



RESEARCH DEMONSTRATION COOPERATIVE
AGREEMENTS
Department of Health and Human Services

Notice of Grant Award

Issue Date: 02/16/2017



FOOD AND DRUG ADMINISTRATION

Grant Number: 5U18FD004433-05 REVISED
FAIN: U18FD004433

Principal Investigator:
Rebecca Gillis

Project Title: Kentucky Department for Public Health DPHPS Food Safety Branch Conformance with t

Reed, Mark
Food Safety Branch Manager
275 East Main Street
HS1CF
Frankfort, KY 406210000

Award e-mailed to: Tony.Adkins@ky.gov

Budget Period: 08/01/2016 – 07/31/2017
Project Period: 08/15/2012 – 07/31/2017

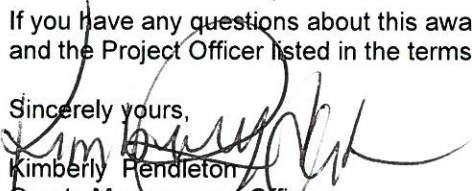
Dear Business Official:

The Food and Drug Administration hereby revises this award (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to KY ST CABINET/HEALTH/FAMILY SERVICES 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 Rendleton
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 – 5U18FD004433-05 REVISED**Award Calculation (U.S. Dollars)**

Salaries and Wages	\$186,522
Fringe Benefits	\$103,594
Personnel Costs (Subtotal)	\$290,116
Equipment	\$20,960
Supplies	\$4,930
Travel Costs	\$18,614
Other Costs	\$127,974

Federal Direct Costs	\$462,594
Federal F&A Costs	\$41,787
Approved Budget	\$504,381
Federal Share	\$504,381
Less Unobligated Balance	\$273,400
TOTAL FEDERAL AWARD AMOUNT	\$230,981

AMOUNT OF THIS ACTION (FEDERAL SHARE) **\$0**

SUMMARY TOTALS FOR ALL YEARS		
YR	THIS AWARD	CUMULATIVE TOTALS
5	\$230,981	\$230,981

* 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:	1610600439B5
Document Number:	UFD004433B
PMS AccountType	P(Subaccount)
Fiscal Year:	2016

IC	CAN	2016
FD	6990928	\$230,981

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

FDA Administrative Data:

PCC: ORA1 / **OC:** 414P / **Processed:** ERAAPPS 02/16/2017

SECTION II – PAYMENT/HOTLINE INFORMATION – 5U18FD004433-05 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
Rockville, MD 20852

Telephone: (301) 443-1660

Included are the following Links & Instructions for drawing down funds, reporting expenditures, required forms, and the help desk info:

Homepage: <http://www.dpm.psc.gov/Default.aspx>

Grant Recipient Information:

http://www.dpm.psc.gov/grant_recipient/grant_recipient.aspx?explorer.event=true

Grant Recipient Forms:

http://www.dpm.psc.gov/grant_recipient/grantee_forms.aspx?explorer.event=true

PMS Help Desk: <http://www.dpm.psc.gov/help/help.aspx?explorer.event=true>

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

SECTION III – TERMS AND CONDITIONS – 5U18FD004433-05 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) U18FD004433. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

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 (FAPIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75.

SECTION IV – FD Special Terms and Condition – 5U18FD004433-05 REVISED

2/15/2017 - This revised notice of grant award reflects a change in PI from Connie Gayle White to Rebecca Gillis requested by The Commonwealth of Kentucky, Cabinet for Health and Family Services, Department of Public Health.

10/27/2016 -This revised notice of grant award reflects a carryover in the amount of \$273,400 for the budget year 8/1/2016-8/31/2017.

