

document identifier HHS-OS-0990-0390-30D for reference.

**Information Collection Request Title: Challenge and Prize Competition Solicitations**

*Abstract:* In 2011, Federal agencies including HHS were given prize authority for administering challenges and competitions. Challenges and competitions enable the Assistant Secretary for Administration, HHS to tap into the expertise and creativity of the public in new ways. In order for HHS to quickly and effectively launch competitions on a continual basis, HHS seeks an extension on currently approved generic clearance to collect information for these challenges and competitions, which will generally include first name, last name, email,

city, state and when applicable other demographic information.

The information collected will be used to understand whether the participant has met the technical requirements for the challenge, assist in the technical review and judging of the solutions that are provided, and understand the impact and consequences of administering the competition and developing solutions for submission. Information may be collected during the competition or after its completion.

**Need and Proposed Use of the Information**

Challenges and competitions enable HHS to tap into the expertise and creativity of the public in new ways. HHS has sponsored challenges and competitions in a wide variety of areas such as recruitment efforts, health data

applications and other types of data, development of novel technologies, and communications to increase public participation and solicit new ideas on a wide array of topics important to the agencies mission. 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 quickly and effectively launch competitions on a continual basis.

*Likely Respondents:* Likely respondents include individuals, businesses, and state and local governments who choose to participate in a challenge or competition hosted by HHS.

**TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS**

Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
Individuals or Households .....	1000	1	1/6	166.6
Organizations .....	1000	1	1/6	166.6
Businesses .....	1000	1	1/6	166.6
State, territory, tribal or local governments .....	60	1	1/6	10
Total .....	.....	.....	.....	510

**Darius Taylor,**  
*Information Collection Clearance Officer.*  
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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Office of the Secretary**

[Document Identifier HHS-OS-0990-0263-30-D]

**Agency Information Collection Activities; Submission to OMB for Review and Approval; Public Comment Request**

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

**SUMMARY:** In compliance with section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, has submitted an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB) for review and approval. The ICR is for renewal of the approved information collection assigned OMB control

number 0990-0263, scheduled to expire on March 31, 2015. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public on this ICR during the review and approval period.

**DATES:** Comments on the ICR must be received on or before March 12, 2015.

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

**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 OMB control number 0990-0263 and document identifier HHS-OS-30D for reference.

*Information Collection Request Title:* Protection of Human Subjects: Assurance Identification/IRB Certification/Declaration of Exemption Form—Extension OMB No. 0990-0263, Assistant Secretary for Health, Office for Human Research Protections.

*Abstract:* The Office for Human Research Protections is requesting a three year extension of the Protection of Human Subjects: Assurance Identification/IRB Certification/Declaration of Exemption Form. That form is designed to promote uniformity among departments and agencies, and to help ensure common means of ascertaining institutional review board certifications and other reporting requirements relating to the protection of human subjects in research. The Federal Policy for the Protection of Human Subjects, known as the Common Rule, requires that before engaging in non-exempt human subjects research that is conducted or supported by a Common Rule department or agency, each institution must: (1) Hold an applicable assurance of compliance [Section 103(a)]; and (2) certify to the awarding department or agency that the application or proposal for research has been reviewed and approved by an IRB designated in the assurance [Sections 103(b) and (f)].

*Need and Proposed Use of the Information:* The information collected through the *Protection of Human Subjects: Assurance Identification/IRB*

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.  
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**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	39.33	1	235,980
.115(a) IRB Recordkeeping .....	6,000	15	10	900,000