current and anticipated uses for sequencing technologies, an open public comment session, and roundtable discussions on selected topics. (See section III of this document.) The roundtable participants will not be asked to develop consensus opinions during the discussion, but rather to provide their individual perspectives. Others in attendance at the public meeting will have an opportunity to listen to the roundtable discussion.

Additional information, including a meeting agenda, will be available on the Internet., immediately after publication of this **Federal Register** notice. This information will be placed on file in the public docket (docket number found in brackets in the heading of this document), which is available at *http://www.regulations.gov*. This information will also be available at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm* (select the appropriate meeting from the list).

III. Topics for Input

FDA seeks input on the following issues:

1. Technical performance:
- Acceptance criteria,
- Validation samples/panels,
- Comparator/analytical standard.

2. Bioinformatics:
- Data format,
- Data analysis.

IV. Transcripts

Please be advised that as soon as a transcript is available, it will be accessible at *http://www.regulations.gov*. It may be viewed at the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. A transcript will also be available in either hardcopy or on CD–ROM, after submission of a Freedom of Information request. Written requests are to be sent to Division of Freedom of Information, 12420 Parklawn Dr., rm. 1050, Rockville, MD 20857.

Dated: May 13, 2011.

Nancy K. Stade,

Deputy Director for Policy, Center for Devices and Radiological Health.

[FR Doc. 2011–12310 Filed 5–18–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Privacy Act of 1974; Report of a New System of Records

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice of a new system of records.

SUMMARY: In accordance with the requirements of the Privacy Act of 1974, the Health Resources and Services Administration (HRSA) is proposing a new system of records. The Countermeasures Injury Compensation Program (CICP), authorized by the Public Readiness and Emergency Preparedness Act (PREP Act), provides compensation to certain individuals for serious physical injuries or deaths resulting from the administration or use of pandemic, epidemic, or security countermeasures identified in declarations issued by the Secretary of the U.S. Department of Health and Human Services (the Secretary) pursuant to section 319F–3(b) of the Public Health Service Act (PHS Act) (42 U.S.C. 247d–6d). The Secretary has issued several declarations specifying covered countermeasures, such as the pandemic 2009 H1N1 influenza vaccines, antiviral medications (*e.g.,* Tamiflu), anthrax vaccines, and smallpox vaccines. The PREP Act directs the Secretary to establish administrative procedures to compensate individuals who sustained serious injuries as the direct result of the administration or use of covered countermeasures. This system of records is required to comply with the implementation directives of the PREP Act, Public Law 109–148. The records will be used for the CICP's resource planning, administrative implementation (*e.g.,* making medical and/or financial eligibility determinations), compensating requesters, evaluation, scientific research, monitoring, and document storage purposes.

DATES: HRSA invites interested parties to submit comments on the proposed New System of Records on or before June 20, 2011. As of the date of the publication of this Notice, HRSA has sent a Report of New System of Records to Congress and to the Office of Management and Budget (OMB). The New System of Records will be effective 40 days from the date submitted to OMB unless HRSA receives comments that would result in a contrary determination.

ADDRESSES: Please address comments to the Director, Countermeasures Injury Compensation Program, Healthcare Systems Bureau, Health Resources and Services Administration, 5600 Fishers Lane, Room 11C–06, Rockville, Maryland 20857; telephone 1–800–ASK–HRSA (275–4772). This is a toll-free number. Comments received will be available for inspection at this same address from 9 a.m. to 3 p.m., Eastern Standard Time, Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Director, Countermeasures Injury Compensation Program, Healthcare Systems Bureau, Health Resources and Services Administration, 5600 Fishers Lane, Room 11C–06, Rockville, Maryland 20857; telephone toll-free 1–800–ASK–HRSA (275–4772).

