

“Previous Grants.gov Tracking Number”; (2) Modification of an existing section “Person to be contacted on matters involving this application” to include the following fields (\* to indicate Mandatory fields): Position/ Title, Street1\*, Street2, City\*, County/ Parish, State\*, Province, Country\*, ZIP/ Postal Code\*; (3) Update current field label for Item 18 from “SF LLL or other Explanatory Documentation” to “SF LLL (Disclosure of Lobbying Activities) or Other Explanatory Documentation”; (4) Addition of a new optional field

numbered 21 entitled “Cover Letter Attachment”.

There are four requested changes to the R&R Other Project Information form: (1) Addition of yes/no question “1.b Is this a Clinical Trial?”; (2) Addition of a new field titled “3.a Areas of Research”; (3) Change existing field label for 4.a from “Does this project have an actual or potential impact on the environment?” to “Does this Project Have an Actual or Potential Impact—positive or negative—on the environment?”; (4) Change existing field

label for 4.b from “If yes, please explain” to “If yes, please explain— Enter an explanation for the actual or potential impact (whether positive or negative) on the environment.”

These changes to the instructions will increase data quality and clarity for the collection. Agencies will not be required to collect all of the information in the proposed data set. The agency will identify the data that must be provided by applicants through instructions that will accompany the application forms.

ESTIMATED ANNUALIZED BURDEN TABLE

Form	Type of respondent	Number of annual respondents	Number of responses per respondent	Average burden on respondent per response in hours	Total burden hours
SF-424 R&R .....	Grant Applicant .....	97,581	1	60	5,854,860
Total .....	.....	97,581	1	60	5,854,860

Comments were received in response to the 60-day **Federal Register** Notice (April 28, 2011, Volume 76, Number 82, pp. 23816–23817). The requested changes will be modified to accommodate the received responses.

**Keith A. Tucker,**  
Office of the Secretary, Paperwork Reduction Act Clearance Officer.  
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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

[Document Identifier OMB No. 0990-0376; 60-day Notice]

**Agency Information Collection Request; 60-Day Public Comment Request**

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

In compliance with the requirement of section 3506(c)(2)(A) 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 information collection request for public comment. 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.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, email your request, including your address, phone number, OMB number, and OS document identifier, to [Sherrette.funncoleman@hhs.gov](mailto:Sherrette.funncoleman@hhs.gov), or call the Reports Clearance Office on (202) 690-6162. Written comments and recommendations for the proposed information collections must be directed to the OS Paperwork Clearance Officer at the above email address within 60 days.

*Proposed Project:* Generic Clearance for Communications Testing for Comprehensive Communication Campaign for HITECH Act—Revision—OMB No. 0990-0376—Office of the National Coordinator for Health Information Technology.

*Abstract:* As part of the Health Information Technology for Economic and Clinical Health Act (HITECH Act) of 2009, ONC is proposing to conduct a nationwide communication campaign to meet the Congressional mandate to educate the public about privacy and security of electronically exchanged personal health information. ONC requires formative and process information about different segments of the public to conduct the campaign effectively. Data collection will occur continuously through the 24 months of

the campaign and be used to inform campaign strategies, messages, materials and Web sites. Due to the growing use of mobile devices in exchanging personal health information electronically, ONC is proposing a revision of the currently approved collection to increase focus group burden hours and explore consumer attitudes and preferences regarding the communication of personal health information electronically using mobile devices. Additionally, an increase in burden hours is necessary to understand attitudes and preferences regarding how privacy and security information is presented to consumers electronically. ONC is collaborating with the HHS Office of Civil Rights to oversee the education and communication activities to build approval for HIT adoption and meaningful use, educate the public about privacy and security and increase participation in health information exchange.

Electronic health information exchange promises an array of potential benefits for individuals and the U.S. health care system through improved health care quality, safety, and efficiency. At the same time, this environment also poses new challenges and opportunities for protecting health information, including methods for individuals to engage with their health care providers and affect how their health information may be exchanged.

