

UNITED STATES FOOD & DRUG ADMINISTRATION

**Pilot Survey to Develop Standardized Reporting Forms for Federally Funded
Public Health Projects and Agreements**

OMB Control No. 0910-NEW

SUPPORTING STATEMENT Part A – Justification:

1. Circumstances Making Collection of Information Necessary

The Food and Drug Administration (FDA, the agency, us or we) is conducting a pilot regarding federally funded public health projects administered by FDA's Office of Regulatory Affairs (ORA). Consistent with applicable regulations, ORA collects information 3 to 4 times annually related to an awardee's progress in completing agreed-upon performance metrics. The authority for collecting such information is found in Code of Federal Regulations Title 2: *Grants and Agreements (Uniform Guidance)*. Section 200.301, Performance Measurement ([2 CFR 200.301](#)), instructs that “[t]he Federal awarding agency must measure the recipient's performance to show achievement of program goals and objectives, share lessons learned, improve program outcomes, and foster adoption of promising practices,” for grants and cooperative agreements. Similarly, Federal Acquisition Regulation Part 42 Contract Administration and Audit Services, subpart [42.15](#) - *Contractor Performance Information*, requires agencies collect sufficient data to support past performance evaluations for contracts.

Related to, but distinct from performance and progress measures and metrics, ORA is seeking to increase its efficiency in analyzing and evaluating program effectiveness, return-on-investment (ROI), and return-on-value (ROV) for the federal partnership projects it administers. This effort aligns with HHS specific performance measurement requirements described in 45 CFR 75.301 -- Performance measurement stating that “*Performance reporting frequency and content should be established to not only allow the HHS awarding agency to understand the recipient progress but also to facilitate identification of promising practices among recipients and build the evidence upon which the HHS awarding agency's program and performance decisions are made.*” Currently, respondents submit requisite information to the FDA in free text and narrative form via portable document format (pdf) and email at the Mid-Year, or in the case of the Annual/End of Year Report, via eRA Commons using the Research Performance Progress Report (RPPR), forms from OMB 0970-0334 and Federal Financial Report (FFR) SF-425. These collection instruments and the eRA Commons submission platform are unable to optimize sufficient data uniformity and aggregation capabilities for ORA to conduct programmatic evaluations on the timeline necessary to make informed decisions for the next funding cycle.

We have developed several digital forms that contain targeted, standardized questions designed to capture the data elements we believe are necessary to monitor and analyze performance, as well as measure and track ROI/ROV. However, at this stage we anticipate forms and questions will need to be revised as we receive new data and user feedback. Also aligned with the FDA and ORA's goal to most effectively apply limited funding resources as indicated by current public health needs, we anticipate further development of forms and questions is still needed.

We have developed the following forms as part of the pilot project:

- *Animal Feed Regulatory Standards (AFRPS) Program Report*
- *Animal Food Contract Quarterly Summary Report*
- *Animal Food Safety Inspection Audit Form*
- *Corrective Action Plan for Program and Individual Performance Deficiencies*
- *Egg Contract Quarterly Summary Report*
- *Emergency Response Course Preregistration Workbook*
- *FDA 3610 Field Inspection Audit*
- *Flexible Funding Model (FFM) Program Report*
- *Food Protection Task Force (FPTF) Program Report*
- *General Program Report Form (non-specific for new cooperative agreement and grant programs)*
- *Human Food Contract Quarterly Summary Report*
- *Laboratory Flexible Funding Model (LFFM) Program Report*
- *LFFM Instructions QTR LFFM Chem_LFFM HAF Results Sheet*
- *LFFM Instructions QTR Data Template Micro HAF Product Testing*
- *LFFM Instructions Sample and Activity Plan Proposal*
- *LFFM ORS Capability Inquiry Template*
- *LFFM QTR Chem_LFFM_HAF_Results_Sheet*
- *LFFM QTR Data Template Micro HAF Product Testing*
- *LFFM Sample and Activity Plan_Proposal Template*
- *LFFM_SRP-Lab Agreement Template_HAF Tracks*
- *Manufactured Food Course Preregistration Workbook*
- *Medical Devices Contract Quarterly Summary Report*
- *MQSA MEU and Spending Update Report*
- *Produce CAP_Project Plan outline*
- *Produce CAP Assessment Template*
- *Produce Course Preregistration Workbook*
- *Produce Educational Needs Assessment Submission Template*
- *Produce Inspection Aggregate Data Workbook*
- *Produce Instructions Inspection Aggregate Data*
- *Produce Inventory & Education Aggregate Data workbook*
- *Produce Instructions Inventory & Education Aggregate Data*
- *Produce Program Report*
- *Request for Audit Reduction*
- *Scientific Conference Program Report*
- *State Implementation Agreement and Year End Evaluation*
- *Veterinary Medicine Course Preregistration Workbook*

We have provided a spreadsheet indexing the forms together with this submission. We are therefore requesting OMB approval for the information collection covered by the pilot project, collected utilizing the proposed forms, and discussed in this supporting statement.

