

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA-2018-D-1216 for “Electronic Study Data Submission; Data Standards; Technical Rejection Criteria for Study Data Effective Date.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- **Confidential Submissions**—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

FOR FURTHER INFORMATION CONTACT: Jonathan Resnick, Center for Drug Evaluation and Research (CDER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 3160, Silver Spring, MD 20993-0002, 301-796-7997, Jonathan.Resnick@fda.hhs.gov, or Stephen Ripley, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911, Stephen.Ripley@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In accordance with the guidance¹ for industry “Providing Regulatory Submissions in Electronic Format—Standardized Study Data,” submissions that are not submitted electronically and electronic submissions that are not in a format that FDA can process, review, and archive will not be filed or received, unless they have an exemption or waiver from the electronic submission requirements. The Agency can process, review, and archive electronic submissions of study data that use the standards specified in the Data Standards Catalog posted to FDA’s Study Data Standards Resources web page (<https://www.fda.gov/industry/fda-resources-data-standards/study-data-standards-resources>).

The technical rejection criteria are automated validations by the CDER or CBER inbound processing system using the specifications set forth in FDA’s “Specifications for eCTD Validation Criteria” to determine compliance with the requirement to submit electronic standardized study data. The eCTD validations referenced in FDA’s TRC will become effective on September 15, 2021. Starting September 15, 2021, FDA will reject submissions that contain any high validation errors included in the TRC. The latest version of the TRC is available on FDA’s web page on Study Data for Submission to CDER and CBER (<https://www.fda.gov/industry/study-data-standards-resources/study-data-submission-cder-and-cber>).

¹ Under section 745A(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 379k-1(a)), at least 24 months after the issuance of a final guidance document in which FDA has specified the electronic format for submitting certain submission types to the Agency, such content must be submitted electronically and in the format specified by FDA.

Dated: July 26, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021-16187 Filed 7-28-21; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0547]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Survey on the Occurrence of Foodborne Illness Risk Factors in Selected Retail and Foodservice Facility Types

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by August 30, 2021.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to <https://www.reginfo.gov/public/do/PRAMain>. Find this particular information collection by selecting “Currently under Review—Open for Public Comments” or by using the search function. The OMB control number for this information collection is 0910-0744. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrahi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-7726, PRASStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Survey on the Occurrence of Foodborne Illness Risk Factors in Selected Retail and Foodservice Facility Types

OMB Control Number 0910-0744—Extension

I. Background

From 1998 to 2008, FDA's National Retail Food Team conducted a study to measure trends in the occurrence of foodborne illness risk factors, preparation practices, and employee behaviors most commonly reported to the Centers for Disease Control and Prevention as contributing factors to foodborne illness outbreaks at the retail level. Specifically, data was collected by FDA Specialists in retail and

foodservice establishments at 5-year intervals (1998, 2003, and 2008) in order to observe and document trends in the occurrence of the following foodborne illness risk factors:

- Food from Unsafe Sources,
- Poor Personal Hygiene,
- Inadequate Cooking,
- Improper Holding/Time and Temperature, and
- Contaminated Equipment/Cross-Contamination.

FDA developed reports summarizing the findings for each of the three data collection periods, released in 2000, 2004, and 2009 (Refs. 1 to 3). Data from all three data collection periods were analyzed to detect trends in improvement or regression over time

and to determine whether progress had been made toward the goal of reducing the occurrence of foodborne illness risk factors in selected retail and foodservice facility types (Ref. 4).

Using this 10-year survey as a foundation, in 2013–2014, FDA initiated a new study in full-service and fast-food restaurants. This study will span 10 years with data collections completed in 2013–2014 and 2017–2018, and an additional collection planned for 2021–2022. Three data collections are necessary to trend the data. Data collected in 2013–2014 is published, and data from 2017–2018 is currently being evaluated for trends and significance.

TABLE 1—DESCRIPTION OF THE FACILITY TYPES INCLUDED IN THE SURVEY

Facility type	Description
Full-Service Restaurants	A restaurant where customers place their orders at their tables, are served their meals at the tables, receive the services of the wait staff, and pay at the end of the meals.
Fast-Food Restaurants	A restaurant that is not a full-service restaurant. This includes restaurants commonly referred to as quick-service restaurants and fast, casual restaurants.

