Notice of Grant Award

RESEARCH DEMONSTRATION COOPERATIVE AGREEMENTS

Issue Date: 01/27/2016

Department of Health and Human Services

FOOD AND DRUG ADMINISTRATION

Grant Number: 4U18FD004473-04 REVISED
FAIN: U18FD004473

Principal Investigator:
Patrick R Shannon

Project Title: Accreditation for Food Testing Laboratories

Mr. Shannon, Patrick
Unit Chief, Environmental Bacti
P.O. Box 570
110 N. Chestnut
Jefferson City, MO 651020570

Budget Period: 09/01/2015 – 08/31/2016
Project Period: 09/30/2012 – 08/31/2017

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

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SECTION I – AWARD DATA – 4U18FD004473-04 REVISED

Award Calculation (U.S. Dollars)

Salaries and Wages	$83,281
Fringe Benefits	$41,642
Personnel Costs (Subtotal)	$124,923
Consultant Services	$75,783
Equipment	$5,600
Supplies	$18,994
Travel Costs	$6,000
Other Costs	$15,374
Federal Direct Costs	$246,674
Federal F&A Costs	$26,109
Approved Budget	$272,783
Federal Share	$272,783
Less Unobligated Balance	$22,783
TOTAL FEDERAL AWARD AMOUNT	$250,000
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$0

SUMMARY TOTALS FOR ALL YEARS		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
4	$250,000	$250,000
5	$250,000	$250,000

* 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:	UFD004473B
PMS AccountType	P(Subaccount)
Fiscal Year:	2015

IC	CAN	2015	2016
FD	6990928	$250,000	$250,000

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

FDA Administrative Data:
PCC: ORA2 / **OC**: 414P / **Processed**: ERAAPPS 01/27/2016

SECTION II – PAYMENT/HOTLINE INFORMATION – 4U18FD004473-04 REVISED

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_ccr.jsp. This registration will be required as electronic grant processing is implemented.

SECTION III – TERMS AND CONDITIONS – 4U18FD004473-04 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 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) U18FD004473. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

This award was issued as a non-competing continuation with a change in document number. This change was made solely to accommodate the HHS mandate to transition award payments to Payment Management System (PMS) subaccounts. Expenses for the project period should be treated as if this were a non-competing continuation award (e.g. Type 5).

Treatment of Program Income:
Additional Costs

SECTION IV – FD Special Terms and Condition – 4U18FD004473-04 REVISED

1/27/2016 - This award is revised to reflect the approved carryover request by the Program Officer and Grants Management in the amount of $22,783.

PLEASE NOTE: ALL PREVIOUS TERMS AND CONDITIONS REMAIN IN EFFECT.

Terms and Condition - 5U18FD004473-04

This award is subject to the Special Requirements of the FOA Number RFA-FD-12-008 entitled ISO/IEC 17025:2005 Accreditation for State Food Testing Laboratories, and incorporates special terms and conditions. Copies of this announcement may be obtained at http://grants.nih.gov/grants/guide/rfa-files/RFA-FD-12-008.html

Cooperative Agreement Terms and Conditions of Award

PROGRAMMATIC TERMS AND CONDITIONS:

EXPANDED AUTHORITIES DO NOT APPLY TO THIS COOPERATIVE AGREEMENT.
Special conditions of the award:
Provide a detailed response to all weaknesses identified in the Summary Statement no later than 6-months from the date of award.

Provide funding certification of the current year?s budget to demonstrate that these funds have supplemented, and not replaced, State allocations on an annual basis. If a decrease in State allocations does occur during the cooperative agreement, a detailed justification must be provided to FDA for approval.

Key personnel (minimum of 2) must attend an annual face-to-face meeting (as determined by FDA DFSR) as a condition of the award. The face-to-face meeting will be held in the continental US for a minimum of 2.5 days. The grantee should budget accordingly to cover all travel expenses using cooperative agreement funds.

The laboratory must remain the primary servicing laboratory for conducting microbiological and chemical food analyses on behalf of the State manufactured food regulatory program to be eligible to receive funds through this cooperative agreement.

The laboratory must maintain active participation in the Food Emergency Response Network (FERN) throughout the cooperative agreement.

The laboratory must successfully participate in proficiency testing programs and submit laboratory results to your technical representative, on a quarterly basis throughout the cooperative agreement.

The State manufactured food regulatory program supported by the laboratory must maintain a food safety inspection contract with FDA in satisfactory standing throughout the cooperative agreement.