2. Purpose and Use of the Information Collected

Respondents to the collection of information are recipients of FDA federally funded public health projects, or participants in related non-funded projects administered by the ORA. We believe the use of standardized forms will reduce the time needed by awardees to complete and submit required progress reports and related performance data, as well as facilitate ORA review of the requisite information. In turn, we believe the reporting data will facilitate ORA's ability to establish and employ best practices for future program and funding decisions for the public health projects it administers.

As part of the pilot, respondents will complete approximately 2 to 4 reports that include specific questions regarding project updates. For some projects, ORA is also introducing an initial report to be submitted annually. The initial report will not be used to capture progress, but ask the awardee for an activity plan which will then be used to set-up targeted report forms for that year. Based upon public feedback, we hope to revise the digital forms, tailoring them to capture specific project data elements including, but not limited to, to improve question clarity, formatting, usability (e.g., drop down menu selections), and potential common response indicators that will reduce time respondents will need to provide information.

To ensure data quality, on a case-by-case basis, we anticipate the potential need for follow-up questionnaire(s) and/or ancillary supporting documentation to supplement the scheduled reports as standard instruments of collection are developed and fine-tuned through this effort. Examples of categorical supporting performance documentation includes, but is not limited to, documentation related to training and verifying conformance activities.

Standardization of data elements and field designations will enable implementation of an easy to use data analysis dashboard for internal use and greatly reduce burden of review activities for project managers as well. We expect this system will eliminate the need to manually search long narratives for specific indicators of awardee progress toward required performance metrics because applicable progress narratives will be linked as the awardee enters information in a specified data entry field. The reduction in review time should improve project managers' response times to awardees and greatly reduce incidences of requesting additional information due to missed performance metrics (e.g. metrics not addressed in the report by mistake or missed during the review).

3. Use of Improved Information Technology and Burden Reduction

Currently, project performance data is reported in free text and narrative form in portable document format (pdf) submitted by email at the Mid-Year, or in the case of the Annual/End of Year Report via eRA Commons using the Research Performance Progress Report (RPPR), OMB 0970-0334 and Federal Financial Report (FFR) SF-425. Under the pilot project, we will utilize digital forms in MS Excel or fillable pdf format with standardized reporting elements common to all awardees. These forms are intended to capture specific data needed to document progress planned and linked to specific performance elements for an individual award at the beginning of each budget year. Planned progress items from standardized forms will be captured in an aggregate data management dashboard for easy review and extraction by project managers. Planned items may also be used to pre-populate data fields in subsequent progress reports for

easy reference by respondents. This approach should reduce the time and effort burden for awardees by providing previously planned progress items and a standard structure with labeled data fields for project progress and performance report data that clearly connect progress narratives to the applicable performance metrics for an award. The addition of drop-down menus for data capture when possible will also reduce the dependence on free-form narrative text and further standardize progress data.

Each progress report form will also include a customizable section by public health project to ensure that project managers have the flexibility to ensure the performance data types unique to that project award will still be captured. Customized sections will still include labeled data fields and standard drop-down menus as opposed to free text when possible. Our hope is that early stage information collection and analysis will reveal whether performance and progress data gathering used to help determine program effectiveness (ROI/ROV data gathering) are germane enough to be done on the same instruments, or distinct and requiring separate instruments.

4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative information collection. The RPPR and other forms available from OMB 0970-0334 lack the specificity needed to capture ROI/ROV and program effectiveness metrics ORA must assess. The format of data submitted using broadly focused generalized questions and free text narrative response structure for both, submissions across a single program and even within a single recipient project is completely inconsistent, preventing uniform data collection and confidence in aggregation for analysis. The eRA Commons system is also restricted to flattened pdf data outputs, requiring numerous project managers and many hours to review and manually extract data needed for their assessments. We believe developing customized reporting forms/collection instruments will better allow ORA to meet its programmatic evaluation needs with regard to budget funding cycles.

5. Impact on Small Businesses or Other Small Entities

No undue burden is imposed on small entities as a result of the information collection.

6. Consequences of Collecting Information Less Frequently

The information collection schedule is consistent with current regulatory requirements and functions in a follow-on reporting capacity for respondents who engage in contractual activities utilizing federal funds.

7. Special Circumstances Relating to the Guidelines in 5 CFR 1320.5

Federally funded public health project managers are charged with ensuring federal monies are used for their intended purpose and achieving the desired ROI and ROV goals. The only times the pilot study may require participants to report the information more often than quarterly or provide a written response in less than 30 days would be for those projects where the data collected via the digitized forms is found to be incomplete at the time of review. While expected to be rare, the project manager may send a follow-up questionnaire to collect additional data needed to complete their review.

There are no other special circumstances associated with this information collection.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency.

In accordance with 5 CFR 1320.8(d), we published a 60 day notice soliciting public comment in the Federal Register of July 29, 2021 (86 FR 40853). No comments were received.

9. Explanation of Any Payment or Gift to Respondents

No payment or gift to respondents associated with this information collection.

10. Assurance of Confidentiality Provided to Respondents

This information collection does not request trade secret or commercial confidential information.