The results of this 10-year study period will be used to:

- Develop retail food safety initiatives, policies, and targeted intervention strategies focused on controlling foodborne illness risk factors;
- Provide technical assistance to State, local, tribal, and territorial regulatory professionals;
- Identify FDA retail work plan priorities; and
- Inform FDA resource allocation to enhance retail food safety nationwide.

The statutory basis for FDA conducting this study is derived from the Public Health Service Act (PHS Act) (42 U.S.C. 243, section 311(a)). Responsibility for carrying out the provisions of the PHS Act relative to food protection was transferred to the Commissioner of Food and Drugs in 1968 (21 CFR 5.10(a)(2) and (4)). Additionally, the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 *et seq.*) and the Economy Act (31 U.S.C. 1535) require FDA to provide assistance to other Federal, State, and local government bodies.

The objectives of this study are to:

- Identify the least and most often occurring foodborne illness risk factors and food safety behaviors/practices in restaurants within the United States;
- Determine the extent to which Food Safety Management Systems and the presence of a Certified Food Protection Manager impact the occurrence of foodborne illness risk factors and food safety behaviors/practices; and

- Determine whether the occurrence of foodborne illness risk factors and food safety behaviors/practices in delis differs based on an establishment's risk categorization and status as a single-unit or multiple-unit operation (*e.g.*, restaurants that are part of an operation with two or more units).

The methodology to be used for this information collection is described as follows. To obtain a sufficient number of observations to conduct statistically significant analysis, FDA will conduct approximately 400 data collections in each facility type. This sample size has been calculated to provide for sufficient observations to be 95 percent confident that the compliance percentage is within 5 percent of the true compliance percentage.

A geographical information system database containing a listing of businesses throughout the United States provides the establishment inventory for the data collections. FDA samples establishments from the inventory based on the descriptions in table 1. FDA does not intend to sample operations that handle only prepackaged food items or conduct low-risk food preparation activities. The "FDA Food Code" contains a grouping of establishments by risk, based on the type of food preparation that is normally conducted within the operation (Ref. 5). The intent is to sample establishments that fall under risk categories 2 through 4.

FDA has approximately 23 Retail Food Specialists (Specialists) who serve

as the data collectors for the 10-year study. The Specialists are geographically dispersed throughout the United States and possess technical expertise in retail food safety and a solid understanding of the operations within each of the facility types to be surveyed. The Specialists are also standardized by FDA's Center for Food Safety and Applied Nutrition personnel in the application and interpretation of the FDA Food Code (Ref. 5).

Sampling zones have been established that are equal to the 175-mile radius around a Specialist's home location. The sample is selected randomly from among all eligible establishments located within these sampling zones. The Specialists are generally located in major metropolitan areas (*i.e.*, population centers) across the contiguous United States. Population centers usually contain a large concentration of the establishments FDA intends to sample. Sampling from the 175-mile radius sampling zones around the Specialists' home locations provides three advantages to the study:

1. It provides a cross-section of urban and rural areas from which to sample the eligible establishments.
 2. It represents a mix of small, medium, and large regulatory entities having jurisdiction over the eligible establishments.
 3. It reduces overnight travel and, therefore, reduces travel costs incurred by the Agency to collect data.
- The sample for each data collection period is evenly distributed among

Specialists. Given that participation in the study by industry is voluntary and the status of any given randomly selected establishment is subject to change, substitute establishments have been selected for each Specialist for cases where the restaurant facility is misclassified, closed, or otherwise unavailable, unable, or unwilling to participate.

Prior to conducting the data collection, Specialists contact the State or local jurisdiction that has regulatory responsibility for conducting retail food inspections for the selected establishment. The Specialist verifies with the jurisdiction that the facility has been properly classified for the purposes of the study and is still in operation. The Specialist ascertains whether the selected facility is under legal notice from the State or local regulatory authority. If the selected facility is under legal notice, the Specialist will not conduct a data collection, and a substitute establishment will be used. An invitation is extended to the State or local regulatory authority to accompany the Specialist on the data collection visit.

