions for Recipient Integrity and Performance Matters.

A final RPPR, invention statement, and the expenditure data portion of the Federal Financial Report are required for closeout of an award, as described in the HHS Grants Policy Statement. The Federal Funding Accountability and Transparency Act of 2006 (Transparency Act), includes a requirement for awardees of Federal grants to report information about first-tier subawards and executive compensation under Federal assistance awards issued in FY2011 or later. All awardees of applicable FDA grants and cooperative agreements are required to report to the Federal Subaward Reporting System (FSRS) available at www.fsrs.gov; on all subawards over $25,000.

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 from all Federal awarding agencies with a cumulative total value greater than $10,000,000 for any period of time during the period of performance of a Federal award, must report and maintain the currency of information reported 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 FAPIIS). This is a statutory requirement under section 872 of Public Law 110-417, as amended (41 U.S.C. 2313). As required by section 3010 of Public Law 111-212, all information posted in the designated integrity and performance system on or after April 15, 2011, except past performance reviews required for Federal procurement contracts, will be publicly available. Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75 – Award Term and Conditions for Recipient Integrity and Performance Matters.

Project Officer, Brett Weed for inquiries and questions regarding programmatic aspects or concerns: Phone 919/348-3909 E-mail: brett.weed@fda.hhs.gov

Grants Management Specialist, Dan Lukash for inquiries and questions regarding administrative matters or financial concerns: Phone: 240/402-7596 E-mail: daniel.lukash@fda.hhs.gov

Direct inquiries regarding scientific programmatic issues to the official listed below.

Direct inquiries regarding fiscal and/or administrative matters to the grants management specialist listed below.

All formal correspondence/reports regarding the grant should be signed by an authorized institutional official and the Principal Investigator and should be sent to the attention of the grants management specialist, unless otherwise explicitly directed.
STAFF CONTACTS
Grants Management Specialist: Daniel Lukash
Email: daniel.lukash@fda.hhs.gov  Phone: 240-402-7596

Program Official: Brett Weed
Email: Brett.Weed@fda.hhs.gov

SPREADSHEET SUMMARY
GRANT NUMBER: 1U18FD006422-01

INSTITUTION: MISSOURI STATE DEPT/ HEALTH & SENIOR SRV

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