Notice of Grant Award

RESEARCH DEMONSTRATION COOPERATIVE AGREEMENTS
Department of Health and Human Services

FOOD AND DRUG ADMINISTRATION

Grant Number: 5U18FD005658-03 REVISED
FAIN: U18FD005658

Principal Investigator:
Eric  Hueste

Project Title: Missouri RRT

Pat Bedell
State of Missouri
Health and Senior Services
PO Box 570
Jefferson City, MO 65102

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

Budget Period: 09/01/2017 – 08/31/2019
Project Period: 09/01/2015 – 08/31/2019

Dear Business Official:

The Food and Drug Administration hereby revises this award (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;Sec2(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 – 5U18FD005658-03 REVISED

Award Calculation (U.S. Dollars)

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<td>Federal Direct Costs</td>
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AMOUNT OF THIS ACTION (FEDERAL SHARE) $0

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

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* 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: FAKPU 09/04/2018 |

SECTION II – PAYMENT/HOTLINE INFORMATION – 5U18FD005658-03 REVISED

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:
Division of Payment Management
P.O. Box 6021
Included are the following Links & Instructions for drawing down funds, reporting expenditures, required forms, and the help desk info:


The ONE-DHHS Help Desk for PMS Support is now available Monday – Friday from 7 a.m. to 9 p.m. EST (except Federal Holidays). Phone (877) 614-5533; Email PMSSupport@psc.gov

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**SECTION III – TERMS AND CONDITIONS – 5U18FD005658-03 REVISED**

This award is based on the application submitted to, and as approved by, FDA on the above-title project and is subject to the terms and conditions incorporated either directly or by reference in the following:

a. The grant program legislation and program regulation cited in this Notice of Grant Award.

b. The restrictions on the expenditure of federal funds in appropriations acts to the extent those restrictions are pertinent to the award.

c. 45 CFR Part 75.

d. The HHS Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.

e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.

f. A required Federal Financial Report (FFR) SF-425 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. 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.

g. 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.

h. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

This award has been assigned the Federal Award Identification Number (FAIN) U18FD005658. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

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**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 – 5U18FD005658-03 REVISED

8/31/2018 - This award is being revised to provide approval of the grantee’s no-cost extension as approved by grants management and the Program Official with no additional cost to the Government as requested in accordance with the correspondence of 8/29/2018. The extension will permit continued enhancement of testing procedures.

12/19/2017 - The Notice of Grant Award revision approves the grantee’s request to carryover funds from the -02 year to the -03 year in the amount of $46,750, as requested in accordance with the purpose of the correspondence dated 12/5/2017 from Eric Hueste. In the event that the estimate unobligated balance from year -02 is less than the estimated amount on the Federal Financial Report (FFR), no additional Federal Funds will be made available to offset a deficit.

12/19/2017 - This action also approves a revised budget revision to purchase a -70 freezer.

Expanded Authorities Do NOT Apply to this Award

The grantee must maintain a food safety inspection contract with the FDA throughout the cooperative agreement project period. The grantee must also maintain enrollment in the MFRPS throughout the cooperative agreement project period.

State manufactured food programs funded under these cooperative agreements shall be required to provide the previous, current, and subsequent years of State funding to demonstrate that these funds have not replaced State allocations. A minimum of 2 key RRT personnel shall attend an annual face-to-face RRT meeting (as determined by FDA OP) and at least one person representing the RRT shall attend the biennial Integrated Foodborne Outbreak Response Management Conference (held in odd number years) as a condition of the award. The awardee should identify funds within the cooperative agreement for travel and plan accordingly.

Facilities, work, and training reimbursed under the FDA food safety inspection contract and other funding mechanisms (including MFRPS, AFRPS, VNFRPS, FERN, ISO or Food Protection Task Force Conference Grants) must remain distinct and separate from the cooperative agreement. The grantee must be able to account separately for fund expenditures, including employee salaries, wages, and benefits, under the food safety inspection contracts and other funding mechanisms and these cooperative agreements.

Future funding will be dependent on recommendations from the OP Programmatic Staff. The scope of the recommendation will confirm that acceptable progress has been made, continued compliance with all FDA regulatory requirements, and, if necessary, a corrective action plan has been implemented.

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 FDA as defined below.

The PD(s)/PI(s) will have the primary responsibility for:

The scientific, technical, and programmatic aspects of the grant and for day-to-day management of the project or program. The PD/PI(s) shall maintain general oversight for ensuring compliance with the financial and administrative aspects of the award, as well as ensuring that all staff has sufficient clearance and/or background checks to work on this project or program. This individual shall work closely with designated officials within the recipient organization to prepare justifications; appropriately acknowledge Federal support in publications, announcements, news programs, and other media; and ensure compliance with other Federal and organizational requirements. All applicants will be required to participate in a cooperative manner with FDA.

The awardee is responsible for submitting interim progress reports, when requested, to the FDA Project Scientist (PS)/Project Officer (PO) including summary data on progress to date.