A standard form is used by the Specialists during each data collection. The form is divided into three sections: Section 1—"Establishment Information"; Section 2—"Regulatory Authority Information"; and Section 3—"Foodborne Illness Risk Factor and Food Safety Management System Assessment." The information in Section 1 "Establishment Information" of the form is obtained during an interview with the establishment owner or person in charge by the Specialist and includes a standard set of questions.

The information in Section 2—"Regulatory Authority Information" is obtained during an interview with the program director of the State or local jurisdiction that has regulatory responsibility for conducting inspections for the selected establishment.

Section 3—"Foodborne Illness Risk Factor and Food Safety Management System Assessment" includes three parts: Part A for tabulating the Specialists' observations of the food employees' behaviors and practices in limiting contamination, proliferation, and survival of food safety hazards; Part B for assessing the food safety management system being implemented by the facility; and Part C for assessing the frequency and extent of food employee handwashing. The information in Part A is collected from the Specialists' direct observations of food employee behaviors and practices.

Infrequent, nonstandard questions may be asked by the Specialists if clarification is needed on the food safety procedure or practice being observed. The information in Part B is collected by making direct observations and asking followup questions of facility management to obtain information on the extent to which the food establishment has developed and implemented food safety management systems. The information in Part C is collected by making direct observations of food employee handwashing. No questions are asked in the completion of Section 3, Part C of the form.

FDA collects the following information associated with the establishment's identity: Establishment name, street address, city, State, ZIP Code, county, industry segment, and facility type. The establishment-identifying information is collected to ensure the data collections are not duplicative. Other information related to the nature of the operation, such as seating capacity and number of employees per shift, is also collected. Data will be consolidated and reported in a manner that does not reveal the identity of any establishment included in the study.

FDA has collaborated with the Food Protection and Defense Institute to develop a web-based platform in FoodSHIELD to collect, store, and analyze data for the Retail Risk Factor Study. This platform is accessible to State, local, territorial, and tribal regulatory jurisdictions to collect data relevant to their own risk factor studies. For the 2015–2016 data collection, FDA piloted the use of hand-held technology for capturing the data onsite during the data collection visits. The tablets that were made available for the data collections were part of a broader Agency initiative focused on internal uses of hand-held technology. The tablets provided for the data collection presented several technical and logistical challenges and increased the time burden associated with the data collection as compared to the manual entry of data collections. For these reasons, FDA will not be further evaluating hand-held technology in subsequent data collections during the 10-year study period.

When a data collector is assigned a specific establishment, he or she conducts the data collection and enters the information into the web-based data platform. The interface will support the manual entering of data, as well as the ability to directly enter information in the database via a web browser.

The burden for the 2021–2022 data collection is as follows. For each data

collection, the respondents will include: (1) The person in charge of the selected facility (whether it be a fast-food or full-service restaurant); and (2) the program director (or designated individual) of the respective regulatory authority. In order to provide the sufficient number of observations needed to conduct a statistically significant analysis of the data, FDA has determined that 400 data collections will be required in each of the two restaurant facility types. Therefore, the total number of responses will be 1,600 (400 data collections \times 2 facility types \times 2 respondents per data collection).

The burden associated with the completion of Sections 1 and 3 of the form is specific to the persons in charge of the selected facilities. The burden includes the time it will take the person in charge to accompany the data collector during the site visit and answer the data collector's questions. The burden related to the completion of Section 2 of the form is specific to the program directors (or designated individuals) of the respective regulatory authorities. The burden includes the time it will take to answer the data collectors' questions and is the same regardless of the facility type.

In the **Federal Register** of March 16, 2021 (86 FR 14433), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received two comments; only one comment we received was responsive to the four collection of information topics solicited.

(Comment) The Academy of Nutrition and Dietetics (the Academy) commented that they support the proposed information collection for the survey on the occurrence of foodborne illness risk factors in various settings. The Academy provided comments pertaining to the following general areas of the study:

- a. Question whether 90 minutes is adequate for surveying larger facilities.
- b. Request FDA evaluate the impact of conducting surveys during peak hours of operation.
- c. Suggest that the use of gloves is not adequately addressed in the survey.
- d. Encourage continued efforts to simplify and standardize expiration dates.

