

make public comments. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations, and request time for a joint presentation, or submit requests for designated representatives to participate in the focused sessions. Based on the number of requests we receive, we will determine the amount of time allotted to each presenter (which we expect to be approximately 3 minutes) and the approximate time each oral presentation is to begin. We will select and notify participants at the time of registration, or by May 19, 2023. If selected for presentation, participants must email presentation materials to MoCRAGMPMeeting@fda.hhs.gov no later than May 22, 2023, 11:59 p.m. EDT. No commercial or promotional material will be permitted to be presented or distributed at the public workshop.

Streaming Webcast of the Listening Session: This listening session will be webcast. Please register online (as described above). Registrants will receive a hyperlink that provides access to the webcast.

FDA has verified the website addresses in this document, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

Transcripts: Please be advised that as soon as a transcript of the listening session is available, it will be accessible at <https://www.regulations.gov>. It may be viewed at the Dockets Management Staff (see **ADDRESSES**).

Dated: April 24, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS-0990-0390]

Agency Father Generic Information Collection Request. 30-Day Public Comment Request

AGENCY: Office of the Secretary, Health and Human Service, HHS.

ACTION: Notice and request for comments. Office of the Assistant Secretary for Public Affairs is requesting OMB approval for a new father generic clearance.

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 May 29, 2023.

ADDRESSES: Submit your comments to OIRA_submission@omb.eop.gov or via facsimile to (202) 395-5806.

FOR FURTHER INFORMATION CONTACT: Sherrette Funn, Sherrette.Funn@hhs.gov or (202) 264-0041. When requesting information, please include the document identifier 0990-0390-30D and project title for reference.

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: Challenge and Prize Competition Solicitations.

Type of Collection: Extension OMB No. 0990-0390—Office of the Assistant Secretary for Health (OASH).

Abstract: The Office of the Secretary (OS), Department of Health & Human Services (HHS) requests that the Office of Management and Budget (OMB) approve a request for an extension of generic clearance approval of the information collected for challenge and prize competition solicitations. Burden hours were increased from 333 to 558.3 total burden hours to provide more time for respondents to complete forms that may include more questions.

Challenges and prize competitions enable HHS to tap into the expertise and creativity of the public in new ways as well as extend awareness of HHS programs and priorities. Within HHS, the Office of the Assistant Secretary for Health (OASH) has taken lead responsibility in coordinating challenges and prize competitions and implementing policies regarding the use of these tools. HHS's goal is to engage a broader number of stakeholders who are inspired to work on some of our most pressing health issues, thus supporting a new ecosystem of scientists, developers, and entrepreneurs who can continue to innovate for public health.

The generic clearance is necessary for HHS to launch several challenges or prize competitions annually in a short turnaround. The information collected

for these challenges and prize competitions will generally include the submitter's or other contact person's first and last name, organizational affiliation and role in the organization (for identification purposes); email address or other contact information (to follow up if the submitted solution is selected as a finalist or winner); street address (to confirm that the submitter or affiliated organization is located in the United States, for eligibility purposes); information confirming whether the submitter's age is 13 years or older (to ensure compliance with the Children's Online Privacy Protection Act of 1998, 15 U.S.C. 6501-6505 (COPPA)) or 18 years or older (to ensure necessary consents are obtained); and a narrative description of the solution. HHS may also request information indicating the submitter's technical background, educational level, ethnicity, age range, gender, and race (to evaluate entrants' diversity and backgrounds), how the submitter learned about the challenge or prize competition and what the submitter currently understands about the HHS agency hosting the challenge or prize competition (to gauge the effect of the challenge or prize competition on increasing public awareness of HHS programs and priorities, and generally to enable HHS to improve its outreach strategies to ensure a diverse and broad innovator constituency is fostered through the use of challenges and prize competitions). Finally, HHS may ask for additional information tailored to the challenge or prize competition through structured questions. This information will enable HHS to create and administer challenges and prize competitions more effectively.

Upon entry or during the judging process, solvers under the age of 18 will be asked to confirm parental consent, which will require them to obtain and provide a parent or guardian signature in a format outlined in the specific criteria of each challenge or prize competition in order to qualify for the contest. To protect online privacy of minors, birthdate may be required by the website host to ensure the challenge platform meets the requirements of COPPA. Eligibility to win a cash prize will be outlined in the specific criteria of each contest and will only apply to U.S. citizens, permanent residents, or private entities incorporated in and maintaining a primary place of business in the U.S. To administer the cash prize, HHS will need to collect additional relevant payment information—such as Social Security Number and/or Taxpayer ID and information regarding the winners' financial institutions—in

order to comply with financial accounting and income tax reporting processes.

Likely Respondents: Likely respondents include individuals, businesses, and state and local governments who choose to participate

in a challenge or prize competition hosted or overseen (*i.e.*, via contract, etc.) by HHS.

ESTIMATED ANNUALIZED BURDEN TABLE

Respondent (if necessary)	Number of respondents	Number of responses per respondent	Average burden per response (hours)	Total burden hours
Individuals or Households	1,500	1	10/60	250
Organizations	750	1	10/60	125
Businesses	1,000	1	10/60	166.7
State, territory, tribal or local governments	100	1	10/60	16.7
Total				558.3

Sherrette A. Funn,
Paperwork Reduction Act Reports Clearance Officer, Office of the Secretary.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS-0990-new]

Agency Information Collection Request. 30-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 May 30, 2023.

ADDRESSES: Written comments and recommendations for the proposed

information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function.

FOR FURTHER INFORMATION CONTACT: Sherrette Funn, Sherrette.Funn@hhs.gov or (202) 264-0041, or PRA@HHS.GOV.

When submitting comments or requesting information, please include the document identifier 0990-New-30D and project title for reference.

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: Research Complaint Form.

Type of Collection: New.

OMB No.: 0990-new.

Abstract: The Office of the Assistant Secretary for Health, Office for Human Research Protections (OHRP), is requesting a new approval from the Office of Management and Budget of OHRP’s Research Complaint Form. This form will provide a simplified standardized format for submitting to OHRP allegations of noncompliance involving human subject research conducted or supported by HHS, which should significantly improve OHRP’s capacity to review and process these allegations. The information collected will help OHRP ensure the rights of human subjects involved in such research and that OHRP-assured institutions are complying with the HHS Protection of Human Subjects regulations.

Type of Respondent: IRB members, IRB Administrators, Research Coordinators, and the Public.

ESTIMATED ANNUALIZED BURDEN TABLE

Type of respondent	Number of respondents	Number responses per respondent	Average burden per response (in hours)	Total burden hours
IRB members, IRB Administrators, Research Coordinators, the Public	500	1	30/60	250
IRB members, IRB Administrators, Research Coordinators, the Public	400	2	30/60	400
IRB members, IRB Administrators, Research Coordinators, the Public	100	3	30/60	150
Total				800

Sherrette A. Funn,
Paperwork Reduction Act Reports Clearance Officer, Office of the Secretary.
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