Certification/Declaration of Exemption Form is the minimum necessary to satisfy the assurance and certification requirements of Section 491 (a) of the Public Health Service Act and HHS Regulations for the protection of human subjects at 45 CFR 46.103.

Likely Respondents: Research institutions engaged in HHS-conducted or —supported research involving human subjects. Institutional use of the form is also relied upon by other federal departments and agencies that have codified or follow the Federal Policy for the Protection of Human Subjects (Common Rule).

TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS

Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
Protection of Human Subjects: Assurance Identification/IRB Certification/ Declaration of Exemption	12,000	2	30/60	12,000
Total				12,000

Darius Taylor,

Information Collection Clearance Officer.

[FR Doc. 2015–02649 Filed 2–9–15; 8:45 am]

BILLING CODE 4150–36–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier HHS–0990–0260–60D]

Agency Information Collection Activities; Proposed Collection; Public Comment Request

AGENCY: Office of the Assistant Secretary for Health, HHS.

ACTION: Notice.

SUMMARY: In compliance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Office of the Secretary, Department of Health and Human Services (HHS), announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). The ICR is for extending the use of the approved information collection assigned OMB control number 0990–0260, which expires on April 30, 2015. Prior to submitting that ICR to OMB, OS seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on the ICR must be received on or before April 13, 2015.

ADDRESSES: Submit your comments to *Information.CollectionClearance@hhs.gov* or by calling (202) 690–6162.

FOR FURTHER INFORMATION CONTACT: Information Collection Clearance staff, *Information.CollectionClearance@hhs.gov* or (202) 690–6162.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the document identifier 0990–0260 for reference.

Information Collection Request Title: Protection of Human Subjects: Assurance of Compliance with Federal Policy/IRB Review/IRB Recordkeeping/ Informed Consent/Consent Documentation-Extension—0990–0260, Assistant Secretary for Health, Office for Human Research Protections.

Abstract: Section 491(a) of Public Law 99–158 states that the Secretary of HHS shall by regulation require that each entity applying for HHS support (*e.g.,* a grant, contract, or cooperative agreement) to conduct research involving human subjects submit to HHS assurances satisfactory to the Secretary that it has established an institutional review board (IRB) to review the research in order to ensure protection of the rights and welfare of the human research subjects. IRBs are boards, committees, or groups formally designated by an entity to review, approve, and have continuing oversight of research involving human subjects.

Pursuant to the requirement of the Public Law 99–158, HHS promulgated regulations at 45 CFR part 46, subpart A, the basic HHS Policy for the Protection of Human Subjects. The June 18, 1991 adoption of the common Federal Policy (56 FR 28003) by 15 departments and agencies implements a recommendation of the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research which was established on November 9, 1974, by Public Law 95–622. The Common Rule is based on HHS regulations at 45 CFR part 46, subpart A, the basic HHS Policy for the Protection of Human Subjects.

Need and Proposed Use of the Information: The information collected through the Protection of Human Subjects: Assurance Identification/IRB Certification/Declaration of Exemption Form Protection of Human Subjects: Assurance of Compliance with Federal Policy/IRB Review/IRB Recordkeeping/ Informed Consent/Consent Documentation collection requirement is the minimum necessary to satisfy the assurance, certification, reporting, disclosure, documentation and recordkeeping requirements of Section 491(a) of the Public Health Service Act and HHS Regulations for the protection of human subjects at 45 CFR part 46.

Likely Respondents: Research institutions engaged in HHS-conducted or —supported research involving human subjects. Institutional use of the form is also relied upon by other federal departments and agencies that have codified or follow the Federal Policy for the Protection of Human Subjects (Common Rule).

TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS

Title	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
.103(b)(4), .109(d)IRB Actions, .116 and .117 Informed Consent	6,000	39.3 3	1	235,980
.115(a) IRB Recordkeeping	6,000	15	10	900,000

TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS—Continued

Title	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
.103(b)(5) Incident Reporting, .113 Suspension or Termination Reporting	6,000	0.5	45/60	2,250
Total	.....	.....	.....	1,138,230

OS 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.

Darius Taylor,

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

[FR Doc. 2015–02650 Filed 2–9–15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–15–0821]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) has submitted the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The notice for the proposed information collection is published to obtain comments from the public and affected agencies.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address any of the following: (a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) Enhance the quality, utility, and clarity of the information to be collected; (d) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses; and (e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639–7570 or send an email to *omb@cdc.gov.* Written comments and/or suggestions regarding the items contained in this notice should be directed to the Attention: CDC Desk Officer, Office of Management and Budget, Washington, DC 20503 or by fax to (202) 395–5806. Written comments should be received within 30 days of this notice.

Proposed Project

Quarantine Station Illness Response Forms: Airline, Maritime, and Land/Border Crossing (0920–0821, exp. 08/31/15)—Revision—National Center for Emerging and Zoonotic Infectious Diseases, Centers for Disease Control and Prevention (CDC).

Background and Brief Description

CDC is requesting a revision to a currently approved information collection, Quarantine Station Illness Response Forms: Airline, Maritime, and Land/Border Crossing). This revision seeks to incorporate the changes that resulted from activities undertaken during the response to Ebola. These changes include two major components, both of which have been given previous emergency clearance by OMB under Control Number 0920–1031 and 0920–1034, with an expiration date of April 30, 2015. As a part of this revision, CDC is requesting the full three year approval and 12 months of burden for the following:

The incorporation of two public health screening forms that are currently used to assess risk for Ebola in travelers coming to the United States from countries experiencing widespread transmission of the disease. These forms are the United States Traveler Health Declaration and a completely revised Ebola Entry Screening Risk Assessment Form, each given approval from OMB under OMB Control No 0920–1031. The additional burden requested for the English versions of the health declaration and the risk assessment form, as well as the French and Arabic translation guides for the health declaration and risk assessment forms, is 13,664 hours.

In this revision, CDC is maintaining the ability to use the Ebola Entry Screening Risk Assessment Form in the event that a traveler is identified as ill on a U.S.-bound flight prior to arrival. In the no material or non-substantive change to a currently approved collection granted by OMB on 9/18/2014, CDC requested 100 respondents and 5 hours of burden. Because the risk assessment form is more comprehensive, it requires more time for a traveler to complete the assessment. CDC is requesting an additional 20 hours of burden for the purpose of assessing ill travelers, for a total of 25 hours of burden. No additional respondents are requested.

CDC is also requesting the incorporation of a telephonic, automated survey administered through the Interactive Voice Response (IVR) phone system, which asks travelers if they have developed a fever or any other symptoms potentially indicative of Ebola exposure (OMB Control No 0920–1034). The IVR system would be implemented to assist state and local public health authorities with active monitoring of individuals coming to the United States from countries affected by the current Ebola outbreak. Use of this information collection tool would be voluntary and provides a cost- and time-saving mechanism for supporting states with their active monitoring responsibilities. The additional 12-month annualized burden requested for the use of the IVR system is approximately 71,400 hours.

No revisions are requested to the Air Travel, Maritime Conveyance or Land Travel Illness and Death Investigation forms or burden associated with these forms. The current burden associated with these routine information collections is 314 hours.