SUPPLEMENTARY INFORMATION: HRSA proposes to establish a new system of records: "The Countermeasures Injury Compensation Program, HHS/HRSA/HSB." The PREP Act which is a part of the "Department of Defense, Emergency Supplemental Appropriations to Address Hurricanes in the Gulf of Mexico, and Pandemic Influenza Act, 2006" (Pub. L. 109–148), was enacted on December 30, 2005, and confers broad liability protections on covered persons, as defined in section 319F–3(i)(2) of the PHS Act, and authorizes the creation of a Countermeasures Injury Compensation Program (CICP or the Program) to compensate individuals injured by the administration or use of covered countermeasures, as defined in section 319F–3(i)(1) of the PHS Act, in the event of designated present or future public health emergencies. The Secretary has issued regulations for the administrative implementation of the Program at 42 CFR part 110.

The PREP Act provides the Secretary the authority, which was delegated by the Secretary on November 8, 2006 to the Administrator of HRSA, to compensate eligible individuals for covered injuries from a covered countermeasure.

Compensation benefits will be provided for eligible individuals who suffer serious physical injuries or death resulting from pandemic, epidemic, or security countermeasures such as vaccines identified in declarations issued by the Secretary under a "PREP Act declaration" issued in response to a current public health emergency, or to a credible risk that the disease, condition, or threat may in the future constitute such an emergency. The Secretary has issued several pandemic influenza declarations specifying

covered countermeasures, such as the pandemic 2009 H1N1 influenza vaccines, antiviral medications (*e.g.,* Tamiflu), diagnostic kits, mechanical ventilators and N–95 masks. The Secretary has also issued declarations for countermeasures against the threats of anthrax, smallpox, botulism, and radiation syndrome.

In order to be considered for CICP benefits, an injured countermeasure recipient must have been administered or used a covered countermeasure according to the terms of a declaration (or in a good faith belief of such). The injured countermeasure recipient must also have sustained a serious physical injury or died as a result of the covered countermeasure. The PREP Act also allows certain survivors of an injured countermeasure recipient to be eligible to receive death benefits if the death resulted from the administration or use of the covered countermeasure. Also, the estate of a deceased injured countermeasure recipient may be eligible for certain benefits, regardless of the cause of death

Subject to certain provisions, the PREP Act authorizes benefits and other compensatory payments as payer of last resort for the following:

- Medical Expenses—Reasonable and necessary costs incurred for unreimbursed medical items and services may be paid to diagnose, treat or prevent a covered countermeasure-related injury of an eligible individual.
- Lost Employment Income—The individual may receive compensation for loss of employment income incurred as a result of the covered countermeasure injury. The amount of compensation is based on income at the time of injury. Certain limitations are placed on such benefits.
- Survivor Death Benefits—Death benefits may be paid to certain survivors of covered countermeasures recipients who have died as a direct result of a covered injury.

Individuals have one (1) year from the date the vaccine or other covered countermeasure was administered or used to request benefits.

This system of records is required to comply with the implementation directives set forth in the PREP Act. It will be used for Program resource planning, administrative implementation, compensation, evaluation, scientific research, monitoring, and document storage purposes. HRSA permits disclosure of the records to third parties pursuant to the following routine uses: The first routine use permits disclosure to a Congressional office to allow subject individuals to obtain assistance from their representatives in Congress, if they wish to do so. The second routine use allows disclosure to Federal, State or local Government entities or to private entities for the purpose of their providing information relevant to medical, legal or financial documentation required for determinations of eligibility or payment. The third routine use allows disclosure of records to contractors engaged by the Department of Health and Human Services (DHHS or the Department) who need access to the records in order to assist the Department, e.g., medical experts or consultants providing advice on requester eligibility for benefits and/or compensation. The fourth routine use allows disclosure of records to contractors engaged by the Department who need access to the records in order to assist the Department, in evaluating the effectiveness of the CICP. The fifth routine use allows disclosure of records to individuals and/or entities as necessary for the purposes of obtaining financial advice and providing benefits to requesters approved for payment under the Program. The sixth routine use allows disclosure of records to a Federal agency administering aspects of the Program under a Memorandum of Agreement or assisting in the accomplishment of a Departmental function related to the purposes of the Program. The seventh routine use allows disclosure of records to the Department of Justice or a court in the event of litigation. The eighth routine use allows disclosure to the appropriate Federal, State or local agency in the event of a violation of law. The ninth routine use allows disclosure of records to researchers for certain scientific research purposes. The following notice is written in the present tense, rather than the future tense, in order to avoid the unnecessary expenditure of public funds to republish the notice after the system becomes effective.