ESTIMATED ANNUALIZED BURDEN TABLE

Forms	Type of respondent	Number of respondents	Number of responses per respondent	Average burden (in hours) per response	Total burden hours
Focus Group .....	General Public .....	621	1	1.5	932
Focus Group screening .....	General Public .....	5544	1	10/60	924
Web usability testing .....	General Public .....	144	1	1.5	216
Web usability screening .....	General Public .....	2160	1	10/60	360
Self-Administered Surveys .....	General Public .....	2000	1	15/60	500
Self-Administered survey screening .....	General Public .....	8000	1	10/60	1333
Omnibus Surveys .....	General Public .....	2000	1	10/60	333
Cognitive testing .....	General Public .....	25	1	2	50
Focus Group .....	Health Professional .....	288	1	1.5	432
Screening .....	Health Professional .....	4320	1	10/60	720
Web usability testing .....	Health Professional .....	144	1	1.5	216
Screening .....	Health Professional .....	2160	1	10/60	360
Self-Administered Surveys .....	Health Professional .....	2000	1	15/60	500
Screening .....	Health Professional .....	8000	1	10/60	1333
Omnibus Surveys .....	Health Professional .....	2000	1	10/60	333
In-Depth Interviews .....	Health Professional .....	100	1	45/60	75
Screening .....	Health Professional .....	1000	1	10/60	167
Total (Overall) .....	.....	40,506	.....	.....	8,784

**Keith A. Tucker,**  
*Office of the Secretary, Paperwork Reduction Act Clearance Officer.*  
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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Agency for Healthcare Research and Quality**

**Common Formats for Patient Safety Data Collection and Event Reporting**

**AGENCY:** Agency for Healthcare Research and Quality (AHRQ), HHS.  
**ACTION:** Notice of Availability—New Common Format.

**SUMMARY:** The Patient Safety and Quality Improvement Act of 2005, 42 U.S.C. 299b-21 to b-26, (Patient Safety Act) provides for the formation of Patient Safety Organizations (PSOs), which collect, aggregate, and analyze confidential information regarding the quality and safety of health care delivery. The Patient Safety Act (at 42 U.S.C. 299b-23) authorizes the collection of this information in a standardized manner, as explained in the related Patient Safety and Quality Improvement Final Rule, 42 CFR part 3 (Patient Safety Rule), published in the **Federal Register** on November 21, 2008: 73 FR 70731-70814. AHRQ coordinates the development of a set of common definitions and reporting formats (Common Formats) that allow health care providers to voluntarily collect and submit standardized information regarding patient safety events. The

purpose of this notice is to announce the availability of a new beta version Common Format for Venous Thromboembolism (VTE) for public review and comment.

**DATES:** Ongoing public input.  
**ADDRESSES:** The new beta version of the Common Format for Venous Thromboembolism (VTE), version dated October 2011, and the remaining Common Formats, can be accessed electronically at the following HHS Web site: <http://www.PSO.AHRQ.gov/index.html>.

**FOR FURTHER INFORMATION CONTACT:** Susan Grinder, Center for Quality Improvement and Patient Safety, AHRQ, 540 Gaither Road, Rockville, MD 20850; Telephone (toll free): (866) 403-3697; Telephone (local): (301) 427-1111; TTY (toll free): (866) 438-7231; TTY (local): (301) 427-1130; Email: [PSO@AHRQ.hhs.gov](mailto:PSO@AHRQ.hhs.gov).

**SUPPLEMENTARY INFORMATION:**

**Background**

The Patient Safety Act and Patient Safety Rule establish a framework by which doctors, hospitals, skilled nursing facilities, and other health care providers may voluntarily report information regarding patient safety events and quality of care. Both the Patient Safety Act and Patient Safety Rule, including any relevant guidance, can be accessed electronically at: <http://www.PSO.AHRQ.gov/regulations/regulations.htm>.

AHRQ develops and maintains the Common Formats in order to facilitate standardized data collection and improve the safety and quality of health

care delivery. Since the initial release of the Common Formats in August 2008, AHRQ regularly revises the formats based upon public comment. Earlier this year, AHRQ released the beta version of the Skilled Nursing Facilities format, as announced in the **Federal Register** on March 7, 2011: 76 FR 12358-12359. With this release, AHRQ had made available Common Formats for two settings of care—acute care hospitals and skilled nursing facilities. The new beta version of the Common Format for Venous Thromboembolism (VTE), which includes Deep Vein Thrombosis (DVT) and Pulmonary Embolism (PE), will apply to both settings of care.

**Definition of Common Formats**

The term “Common Formats” refers to the common definitions and reporting formats that allow health care providers to collect and submit standardized information regarding patient safety events. The Common Formats are not intended to replace any current mandatory reporting system, collaborative/voluntary reporting system, research-related reporting system, or other reporting/recording system; rather the formats are intended to enhance the ability of health care providers to report information that is standardized both clinically and electronically.

The scope of Common Formats applies to all patient safety concerns including:

- Incidents—patient safety events that reached the patient, whether or not there was harm,