The State manufactured food regulatory program must maintain enrollment in the Manufactured Food Regulatory Program Standards (MFRPS) and demonstrate satisfactory progress towards achieving conformance with the MFRPS.

Facilities, work, training, and other expenses reimbursed under the FDA food safety inspection contract and other funding mechanisms (such as other cooperative agreements, grants, and State allocations) 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.

Fully participate in initiatives supporting ISO 17025 accreditation and assisting State manufactured food programs in achieving conformance with Standard 10 of the Manufactured Food Regulatory Program Standards (MFRPS), such as an annual face-to-face meeting (as determined by FDA DFSR), committees, conference calls, sharing of best practices and resources, and on-site visits and assessments. During on-site visits and assessments, all key personnel, records (electronic and paper-based), facilities, and other resources necessary for FDA to conduct a complete program assessment will be made available.

Future funding will be dependent on recommendations from the Project Officer. The scope of the recommendation will confirm that acceptable progress has been made in obtaining, maintaining, and/or enhancing the scope of ISO/IEC 17025:2005 laboratory accreditation and other cooperative agreement goals. The laboratory must develop and execute a detailed Sampling Agreement, which will fulfill the commitment to analyze surveillance samples. The Sampling Agreement must be submitted for approval within 6 months from the date of this award, and implemented by the beginning of Year 3 of this cooperative agreement. The Sampling Agreement must be developed in conjunction with the State manufactured food regulatory program supported by the laboratory and FDA. The Sampling Agreement must outline a minimum number of samples, types of analyses, and frequency of testing that will be performed in support of the State manufactured foods regulatory program on an annual basis. Consideration should also be given to sample collection. The Sampling Agreement must support the laboratory achieving, maintaining, or expanding the scope of ISO 17025 accreditation and the goals of the cooperative agreement program. The Sampling Agreement must be risk-based and support the food safety priorities of FDA. Only manufactured food products regulated by FDA should be included in the Sampling Agreement. Guidance on products and methods relevant to FDA regulation will be provided.

These awards may only be used for obtaining, maintaining, and enhancing the scope of ISO/IEC 17025:2005 laboratory accreditation and other projects that support the intended outcomes of the cooperative agreement program. Funds should be requested in the budget for key project personnel to travel to meetings, on-site visits, and assessments with FDA program staff to discuss the project. A portion of budgeted travel funds should also be set aside for key personnel to attend an annual face-to-face meeting (as determined by FDA DFSR) and committee meetings supporting laboratory accreditation and assisting State manufactured food programs in achieving conformance with Standard 10 of the Manufactured Food Regulatory Program Standards (MFRPS). Training needs should also be anticipated and budgeted for accordingly.

Costs:
Allowable costs include:
1) Consultant services
2) Employee salaries, wages and fringe benefits
4) Rental, purchasing, calibration, installation and maintenance of equipment

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5) Indirect costs
6) Recruitment costs for hiring new employees
7) Registration fees
8) Purchase or development of IT equipment, software, and support
9) Shipping and mailing of equipment and supplies
10) Travel (must not exceed coach class fare)
11) Speaker fees
12) Accreditation fees
13) Training courses and materials
14) Laboratory and office supplies
15) Office supplies

Non-allowable costs:
1) Facilities and work covered under current FDA food safety inspection contracts cannot be counted towards fulfillment of the cooperative agreement and must remain distinct and separate from the cooperative agreement. The State must be able to account separately for fund expenditures under the food safety inspection contracts and these cooperative agreements.
2) Vehicle purchases are not permitted.
3) Subcontracting to third parties is limited to 25% of each year's award.
4) 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.

Reporting requirements:
Mid-year reports must contain the elements below as applicable to their proposal and award, but are not limited to, the following:
1) An updated improvement plan demonstrating significant progress towards implementing a quality management system that will result in the laboratory receiving ISO/ISE 17025:2005 accreditation for laboratories seeking ISO/IEC 17025:2005 accreditation within the established timeframe. For laboratories currently accredited, an updated improvement plan for enhancing the scope of accreditation and maintaining accreditation within the established timeframes.
2) A proficiency testing plan and results of participation in a recognized proficiency testing program(s) to ensure and demonstrate the quality of the tests performed in the lab.
3) Hiring of new personnel and training of personnel in the implementation and maintenance of a quality system to achieve, maintain, and/or enhance ISO/IEC 17025:2005 accreditation. The program must include initial and ongoing training to ensure consistent quality and continuous improvement, including assisting laboratory personnel in maintaining current knowledge of scientific and technological advances in relevant areas.
4) Summary report on the facility inventory that is maintained by the laboratory.
5) Status report on the installation and operational readiness of any analytical equipment that is purchased.
6) Summary of laboratory data shared with FDA and other regulatory agencies, including any regulatory actions taken by FDA or another regulatory agency or any significant laboratory findings that advanced the protection of public health.
7) Current funding level certification for the laboratory program from State funding appropriations.