FDA staff will have substantial programmatic involvement that is above and beyond the normal stewardship role in awards, as described below:

An FDA Project Scientist (PS) will have substantial programmatic involvement that is above and beyond the normal stewardship role in awards, as described below. However, the dominant role and prime responsibility for the activity reside with the awardee(s) for the project as a whole, but not necessarily for each task.

The responsibilities of the PS include involvement during conduct of the activity, through technical assistance, advice, coordination, and/or other assistance activities that is above and beyond normal program stewardship for grants.

As appropriate, the PS will participate in the definition of objectives and approaches, and in planning, conducting, analyzing, and publishing results, interpretations, and conclusions of their studies.

Also, the grantee organization must comply with all special terms and conditions of the cooperative agreement, including those which state that future funding of the project will depend on recommendations from the Project Officer.

In addition to the PS, there may be a separate FDA Program Official (PO) who will be responsible for the normal scientific and programmatic stewardship of the award and will be named in the award notice.

The PO officer will monitor the recipient periodically. The monitoring may be in the form of telephone conversations, e-mails, or written correspondence between the project officer/grants management officer and the principal investigator. The recipients shall also work with the FDA District Offices in development, training, and exercises for the developing RRT. Periodic site visits with officials of the recipient organization may also occur. The results of these monitoring activities will be recorded in the official cooperative agreement file and will be available to the grant recipient, upon request, consistent with applicable disclosure statutes and FDA disclosure regulations.

Areas of Joint Responsibility include:

During performance of the award, the PS/PO, with assistance from other scientific program staff who are designated based on their relevant expertise, may provide appropriate assistance, advice and guidance. The role of the PS/PO will be to facilitate and not to direct the activities. It is anticipated that decisions in all activities shall be reached by consensus between the PI and the PS, PO and that the FDA staff shall be given the opportunity to offer input into this process. The PS/PO will facilitate liaison activity for partnerships, and provide assistance with access to FDA supported resources and services as deemed necessary.
The PI(s) shall be responsible for the timely submission of all abstracts, manuscripts and reviews (co)authored by members of the grant and supported in part or in total under this Cooperative Agreement. Manuscripts shall be submitted to FDA PS/PO within two weeks of acceptance for publication. Publications or oral presentations of work performed under this Cooperative Agreement shall require appropriate acknowledgement of FDA support. Timely publication of major findings is encouraged.

The PS/PO and relevant FDA field offices will have continuous interaction with the recipient through activities such as the following: collection of progress reports; training; joint inspections; investigational and compliance activities; RRT exercises and coordination; and other activities necessary for the completion of objectives as outlined in this RFA. There may be other regular meetings with recipients to assist in fulfilling the requirements of the cooperative agreement. Specific interactions between relevant FDA field offices and the award recipients include:

a. Coordination, training, and exercises with FDA District and Regional RRT partners (including emergency response coordinators), the FDA Emergency Operations Center, CFSAN and CVM, the FDA CORE, and other federal agencies.

b. Working with other State entities in food protection such as State Departments of Health or Agriculture, emergency operations centers, environmental programs, epidemiologists, local food protection agencies, and others, in the accomplishment of objectives as outlined in this announcement.

c. Engaging other relevant initiatives within the RRT Concept, such as CDC Integrated Food Safety Centers of Excellence, CDC FoodCORE, FoodNet, and EHS-Net sites.

d. All cooperative agreement recipients must have existing food safety inspection and surveillance programs under contract to FDA for food safety inspections and be enrolled in the MFRPS, both of which require extensive District-State coordination (with the caveat that all funding streams must be kept distinct and separate, as described above under Section VI.2 Cooperative Agreement Terms and Conditions of Award).

The equipment purchased by FDA will remain the property of FDA under loan to the awardee’s laboratory for a specified time period with a review every twelve months. FDA may terminate the loan at any time. Unless approved by ORA/OP, the FDA provided equipment may not be transferred by the awardees' laboratory to a third party, and the awardees’ laboratory assumes full responsibility and liability for any claims that may arise as a result of operation of this equipment for the period it is in the possession of the awardees’ laboratory.

The Government, via the PO, will have access to data generated under this Cooperative Agreement and may periodically review the data and progress reports. The FDA PO may use information obtained from the data for the preparation of internal reports on the activities of the study. However, awardees shall retain custody of and have primary rights to all data developed under these awards.

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.

Performance Progress Reporting:

1. Annual progress reports are required. The Annual Progress Report will be due as part of the Research Performance Progress Report (RPPR).

2. Grants with Multiple Years: When multiple years are involved, awardees will be required to submit the Research Performance Progress Report (RPPR).

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
Grant’s Management Specialist: Dan Lukash
Email: daniel.lukash@fda.hhs.gov Phone: 240-402-7596

Program/Scientific Contact: Brett Weed
Email: brett.weed@fda.hhs.gov Phone: 919/348-3909

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: 5U18FD005658-03 REVISED

INSTITUTION: MISSOURI STATE DEPT/ HEALTH & SENIOR SRV

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