Dated: April 15, 2011.

Mary K. Wakefield,

Administrator, Health Resources and Services Administration.

SYSTEM NUMBER:

09–15–0071.

SYSTEM NAME:

Countermeasures Injury Compensation Program, HHS/HRSA/HSB.

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

Healthcare Systems Bureau (HSB), Health Resources and Services Administration (HRSA), 5600 Fishers Lane, Room 11C–06, Rockville, Maryland 20857.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individuals covered by the system are injured countermeasure recipients or their representatives, survivors of such recipients or their representatives, and representatives of the estates of deceased injured countermeasure recipients, filing for benefits under the Countermeasures Injury Compensation Program (CICP or the Program).

CATEGORIES OF RECORDS IN THE SYSTEM:

Records consist of documents that may include, but are not limited to, general or congressional correspondence, requests, case number assignment, HHS responses to correspondence, medical and legal documentation, employment documentation, documentation concerning services or benefits available from the United States or any third party (including any State or local governmental entity, private insurance carrier, or employer), payment information, and other related case processing documents.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

The authority for maintaining this system of records is 42 U.S.C. 247d–6e. Management of the system is authorized by Public Law 109–148, the Public Readiness and Emergency Preparedness Act (PREP Act), enacted on December 30, 2005 (42 U.S.C. 247d–6e).

PURPOSE(S):

The purpose of the system is to provide benefits to certain individuals who have sustained a covered injury as a result of the administration or use of a covered countermeasure, and to provide benefits to the survivors and/or estates of deceased injured countermeasure recipients. Requests for Benefits must be submitted to the CICP no later than (one) 1 year from the date the recipient was administered or used a covered countermeasure.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

1. Disclosure may be made to a Congressional office from the record of a subject individual, in response to an inquiry from the Congressional office made at the written request of that individual or his/her legal or personal representative.

2. Disclosure may be made to Federal, State or local Government entities or to private entities for the purpose of their providing information relevant to

medical, legal, or financial (e.g., insurance, payment) documentation required for determinations of eligibility or payment, provided that such disclosure is compatible with the purpose for which the records were collected.

3. Disclosure of records may be made to contractors engaged by the Department who need access to the records in order to assist the Department, *e.g.,* medical experts or consultants providing advice on requesters' eligibility for benefits. All such individuals shall be required to maintain Privacy Act safeguards with respect to such records and return all records to HRSA and not retain any copies.

4. Disclosure of records may be made to contractors engaged by the Department who need access to the records in order to assist the Department in evaluating the effectiveness of the CICP.

5. Disclosure of records may be made to individuals and/or entities as necessary for the purposes of obtaining financial advice and providing benefits to requesters approved for payment under the Program. All individuals and/or entities permitted disclosure for this use shall be required to maintain Privacy Act safeguards with respect to such records and return all records to HRSA without retaining any copies.

6. Disclosure of records may be made to a Federal agency assisting in the accomplishment of a Departmental function relating to the purposes of this system of records, provided that such disclosure is compatible with the purposes for which the records are collected, or to a Federal agency administering aspects of the Program, as authorized by a Memorandum of Agreement between the Secretary or her designee and the head of the Federal agency or designee.

7. Disclosure of records may be made in the event of litigation where the defendant is:

(a) The Department, any component of the Department, or any employee of the Department in his or her official capacity;

(b) the United States where the Department determines that the action, if successful, is likely to affect directly the operation of the Department or any of its components; or

(c) any Department employee in his or her individual capacity where the Department of Justice (DOJ) has agreed to represent such employee, for example, in defending an action against the Department in connection with such individual, disclosure may be made to DOJ to enable DOJ to present an effective defense, provided that such disclosure is compatible with the purpose for which the records were collected.