Related to foodservice operations at the retail level, the Academy provided the following comments:

- e. FDA consider modifying the survey to account for new foods and new means of conveying food.

The Academy provided the following comment specific to pandemic-related considerations:

f. FDA consider modifying the survey to include trends for hot-holding and online delivery due to the COVID-19 pandemic.

The Academy also provided comments related to statistical analysis and data sharing:

g. FDA make the dataset public for further analysis.

h. FDA consider peer review of the report.

(Response) FDA thanks the submitter for their comments and appreciates their support. Regarding general areas of the study, FDA provides the following responses:

a. The current 10-year study estimates 90 minutes as the average time needed to adequately collect necessary information, taking into account both small and large facilities. This average time is consistent with the amount of time burden estimated for the previous data collection periods and provides a sufficient timeframe to observe food safety practices and procedures that are the focus of the study.

b. Based on the methodology of the study, the information collection is performed during hours of operation of the randomly selected facility. Data collections are scheduled at times that provide the best opportunity to observe food preparation activities, which often include peak operations.

c. Information collection related to handwashing and no bare hand contact with ready-to-eat foods, which may include use of gloves, is based on assessment of observations against the most current addition of the FDA Model Food Code. Provisions of the FDA Food Code identify when handwashing and no bare hand contact with ready-to-eat food are required during food preparation and service. The current FDA Food Code does not recognize the use of hand antiseptics in lieu of handwashing during food preparation and service.

d. The scope of this data collection focuses on foodborne illness risk factors and does not include assessment of expiration dates of manufactured foods as part of this research assessment.

Related to foodservice operations at the retail level, FDA provides the following responses:

e. The study design accounts for a variety of food conveyances in the retail food setting. The study includes four major segments of the retail and foodservice industries that account for over a million varied and diverse types of operations in the United States:

- Restaurants
- Healthcare Facilities
- Schools (K–12)
- Retail Food Stores

Related to the Academy's comments on pandemic-related considerations, FDA provides the following response:

f. The study design is based on operations regardless of extenuating circumstances. While there is utility in investigating the trends in food service, this study must focus its efforts throughout the 10-year period to ensure data can be adequately trended. Two of the three data collections for this trending were already complete before the pandemic and a singular data point with these new metrics would not be of much utility. FDA fully supports the New Era of Smarter Food Safety blueprint and endeavors to collect data to support that effort.

Regarding statistical analysis and data sharing, FDA provides the following responses:

g. FDA strives to ensure the data is available to parties upon request. Additionally, a new Topline Summary is published to <https://www.fda.gov/food/retail-food-protection/retail-food-risk-factor-study> along with the technical report, with much of the data commonly requested for independent analysis.

h. FDA acknowledges the benefit of peer review. For any manuscripts

published resulting from the dataset, peer review is sought. For the technical report of the data, FDA will continue to utilize the format which is familiar to and accepted by our stakeholders.

To calculate the estimate of the hours per response, FDA will use the average data collection duration for the same facility types during the 2015–2016 data collection. FDA estimates that it will take the persons in charge of full-service restaurants and fast-food restaurants 104 minutes (1.73 hours) and 82 minutes (1.36 hours), respectively, to accompany the data collectors while they complete Sections 1 and 3 of the form. In comparison, for the 2017–2018 data collection, the burden estimate was 106 minutes (1.76 hours) in full-service restaurants and 73 minutes (1.21 hours) in fast-food restaurants. FDA estimates that it will take the program director (or designated individual) of the respective regulatory authority 30 minutes (0.5 hours) to answer the questions related to Section 2 of the form. This burden estimate is unchanged from the last data collection. Hence, the total burden estimate for a data collection in a full-service restaurant, including both the program director's and the person in charge's responses, is 134 minutes (104 + 30) (2.23 hours). The total burden estimate for a data collection in a fast-food restaurant, including both the program director's and the person in charge's responses, is 112 minutes (82 + 30) (1.86 hours).

