DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: Countermeasures Injury Compensation Program—OMB No. 0915–0334—Extension

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this ICR should be received no later than April 24, 2023.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or by mail to the HRSA Information Collection Clearance Officer, Room 14N39, 5600 Fishers Lane, Rockville, Maryland 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call Samantha Miller, the HRSA Information Collection Clearance Officer, at (301) 594–4394.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the ICR title for reference.

Information Collection Request Title: Countermeasures Injury Compensation Program—OMB No. 0915–0334—Extension.

Abstract: This is a request for continued OMB approval of the information collection requirements for the Countermeasures Injury Compensation Program (CICP or Program). The CICP, within the Division of Injury Compensation Programs, Health Systems Bureau, HRSA, administers this compensation program as specified by the Public Readiness and Emergency Preparedness Act (PREP Act). CICP is requesting continued approval for this information collection which includes documents specified in the CICP's regulations (42 CFR part 110).

The PREP Act created the CICP and provides liability immunity to covered persons for claims of loss caused by, arising out of, relating to, or resulting from the administration or use of covered countermeasures for diseases, threats, and conditions identified in PREP Act declarations. The immunity extended in the PREP Act encourages the development, manufacture, testing, distribution, and administration/use of countermeasures (*e.g.,* vaccine, medication, device) when a disease, health condition, or other threat to health constitutes a public health emergency, or there is a credible risk that it may in the future constitute such an emergency.

A 60-day notice was published in the **Federal Register** on January 4, 2023, vol. 88, No. 2; pp. 358. There were no public comments.

Need and Proposed Use of the Information: CICP provides compensation to eligible individuals who suffer serious injuries or death directly caused by a covered countermeasure administered or used pursuant to a PREP Act Declaration or to their estates and/or to certain survivors. An individual who is an injured countermeasure recipient, the individual's legal representative, or the estate or survivor(s) of an injured countermeasure recipient is responsible for submitting the Request for Benefits (RFB) package, as well as the injured countermeasure recipient's medical records and supporting documentation. Individuals are able to apply at any time, but eligibility for compensation is subject to meeting applicable filing deadlines and other requirements.

To determine whether a requester is eligible for Program benefits (compensation) for a countermeasure injury, CICP staff must review the RFB package which includes the following:

(1) RFB Form and Supporting Documentation

The RFB Form and supporting documentation initiate the CICP claims review process. They also serve as the CICP's mechanism for gathering required information about the requester, documenting the use or administration of a countermeasure, and obtaining medical information about the countermeasure recipient.

(2) Authorization for Use or Disclosure of Health Information Form (Authorization Form) The Authorization Form is completed by the requester and gives medical providers permission to disclose the countermeasure recipient's health information via medical records to CICP for the purpose of determining eligibility for CICP benefits.

(3) Additional Documentation and Certification

During the eligibility review, CICP provides requesters with the opportunity to supplement their RFB with additional medical records and supporting documentation before the Program makes a final decision. CICP asks requesters to complete and sign a form indicating whether they intend to submit additional documentation prior to the final determination of their case. After CICP makes a final decision on a case, there are no other opportunities for a requester to submit additional medical records or supporting documents.

(4) Benefits Package and Supporting Documentation

A requester who is an injured countermeasure recipient may be eligible to receive benefits for unreimbursed medical expenses and/or lost employment income. The estate of a deceased countermeasure recipient may also be eligible to receive payment for unreimbursed medical expenses and/or lost employment income accrued prior to the injured countermeasure recipient's death. These documents ask the requester to submit documentation of the countermeasure recipient's unreimbursed medical expenses and lost employment income. If death was the result of the administration or use of the countermeasure, certain survivor(s) of eligible deceased countermeasure recipients may be eligible to receive a death benefit, but not unreimbursed medical expenses or lost employment income benefits (42 CFR 110.33). These documents request additional information, such as a marriage license, from the requester to prove that they are a survivor of the deceased countermeasure recipient.

The RFB that CICP sends to requesters who may be eligible for compensation includes certification forms and instructions outlining the supporting documentation needed to determine the type and amount of benefits. This documentation is required under 42 CFR 110.60–110.63 of CICP's implementing regulation to enable the Program to determine the type and amount of benefits the requester may be eligible to receive.

Likely Respondents: Countermeasure claimants are the most likely respondents to this **Federal Register** notice regarding the CICP information collection request because CICP reviews and, if eligible, compensates countermeasure recipient injury claims.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain,

disclose, or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
RBF Form and Supporting Documentation	100	1	100	11.000	1,100.00
Authorization Form	100	1	100	2.000	200.00
Additional Documentation and Certification	30	1	30	0.750	22.50
Benefits Package and Supporting Documentation	30	1	30	0.125	3.75
Total	260		260		1,326.25

HRSA specifically requests comments on (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.

Maria G. Button,

Director, Executive Secretariat.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier OS–0937–0198]

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 May 23, 2023.

ADDRESSES: Submit your comments to *Sherrette.Funn@hhs.gov* or by calling (202) 264–0041 and *PRA@HHS.GOV.*

FOR FURTHER INFORMATION CONTACT: When submitting comments or requesting information, please include the document identifier 0937–0198–60D and project title for reference, to Sherrette A. Funn, email: *Sherrette.Funn@hhs.gov, PRA@HHS.GOV* or call (202) 264–0041 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: Public Health Service Policies on Research Misconduct (42 CFR part 93).

Type of Collection: Extension.

OMB No: OS–0937–0198.

Abstract: The Office of Research Integrity is requesting an extension on a currently approved collection. The purpose of the Institutional Assurance and Annual Report on Possible Research Misconduct form PHS–6349 is to provide data on the amount of research misconduct activity occurring in institutions conducting PHS-supported research. The purpose of the Assurance of Compliance by Sub-Award Recipients forms PHS–6315 is to establish an assurance of compliance for a sub-awardee institution. Forms PHS 6349 and PHS–6315 are also used to provide an annual assurance that the institution has established and will follow administrative policies and procedures for responding to allegations of research misconduct that comply with the Public Health Service (PHS) Policies on Research Misconduct (42 CFR part 93). Research misconduct is defined as receipt of an allegation of research misconduct and/or the conduct of an inquiry and/or investigation into such allegations. These data enable the ORI to monitor institutional compliance with the PHS regulation.

There were minor revisions made on forms PHS–6349 and PHS–6315. The revisions will not alter the data collection.

Need and Proposed Use: The information is needed to fulfill section 493 of the Public Health Service Act (42 U.S.C. 289b), which requires assurances from institutions that apply for financial assistance under the Public Health Service Act for any project or program that involves the conduct of biomedical or behavioral research. In addition, the information is also required to fulfill the assurance and annual reporting requirements of 42 CFR part 93. ORI uses the information to monitor institutional compliance with the regulation. Lastly, the information may be used to respond to congressional requests for information to prevent misuse of Federal funds and to protect the public interest.