8. Disclosure may be made in the event that a system of records maintained by this agency to carry out its functions indicates a violation or potential violation of law, whether civil, criminal, or regulatory in nature, and whether arising by general statute or particular program statute, regulation, rule, or order issued pursuant thereto, the relevant records in the system of records may be referred to the appropriate agency, whether Federal, State or local, charged with the responsibility of investigating or prosecuting such violation, or charged with enforcing or implementing the statute, rule, regulation or order issued pursuant thereto, provided that such disclosure is compatible with the purpose for which the records were collected.

9. A record may be disclosed to researchers for a scientific research purpose, only when the Department has determined:

(a) That the use or disclosure does not violate legal or policy limitations under which the record was provided, collected, or obtained;

(b) That the research purpose is consistent with the purpose for which the Program was formed;

(c) That the proposed research is scientifically sound in its methods and analyses and is likely to answer the proposed research question;

(d) That the information sought is not available from any other source;

(e) That the record made available for scientific research is redacted of all personal identifiers regarding injured individuals, health care practitioners and employers that are not essential for the accomplishment of the approved research purpose, and;

(f) That the recipient of records for scientific research purposes:

(1) Established strict limitations acceptable to the Department concerning the receipt and use of any patient-identifiable data;

(2) Established reasonable administrative, technical, and physical safeguards and/or protocols acceptable to the Department to protect the confidentiality of the data and to prevent the unauthorized use or disclosure of the record;

(3) Removes or destroys the information that identifies an individual at the earliest time that removal or destruction can be accomplished consistent with the purpose of the research project;

(4) Makes no further use or disclosure of the record except when required by law; and

(5) Secures and approves a written statement attesting to the recipient's understanding of, and agreement to abide by, these conditions of disclosure.

Violation of these provisions is subject to penalties set forth under 5 U.S.C. 552a(i)(3) and any other applicable Federal law.

10. Disclosure of records may be made to appropriate federal agencies and Department contractors that have a need to know the information for the purpose of assisting the Department's efforts to respond to a suspected or confirmed breach of the security or confidentiality of information maintained in this system of records, and the information disclosed is relevant and necessary for that assistance.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records are maintained in file folders, on computer hard drives and shared drives, and/or in electronic media storage.

RETRIEVABILITY:

Records can be retrieved by the requester's name and by the case number assigned based on the order in which the Letter of Intent to File a Request for Benefits or the Request for Benefits form is filed.

SAFEGUARDS:

1. Assign Responsibility for Security: Responsibility is assigned to a CICP management official who is knowledgeable about the nature of the information in this system of records, the process of reviewing records contained in it, and in the management, personnel, operational, and technical controls used to protect it.

2. Perform Risk Assessment: A risk assessment is to be conducted in conjunction with the development of, and prior to the approval of, the system design and will ensure that vulnerabilities, risks, and other security concerns are identified and addressed in the system design and throughout the life cycle of the project. This is consistent with the Information Security Program Policy, HHS IRM Policy 2004–002.001 (Dec. 15, 2004), Section 3.7.3.

3. Develop CICP Request Security Plan: Plan for the adequate security of the CICP Request for Benefits system, taking into account the security of all systems in which Requests for Benefits will operate. CICP request security plans shall address request rules, training on

use of the system, personnel security, contingency planning, technical controls, information sharing, and public access controls.

4. Review CICP Request for Benefits System Controls: Perform an independent review or audit of the CICP Request for Benefits system security control in accordance with applicable Federal requirements and/or guidelines.

5. Authorize Processing: Ensure that a management official authorizes, in writing, confirmation that the security plan as implemented adequately secures the CICP Request for Benefits system. The CICP Request for Benefits system must be authorized prior to operating and reauthorized in accordance with applicable Federal requirements and/or guidelines.

6. Implementation Guidelines: DHHS Chapter 45–13 "Safeguarding Records Contained in Systems of Records;" the Information Security Program Policy, HHS IRM Policy 2004–002.001 (Dec. 15, 2004); and Appendix III to OMB Circular No. A–130 "Security of Federal Automated Information Resources;" Appendix I to OMB Circular No. A–130, "Federal Agency Responsibilities for Maintaining Records About Individuals."

