Notice of Grant Award  

RESEARCH DEMONSTRATION COOPERATIVE AGREEMENTS  
Department of Health and Human Services  
FOOD AND DRUG ADMINISTRATION  

Grant Number: 1U18FD005658-01  
FAIN: U18FD005658  

Principal Investigator:  
Eric Hueste  

Project Title: Missouri RRT  
State of Missouri  
Health and Senior Services  
PO Box 570  
Jefferson City, MO 65102  

Budget Period: 09/01/2015 – 08/31/2016  
Project Period: 09/01/2015 – 08/31/2018  

Dear Business Official:  

The Food and Drug Administration hereby awards a grant in the amount of $300,000 (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;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 – 1U18FD005658-01

Award Calculation (U.S. Dollars)

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<tbody>
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<td><strong>AMOUNT OF THIS ACTION (FEDERAL SHARE)</strong></td>
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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: 93.103
- EIN: [Redacted]
- Document Number: UFD005658A
- PMS Account Type: P(Subaccount)
- Fiscal Year: 2015

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FDA Administrative Data:
- PCC: ORA7 / QC: 414L / Processed: ERAAPPS 08/10/2015

SECTION II – PAYMENT/HOTLINE INFORMATION – 1U18FD005658-01

PHS policy requires that you be informed that the DHHS Inspector General maintains a toll free telephone number (800-368-5779) for receiving information concerning fraud, waste and abuse under the grants and cooperative agreements. Such reports will be kept confidential and callers may decline to give their names if they choose to remain anonymous.

Payments under this award will be made available through the DHHS Payment Management System (PMS). PMS is administered by the Division of Federal Assistance Financing (DFAF),
Office of the Deputy Assistant Secretary, Finance, which will forward instructions for obtaining payments. Inquiries regarding the payment should be directed to:

Division of Federal Assistance Financing
DASP/DASF/OS/ DHHS
P.O. Box 6021
Rockville, MD 20852
Telephone Number: 877-614-5533

Grantees are asked to register in the Central Contractor Registration (CCR) database. Information about CCR is available at http://www.grants.gov/applicants/register_crr.jsp. This registration will be required as electronic grant processing is implemented.

SECTION III – TERMS AND CONDITIONS – 1U18FD005658-01

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

a. The grant program legislation and program regulation cited in this Notice of Grant Award.
b. The restrictions on the expenditure of federal funds in appropriations acts to the extent those restrictions are pertinent to the award.
c. 45 CFR Part 74 or 45 CFR Part 92 as applicable.
d. The PHS Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
e. An annual Financial Status Report (SF-269) is required. An original and two copies of this report must be submitted to the FDA Grants Management Officer within 90 days after the expiration date of the budget period.
f. A Final Program Report, Financial Status Report and Invention Statement must be submitted within 90 days after the expiration date of the project period.
g. 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.

Treatment of Program Income:
Additional Costs

SECTION IV – FD Special Terms and Condition – 1U18FD005658-01

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, VNRFRPS, 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 awardees(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.

3. Reporting
When multiple years are involved, awardees will be required to submit the annual Non-Competing Progress Report (PHS 2590 or RPPR) and financial statements.

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.

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.

A mid-year Progress Report is required no later than 30 days after the midyear point of the budget period. If funds or equipment from the cooperative agreement are provided to a State food/feed laboratory, the applicant must provide a complete description of the laboratory facilities with the mid-year report submission (unless it is the same as was submitted in a previous year under this cooperative agreement, in which case a modified report shall be required). The description must include the following information: The name and address of the State facility conducting the food sample tests; the name of the most responsible individual for the facility conducting the tests; and the location and installation requirements of any equipment purchased with cooperative agreement funds.

The annual Progress Report is required no later than 30 days after the end of the budget period. The mid-year and annual Progress Report should contain a description of project activities covering the applicable reporting period. A report guidance will be provided to grantees by the Grants Management staff upon award. A progress report is also due with each continuation application.

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

1. General Progress on Cooperative Agreement Project
   A) Progress & achievements for each yearly goal.
   B) Progress & achievements for other projects, identified by the grantee in the application or subsequent to receiving funding.

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

3. Point of Contact and Project Key Personnel

4. Pending Issues/Concerns and Proposed Solutions

5. Funding Expended and Remaining as of date of this report (provide detailed list of funds expended)

All reports, requests for changes and any questions should be addressed to:

Dan Lukash, Grants Management Specialist
Food and Drug Administration
Telephone: 240-402-7596; E-mail: daniel_lukash@fda.hhs.gov
AND

Travis Goodman; Project Officer
Food and Drug Administration
Telephone: 317-226-6500 X108 ; E-mail: travis.goodman@fda.hhs.gov

AND

Lauren Yeung
Food and Drug Administration
Telephone: 301-796-6623; E-mail: Lauren.Yeung@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

SPREADSHEET SUMMARY
GRANT NUMBER: 1U18FD005658-01

INSTITUTION: MISSOURI STATE DEPT/ HEALTH & SENIOR SRV

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