MFRPS Conditions of the Award

Special conditions:

- The grantee must maintain a food safety inspection contract in satisfactory standing with the FDA throughout the cooperative agreement.
- Provide funding certification of the current year's budget for the State manufactured food regulatory program to demonstrate that these funds have supplemented, and not replaced, State allocations. 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 OP) 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.
- Facilities, work, training, and other expenses reimbursed under the FDA food safety inspection contract and other funding mechanisms 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, equipment, supplies, and other costs, under the food safety inspection contracts and other funding mechanisms and the cooperative agreement.
- Fully participate in initiatives supporting the MFRPS, such as an annual face-to-face meeting (as determined by FDA OP), committees, OP MFRPS conference calls, sharing of best practices and resources, on-site visits, and FDA assessment to determine implementation and conformance. During on-site visits and program 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.
- All appendices as found in the most current version of the MFRPS or alternate forms that are equivalent, databases/IT systems, records, and other documents will be made available upon request to FDA for purposes of monitoring program progress towards

meeting the goals of the cooperative agreement and achieving conformance with the MFRPS.

- Future funding will be dependent on recommendations from the Project Officer and the availability of funds. The Project Officer will base the recommendation on whether acceptable progress has been made in achieving significant to full conformance with the MFRPS within the required timeframes, approval of an ESS (when applicable), implementation of SEP(s) (if pursued), continued compliance with all FDA regulatory requirements, and, if applicable, whether a corrective action plan has been developed and corrective actions are being satisfactorily implemented. The grantee must implement corrective action plans for all observations reported by the FDA Office of Operations, Audit Staff during scheduled MFRPS program assessment validation audits (PAVAs) and full program audits.
- A determination of the grantee's conformance with the MFRPS will be made based upon multiple factors, including the grantee's assessment, progress reports, on-site visits, and audits. If progress concerns are identified, then the grantee will be placed in special condition status and be required to implement corrective actions. Failure to implement corrective actions may result in reduction of funding or termination of the cooperative agreement.

Funding restrictions:

These awards may only be used for achieving and sustaining conformance with the MFRPS, development and implementation of Standard Enhancement Projects (SEPs), 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 audits 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 OP) and committee meetings supporting the MFRPS. Training needs should also be anticipated and budgeted for accordingly.

Prior approval from FDA for budget modifications of $\geq 10\%$ of the total award or substantial changes to the project proposal is required.

Allowable costs include:

- 1) Audiovisual materials such as videotapes, DVDs, public service announcements, etc.
- 2) Consultant services
- 3) Employee salaries, wages and fringe benefits
- 4) Rental, purchasing, calibration, and maintenance of supplies and equipment
- 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 (including per diem for meals)
- 11) Speaker fees
- 12) Subcontracting to third parties (other than local/county/tribal agencies conducting work on behalf of the State manufactured food regulatory agency) is allowed but limited to 25% of each year's award.

Non-allowable costs:

- 1) Facilities, work, and training reimbursed under other funding mechanisms must remain distinct and separate from the cooperative agreement. The State 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.
- 2) Vehicle purchases are not permitted.

- 3) 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.
- 4) Food is not an allowable cost.
- 5) Please also refer to the HHS Grants Policy Statement for additional information regarding costs.

Reporting requirements:

Mid-year and final project progress reports must contain the elements below as applicable to their proposal and award, but are not limited to, the following:

- 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 broken out and specific progress reported.
- Status report on the hiring and training of cooperative agreement funded personnel and other manufactured food program personnel.
- Contributions of personnel, especially for employees receiving salary and/or benefits through the cooperative agreement or identified as key personnel, towards the goals of the cooperative agreement should be reported against.
- Status report on the purchasing, development, and operational readiness of any equipment, computers, or software purchased.
- Summary of improvements (identify and quantify) in the overall food safety or system resulting from the cooperative agreement.
- Demonstration of progress, steady improvement, advancement or development of growth of the individual program elements of the MFRPS or SEPs to indicate the grantee will accomplish the proposed project and objectives of the cooperative agreement, including achieving significant to full conformance with the MFRPS, within the proposed project period. Documentation to demonstrate this requirement is being met includes, but is not limited to, self-assessment, policies and procedures, record-keeping systems (electronic and paper-based) and documentation requirements.
- 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.