RETENTION AND DISPOSAL:

HRSA is working with NARA to obtain the appropriate retention value. Records will be retained and disposed of in accordance with the Records Control Schedule of the Health Resources and Services Administration.

SYSTEM MANAGER(S) AND ADDRESS:

Director, Countermeasures Injury Compensation Program, Healthcare Systems Bureau, Health Resources and Services Administration, 5600 Fishers Lane, Room 11C–06, Rockville, Maryland 20857, or the Director's designee.

NOTIFICATION PROCEDURE:

Requests must be made to the System Manager.

Requests by mail: Requests for information and/or access to records received by mail must contain information providing the identity of the writer, and a reasonable description of the record desired, and whom it concerns. Written requests must contain the name and address of the requester, his/her date of birth and his/her signature for comparison purposes. Requests must be notarized to verify the identity of the requester, or the requester must certify that (s)he is the individual who (s)he claims to be and that (s)he understands that to knowingly and willfully request or acquire a record pertaining to another individual under false pretenses is a criminal offense under the Privacy Act subject to a $5,000 fine (45 CFR 5b.5(b)(2)(ii)).

Requests in person: Record access procedures are the same as notification procedures. The requester should provide a reasonable description of the contents of the record being sought. Records will be mailed only to the requester's address that is on file, unless a different address is demonstrated by official documentation. A parent or guardian who requests notification of, or access to, a minor/legally incompetent person's medical records must verify his/her relationship to the minor/legally incompetent person as well as his/her own identity and shall designate a family physician or other health professional (other than a family member) to whom the record, if any, will be sent.

Requests by telephone/facsimile/electronic mail: Since positive identification of the requester cannot be established, telephone, facsimile, or electronic mail (e-mail) requests will not be honored.

RECORD ACCESS PROCEDURES:

Record access procedures are the same as Requests in Person procedures above.

CONTESTING RECORDS PROCEDURES:

To contest a record in the system, contact the System Manager at the address specified above and reasonably identify the record, stipulate the information being contested, state the corrective action sought and the reason(s) for requesting the correction, along with supporting documentation to show how the record is inaccurate, incomplete, untimely, or irrelevant.

RECORD SOURCE CATEGORIES:

Sources of records include, but are not limited to, countermeasure recipients and/or their legal or personal representatives under the Countermeasures Injury Compensation Program, and any other sources of information or documentation submitted by any other person or entity for inclusion in a request for the purpose of determining medical or legal eligibility for, or amount of benefits and/or compensation under, the Program (*e.g.,* Federal, State, or local government or private health care entities participating in the administration of covered countermeasures under a Secretarial declaration).

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

[FR Doc. 2011–12258 Filed 5–18–11; 8:45 am]

BILLING CODE 4160–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request; A Generic Submission for Formative Research, Pre-Testing, Stakeholder Measures and Advocate Forms at NCI

Summary: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Cancer Institute (NCI), the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the **Federal Register** on March 15, 2011 (76 FR 14034) and allowed 60-days for public comment. No comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Proposed Collection: Title: A Generic Submission for Formative Research, Pre-testing, Stakeholder Measures and Advocate Forms at NCI. *Type of Information Collection Request:* New. *Need and Use of Information Collection:* In order to carry out NCI's legislative mandate, the Office of Advocacy Relations (OAR) disseminates cancer-related information to a variety of stakeholders, seeks their input and feedback, and facilitates collaboration between the Institute and these external partners to advance NCI's authorized programs. It is beneficial for NCI, through the OAR, to pretest strategies, concepts, activities and materials while they are under development. Additionally, administrative forms may be part of this generic submission since they are a necessary part of collecting demographic information and areas of interest for advocates. Pre-testing, or formative evaluation, helps ensure that the products and services developed by NCI have the greatest capacity of being received, understood, and accepted by their target audiences. Since OAR is