Privacy Act

Although the ICR is collecting personally identifiable information (PII), it is collected in the context of the subject individuals' professional capacity and the FDA-related work performed for their employer. Information will be collected through the listed report forms. The PII collected is name, address, telephone number and email address. Although PII is collected, the information collection is not subject to the Privacy Act of 1974, and the particular notice and other requirements of the Privacy Act do not apply. Specifically, FDA does not use name or any other personal identifier to retrieve records from the information collected.

11. Justification for Sensitive Questions

There are no sensitive questions associated with this announcement.

12. Estimates of Annualized Hour Burden and Costs

12a. Annualized Hour Burden Estimate:

Table 1.--Estimated Annual Reporting Burden ¹					
Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Initial report	330	1	330	10 hours	3,300
Update reports	330	2	660	40 hours	26,400
Supplement or Follow-up reports (if applicable)	100	1	100	10 hours	1,000
TOTAL					30,700

¹There are no capital costs or operating and maintenance costs associated with this collection of information.

We estimate that 330 respondents will participate under this pilot project and will submit an average of 3 to 4 reports (including the initial report) annually (Table 1). To ensure adequate reporting will be achieved over the course of this pilot, the option for a supplement or follow-up report is included in the estimated reporting burden; however, the need for these reports will be

determined on a case-by-case basis with the FDA project manager. Examples of ancillary performance supporting documentation may include, but are not limited to, those funded projects that include training, audit verification, or other documentation as part of their performance metrics.

Activity	No. of Records	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
Records related to Initial Report	330	1	330	0.5 hour	165
Records related to Update Reports	330	2	660	0.5 hour	330
Records related to Supplement or Follow-up Report (if applicable)	100	1	100	0.5 hour	50
TOTAL					545

¹There are no capital costs or operating and maintenance costs associated with this collection of information.

Recordkeeping activities include storing and maintaining records related to submitting a request to participate in the project and compiling reports. We assume respondents use current record retention capabilities for electronic or paper storage to achieve these activities. We assume it will take 0.5 hour/year to ensure the documents related to submitting a request to participate in the program and compiled reports are retained properly according to their existing recordkeeping policies, but no less than three years, as recommended by FDA (Table 2).

Awardee Activity	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Average Burden per Disclosure	Total Hours
Coordination with partnering entities related to Initial Report	200	2	400	8 hours	3,200
Coordination with partnering entities related to Update Reports	200	4	800	8 hours	6,400
Coordination with partnering entities related to Supplement or Follow-up Report (if applicable)	100	2	200	8 hours	1,600
TOTAL					11,200

¹There are no capital costs or operating and maintenance costs associated with this collection of information.

For those pilot projects that involve a participant composed of partnering entities in the program, we are taking into consideration the time that partnering entities will spend coordinating with each other in a pilot project. We estimate 200 respondents will work with their respective partnering entities, and the average number of partnering entities will be 2. We assume each respondent will spend eight hours coordinating with each partnering entity on each response for this pilot. We estimate that seven respondents will need to coordinate with an average of two partnering entities to create progress reports and the final report to submit to FDA (Table 3).

12b. Annualized Cost Burden Estimate:

The annualized cost to all participants for the hour burden for the collection and reporting of information is estimated at \$1,014,436 (42,445 hours x \$23.90 per hour). The hourly wage estimate is the average of mean wages received by Agricultural and Food Science Technicians at \$22.08, Biological Technicians at \$23.79, and Chemical Technicians at \$25.82 (May 2020 National Occupational Employment and Wage Estimates United States) who represent the primary roles expected to contribute effort in compiling report information. See http://www.bls.gov/oes/current/oes_nat.htm.

Activity	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Initial Report	6,665	\$23.90	\$159,294
Update Reports	33,130	\$23.90	\$791,807
Supplement Report	2,650	\$23.90	\$63,335
Total			\$1,014,436

13. Estimates of Other Total Annual Cost Burden to Respondents and/or Recordkeepers/Capital Costs

There are no capital, start-up, operating, or maintenance costs associated with this pilot program.

14. Annualized Cost to the Federal Government

ORA intends to communicate with all pilot project participants to ensure the learnings from the pilot project(s) will be complementary in informing the direction of the development of the new fillable forms for partners. ORA will work with participants to develop an appropriate schedule for the submission of update reports based on the design and duration of the pilot project. The annualized government cost estimate is \$46,210.77 as shown in Table 5, which will be supported by existing ORA program budgets.

Government Personnel	Effort Commitment	Average Annual Salary	Total Costs
GS-11 (1)	25%	\$64,009	\$16,002.25
GS-13 (9 @ 3% each)	27%	\$91,796	\$24,784.92
GS-14 (1)	5%	\$108,472	\$5,423.60
Total			\$46,210.77

15. Explanation for Program Changes or Adjustments

This is a new information collection. This burden estimate was adjusted from 400 respondents published in 30-day notice, 87 FR 38165, to 330 respondents to reflect the actual enrollment in ORA funded public health projects under this collection.

16. Plans for Tabulation and Publication and Project Time Schedule

There are no plans for tabulation, publication, and project time scheduling.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

The OMB expiration date will be displayed as required on all subject forms.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification in 5 CFR 1320.9.