Additional requirements for the mid-year progress report (due January 31, 2017):

- Submission of the following documents in the most current version of the MFRPS reviewed and updated within the current budget period:
 - a. Appendix 1 or alternate form that is equivalent
 - b. Appendix 2.1 or alternate form that is equivalent
 - c. Appendix 3.1 or alternate form that is equivalent
 - d. Appendices 4.1, 4.2, 4.3, 4.4 or alternate forms that are equivalent
 - e. Appendix 5.1 or alternate form that is equivalent
 - f. Appendices 6.1 and 6.2 or alternate forms that are equivalent
 - g. Appendix 7.1 or alternate form that is equivalent
 - h. Appendices 8.1 and 8.2 or alternate forms that are equivalent
 - i. Appendix 9.1 or alternate form that is equivalent
 - j. Appendix 10.1 or alternate form that is equivalent
 - Submission of a strategic improvement plan updated within the current budget period will include the following at the minimum to demonstrate program advancement in achieving conformance with the MFRPS:
 - k. Specific objectives and tasks that once completed and/or implemented will result in significant to full conformance with the MFRPS within the project period of the cooperative agreement. Previously completed objectives and tasks should also be included.
 - l. For programs in significant to full conformance with the MFRPS, or are expected to achieve significant to full conformance in the upcoming budget period, the

strategic plan shall also include the implementation of a Standard Enhancement Project (SEP).

- m. Timelines, responsible personnel, and dedication of any additional resources (such as IT, training, etc.) assigned to each objective and task.
- n. Identification of objectives and/or tasks completed during the current project year
- o. An assigned MFRPS Project Coordinator with the overall responsibility for implementation of the strategic plan.
- Certification of current State appropriation funding levels for the State manufactured food regulatory program demonstrating that grant funds are supplementing, not supplanting, existing non-Federal and other Federal sources of funding at a level equal to the level of such funding in the previous year, increased by the Consumer Price Index.

Additional requirements for the final project progress report (due October 31, 2017):

- 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.
- The independent FDA assessment (referred to as the 60-month audit) of the program by FDA should verify the program is in significant to full conformance with the MFRPS

An Exit Strategy of Sustainment (ESS) that outlines the State program's plans to sustain significant conformance with the MFRPS and ensure progress continues within their agency to achieve full conformance with the MFRPS. The ESS must detail:

- Strategy to sustain MFRPS implementation, including identifying personnel/FTEs, current funding sources for these personnel, and plans to sustain those personnel using grantee resources to the best of the grantee's ability.
- Manufactured program data (all data should be pulled from a recent 12 month period): Number of manufactured food (MF) inspectors (FTE), Number of manufactured food facilities in inventory, Number of routine MF inspections conducted, number of MF food related emergency response events (FBI, non-FBI) investigated, number of MF compliance actions taken (embargo, disposal, emergency closures, re-inspections and fines issued.)

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. Required Federal Financial Report (FFR) must be submitted annually. FDA now requires all 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.

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 75 , 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 45 CFR Part 75 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 against 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, Wendy Campbell for inquiries and questions regarding programmatic aspects or concerns: Phone 615-310-0483/E-mail: Wendy.Campbell@fda.hhs.gov

Grants Management Specialist, Allison Mandel for inquiries and questions regarding administrative matters or financial concerns: Phone: 240-402-7602/E-mail: allison.mandel@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: Allison Mandel
Email: Allison.Mandel@fda.hhs.gov **Phone:** 240-402-7602

SPREADSHEET SUMMARY

GRANT NUMBER: 5U18FD004433-05 REVISED

INSTITUTION: KY ST CABINET/HEALTH/FAMILY SERVICES

Budget	Year 5
Salaries and Wages	\$186,522
Fringe Benefits	\$103,594
Personnel Costs (Subtotal)	\$290,116
Equipment	\$20,960
Supplies	\$4,930
Travel Costs	\$18,614
Other Costs	\$127,974
TOTAL FEDERAL DC	\$462,594
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