Based on the number of entry refusals from the 2017–2018 data collection, we estimate a refusal rate of 2 percent for the data collections within restaurant facility types. The estimate of the time per non-respondent is 5 minutes (0.08 hours) for the person in charge to listen to the purpose of the visit and provide a verbal refusal of entry.

FDA estimates the burden of this collection of information as follows:

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN ¹

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Number of non-respondents	Number of responses per non-respondent	Total annual non-responses	Average burden per response	Total hours
2021–2022 Data Collection (Fast-Food Restaurants)—Completion of Sections 1 and 3	400	1	400	1.36	544
2021–2022 Data Collection (Full-Service Restaurants)—Completion of Sections 1 and 3	400	1	400	1.73	692

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN ¹—Continued

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Number of non-respondents	Number of responses per non-respondent	Total annual non-responses	Average burden per response	Total hours
2021–2022 Data Collection—Completion of Section 2—All Facility Types	800	1	800	0.5 (30 minutes)	400
2021–2022 Data Collection—Entry Refusals—All Facility Types	16	1	16	0.08 (5 minutes)	1.28
Total Hours	1,637.28

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

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

II. References

The following references are on display in the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500 and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at <https://www.regulations.gov>. FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

1. FDA, “Report of the FDA Retail Food Program Database of Foodborne Illness Risk Factors (2000).” Available at <https://wayback.archive-it.org/7993/20170406023019/https://www.fda.gov/downloads/Food/GuidanceRegulation/UCM123546.pdf>.
2. FDA, “FDA Report on the Occurrence of Foodborne Illness Risk Factors in Selected Institutional Foodservice, Restaurant, and Retail Food Store Facility Types (2004).” Available at <https://wayback.archive-it.org/7993/20170406023011/https://www.fda.gov/downloads/Food/GuidanceRegulation/RetailFoodProtection/FoodborneIllnessRiskFactorReduction/UCM423850.pdf>.
3. FDA, “FDA Report on the Occurrence of Foodborne Illness Risk Factors in Selected Institutional Foodservice, Restaurant, and Retail Food Store Facility Types (2009).” Available at <https://wayback.archive-it.org/7993/20170406023004/https://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/FoodborneIllnessRiskFactorReduction/ucm224321.htm>.
4. FDA National Retail Food Team, “FDA Trend Analysis Report on the Occurrence of Foodborne Illness Risk

Factors in Selected Institutional Foodservice, Restaurant, and Retail Food Store Facility Types (1998–2008).” (2010). Available at <https://wayback.archive-it.org/7993/20170406022950/https://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/FoodborneIllnessRiskFactorReduction/ucm223293.htm>.

5. FDA, “FDA Food Code.” Available at <https://www.fda.gov/FoodCode>.

Dated: July 26, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–16199 Filed 7–28–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS–0990–New]

Agency Information Collection Request; 60-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.
ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the ICR must be received on or before September 27, 2021.

ADDRESSES: Submit your comments to Sherrette.Funn@hhs.gov or by calling (202) 795–7714.

FOR FURTHER INFORMATION CONTACT: When submitting comments or requesting information, please include the document identifier 0990–New–60D and project title for reference, to

Sherrette A. Funn, email: Sherrette.Funn@hhs.gov, or call (202) 795–7714 the Reports Clearance Officer.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency’s functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Title of the Collection: Institutional Review Board (IRB) Records for HHS/OASH Consultation Process.

Type of Collection: New.

OMB No.: OS–0990–New.

Abstract: The Office of the Assistant Secretary for Health, Office for Human Research Protections is requesting a new approval from the Office of Management and Budget of the Office for Human Research Protections (OHRP) requirement that Institutional Review Board records be submitted when an IRB or its institution request an HHS consultation process, for proposed research involving, respectively: (1) Pregnant women, human fetuses and neonates; (2) prisoners; or, (3) children, as subjects that are not otherwise approval by an IRB. The Office of the Assistant Secretary for Health, on behalf of the Secretary of HHS, may determine that such research can be conducted or supported by HHS after consulting with experts and allowing for public review of, and comment on, the proposed research.

Likely Respondents: Institutional Review Boards (IRBs).