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All recipients must file a final program progress report, FSR, invention Statement, and disposition of equipment Statement within 90 days after the end date of the project period as noted on the notice of the cooperative agreement award.
The final program progress report must provide 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. An audit by an independent accrediting body should confer ISO/ISE 17025:2005 accreditation upon the laboratory. The final program progress report should also detail the strategy, including commitment of personnel, resources, and funding, for maintaining of ISO/ISE 17025:2005 accreditation after the completion of the project.

Reporting Requirements:

1. Annual Financial Status Report (FSR) (SF-269) is required at the END of EACH BUDGET PERIOD. This form is available at the link: http://grants.nih.gov/grants/fsr_sf269_long.pdf. It must be signed, dated, and submitted to the FDA Grants Management Specialist within 90 days after the expiration date of the project period.

2. The FSR is available at the link: http://grants.nih.gov/grants/fsr_sf269_;pmg/pdf

3. The Invention Statement is available at the link: http://grants.nih.gov/grants/hhs568.pdf

NOTE: All formal correspondence/reports regarding the grant should be signed by an Authorized Institutional Official and the Principal Investigator, and sent to the attention of the contact below. Please submit all reports via E-MAIL or Express mail to:

Kimberly Pendleton; Chief Grants Management Officer
Food and Drug Administration, OAGS/DAASG
5630 Fishers Lane, Room 2031
Rockville, MD 20857
kimberly.pendleton@fda.hhs.gov

PAYMENT MANAGEMENT SYSTEM (PMS):

Included are the following LINKS & Instructions for drawing down funds, reporting expenditures, REQUIRED FORMS, and the help desk info:

http://www.dpm.psc.gov/ - PMS Homepage
http://www.dpm.psc.gov/grant_recipient/guides_forms/ffr_user_form.aspx?- LINK for PMS Contact/User Form
http://www.dpm.psc.gov/grant_recipient/new_grantee_information/hhs_1199a.aspx? - Required FORM > SF 1199A

You can find these forms by clicking on PMS Homepage, then clicking on ?Grant Recipient Info?, then click on ?Forms?
http://www.dpm.psc.gov/help/help.aspx?explorer.event=true - LINK for PMS Help Desk Information
The phone number for the Help Desk is 877-614-5533, and the email address is PMSSupport@psc.gov.

SUBSTANTIAL INVOLVEMENT:

Delineation of Substantive Involvement:

1. FDA will monitor and evaluate the overall conduct of the awardee under this cooperative agreement.
2. FDA will collaborate and work closely with awardees continued development.
3. FDA will take any action that may be necessary to ensure compliance with this cooperative agreement.

Support will be in the form of a cooperative agreement. FDA will have substantial involvement in the program activities of the project funded by the cooperative agreement.

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 Project Director (PD)/Principal Investigator (PI) will have the primary responsibility for:

The technical and programmatic aspects of the grant, and for day-to-day management of the project or program. 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 has sufficient clearance and/or background checks to work on this project or program. This individual will 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.

The awardee is required to participate in a cooperative manner with FDA.

The awardee is responsible for submitting interim progress reports, when requested, to the FDA PO including summary data on progress to date.

The awardee will retain custody of, and have primary rights to, the data and software developed under these awards, subject to Government rights of access consistent with current DHHS, PHS, and FDA policies.

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

The responsibilities of the designated support staff 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 designated support staff will participate in the definition of objectives and approaches, and in planning, conducting, analyzing, publishing, interpretations, and conclusions of the project activity.

However, the dominant role and prime responsibility for the activity reside with the awardee for the project as a whole, but not necessarily for each task.
In addition to, or in the absence of the PO, a separate FDA PO will be responsible for the normal scientific and programmatic stewardship of the award and will be named in the award notice.

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 project. However, awardees will retain custody of and have primary rights to all data developed under these awards.

Areas of Joint Responsibility include:

As relevant, the PD/PI will work collaboratively with the designated support staff in evaluating the most appropriate methods, data quality control strategies and implementation, data analysis and interpretation, publication, and dissemination of project activity and results.

During performance of the award, the 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 PO will be to facilitate and not to direct the activities. It is anticipated that decisions in all activities will be reached by consensus between the awardee and PO, and that selected FDA staff will be given the opportunity to offer input into this process. The PO will facilitate liaison activity for partnerships, and provide assistance with access to FDA supported resources and services.

The PD/PI will 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 PO within two weeks of acceptance for publication. Publications or oral

presentations of work performed under this Cooperative Agreement will require appropriate acknowledgement of FDA support. Timely publication is encouraged as appropriate.

ADDITIONAL TERMS AND CONDITIONS:

1. Program Income: If any Program Income is generated, Grantees are required to report the Program Income on the FSR (see below), and on the 2590-FORM. Except for royalty income generated from patents and inventions, the amount and disposition of Program Income must be identified on lines 10(q), (r), (s), and (t) of the grantees Financial Status Report (see SF-269 Long form FSR).
2. Financial status Report (FSR (SF-269) Long Form) may be downloaded at the link: http://grants.nih.gov/grants/fsr_sf269_long.pdf. 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 copyright royalties; and proceeds from the sale of products and technology under the grant.
3. Any Program Income generated during the Project Period of this grant by the Grantee or sub grantee is subject to the Addition Alternative for Program Income and, therefore, must only be used to further the goals of the project for which this grant was awarded.

The following special terms of award are in addition to, and not in lieu of, otherwise applicable U.S. Office of Management and Budget (OMB) administrative guidelines, U.S. Department of Health and Human Services (DHHS) grant administration regulations at 45 CFR Parts 74 and 92 (Part 92 is applicable when State and local Governments are eligible to apply), and other HHS, PHS, and FDA grant administration policies.

Dispute Resolution:

Any disagreements that may arise in programmatic matters (within the scope of the award) between the awardee and the FDA may be brought to Dispute Resolution. A Dispute Resolution Panel composed of three academic members who are not involved in the study will be convened. This special dispute resolution procedure does not alter the awardees? right to appeal an adverse action that is otherwise appealable in accordance with PHS regulation 42 CFR Part 50, Subpart D and DHHS regulation 45 CFR Part 16.

Additional Terms and Conditions:

As resources permit, FDA will continue to support the Cooperative Agreement with input from FDA staff and other Subject Matter Experts (SMEs).

FDA retains the right to conduct audits and/or request meetings with the awardee management to discuss training programs and other related activities. FDA shall be responsible for funding the travel and travel related costs for FDA personnel.

Any travel cost incurred by the awardee to meet with FDA is the responsibility of the awardee under this grant.

Any FDA curriculum or course content provided by FDA will remain the property of FDA and any proposed changes are not to be made without concurrence from FDA.

Curriculum and course content developed under this Cooperative Agreement such as objectives, learning outcomes, presentations, manuals, scripts, exercises, handouts, reports, documents or other tangible materials produced by the awardee shall be free of copyrights and be free domain for use by FDA.

The awardee is expected to remain flexible in support of the overall purpose of the Cooperative Agreement. This may include delivery of training to FDA, State, Local, territorial, tribal regulators as well as academia and regulated industry personnel.

Credentials (e. g. certificates, certifications, licenses, continuing education units) should be developed under the appropriate standards such as those found under American National Standards Institute (ANSI).

The awardee should not previously or presently be involved in legal suits again the Federal Government.

Pre-Award Costs:

According to PHS policy, if pre-award costs are necessary, they may be approved by the authorized institutional official(s).

Failure to comply with the above stated Terms and Conditions could result in the suspension or termination of this cooperative agreement.

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 directed.

Failure to comply with the above stated Standard and Special Terms and Conditions could result in the suspension or termination of this grant project.

THE EXPANDED AUTHORITIES DO NOT APPLY TO THIS GRANT.

Project Officer, Erin Woodom-Coleman for inquiries and questions regarding programmatic aspects or concerns: Phone 240-205-1606/E-mail: Erin.Woodom-Coleman@fda.hhs.gov

Grants Management Specialist, Oluyemis (Yemisi) Akinneye for inquiries and questions regarding administrative matters or financial concerns: Phone: 240-402-7560/E-mail: Oluyemisi.Akinneye@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: Oluyemisi Faderin Akinneye
Email: oluyemisi.akinneye@fda.hhs.gov **Phone**: (301) 827-0079 **Fax**: (301) 827-7101

SPREADSHEET SUMMARY
GRANT NUMBER: 4U18FD004473-04 REVISED

INSTITUTION: MISSOURI STATE DEPT/ HEALTH & SENIOR SRV

Budget	Year 4	Year 5
Salaries and Wages	$83,281	
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TOTAL FEDERAL F&A	$26,109	
TOTAL COST	$250,000	$250,000