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**Accommodations:** Attendees are responsible for their own accommodations. Reservations can be made on a space-available basis at The Legacy Hotel and Meeting Centre (see *Location*).

**Registration:** You are encouraged to register at your earliest convenience. A registration fee will be charged to help defray the costs of rental of the meeting spaces, meals and snacks provided, travel expenses incurred by invited speakers, and other costs. The registration fee is \$325. Registration fees will be waived for invited speakers and administrative personnel.

The registration process, including payment of the registration fee, will be handled by CPDD. Additional information on the workshop, program agenda, and registration procedures is available on the Internet at <http://www.seiservices.com/nida/1014102/>. (FDA has verified the NIDA Web site address, but FDA is not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register**.)

If you need special accommodations due to a disability, please contact Ellen B. Geller or Corinne Moody (see *Contact Person*) at least 7 days in advance of the workshop.

**Comments:** FDA is holding this public workshop to obtain information about the science of abuse liability assessment. The workshop will center on status, needs, new approaches, and paradigms regarding preclinical studies, challenges associated with human subject abuse potential studies, and adverse events that signal abuse potential during clinical trials. The deadline for submitting comments about this public workshop is January 10, 2012.

Regardless of attendance at the public workshop, interested persons may submit either electronic or written comments regarding the issues presented at the workshop. Submit electronic comments to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets

Management between 9 a.m. and 4 p.m., Monday through Friday.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of January 27, 2010 (75 FR 4400), FDA announced the publication of a draft guidance for industry on "Assessment of Abuse Potential of Drugs," and requested comments on the draft guidance. There were 23 submissions to the docket with approximately 750 comments received from academia, industry, and the government. General and specific comments were received on every section of the draft guidance. The comment period has closed and FDA is gathering current information that may relate to some of the comments received. Questions remain, for example, about when abuse potential studies should be conducted, and about the signals of abuse or potential abuse observed in clinical trials. This workshop is another mechanism for continuation of discussion with interested stakeholders before FDA finalizes the draft guidance.

**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 (see *Comments*). 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 the Division of Freedom of Information (ELEM-1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857.

Dated: October 3, 2011.

**David Dorsey,**

*Acting Associate Commissioner for Policy and Planning.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### Statement of Organization, Functions and Delegations of Authority

This notice amends Part R of the Statement of Organization, Functions and Delegations of Authority of the Department of Health and Human Services (HHS), Health Resources and Services Administration (HRSA) (60 FR 56605, as amended November 6, 1995; as last amended at 76 FR 54236 dated August 31, 2011).

This notice reflects organizational changes to the Health Resources and

Services Administration. Specifically, this notice updates the Office of Information Technology (RB5) functional statement. The update to the functional statement will better align functional responsibility with improved security management capabilities and improved alignment of current security initiatives within the Office of Information Technology (RB5).

#### Chapter RB5—Office of Information Technology

##### Section RB5-10, Organization

The Office of Information Technology (RB5) is headed by the Director and Chief Information Officer, who reports directly to the Chief Operating Officer.

##### Section RB5-20, Functions

(1) Delete the functional statement for the Office of the Director (RB5) and replace in its entirety; and (2) delete the functional statement for the Division of IT Operational Support Services (RB58) and replace in its entirety.

##### Office of the Director (RB5)

The Chief Information Officer (CIO) is responsible for the organization, management, and administrative functions necessary to carry out the responsibilities of the CIO including: (1) Provides organizational development, investment control, budget formulation and execution, policy development, strategic and tactical planning, and performance monitoring; (2) provides leadership in the development, review and implementation of policies and procedures to promote improved information technology management capabilities and best practices throughout HRSA; and (3) coordinates IT workforce issues and works closely with the departmental Office of Human Resources Management on IT recruitment and training issues.

The Chief Information Security Officer (CISO), reporting to the CIO, provides leadership for, and collaborates with, Agency staff to oversee the implementation of security and privacy policy in the management of their IT systems, and plans all activities associated with Federal Information Security Management Act (FISMA) or other agency security and privacy initiatives, and also carries out the responsibilities including: (1) Implements, coordinates, and administers security and privacy programs to protect the information resources of HRSA in compliance with legislation, Executive Orders, directives of the Office of Management and Budget (OMB), or other mandated requirements e.g., Presidential Decision Directive 63,

OMB Circular A-130, the National Security Agency, the Privacy Act, and other Federal agencies; (2) executes the Agency's Risk Management Program, evaluates and assists with the implementation of safeguards to protect major information systems, and IT infrastructure; (3) manages the development, implementation, and evaluation of the HRSA information technology security and privacy training program to meet the requirements as mandated by OMB Circular A-130, the Computer Security Act, and Privacy Act; (4) assesses all new emerging technologies and impact on technology integration on HRSA missions and program objectives; (5) provides leadership for strategic planning that leverages information systems security, program strategies, and advanced technology integration to achieve program objectives through innovative technology use; (6) the HRSA Incident Response Center (HIRC) provides a centralized, responsive resource for computer security incident reporting, management, and situational awareness of the Department's information security posture; (7) provides services include computer security situational awareness reports, computer forensics, cyber-related advisories, as well as cyber alerts, warnings, and Block/Watch lists are utilized and disseminated; (8) the HIRC coordinates with other Agencies and organizations for computer security and maintains a lab where new products are tested to insure that HRSA is utilizing state of the art, cutting edge technologies to ensure the secure operation of the HRSA infrastructure; and (9) provides leadership for ongoing cyber protection and incident detection response, reporting, and handling in accordance with OMB and departmental guidance.

*Division of IT Operational Support Services (RB58)*

The Division of IT Operational Support Services (ITOSS) (1) provides leadership, consultation, training, and management services for HRSA's enterprise computing environment; (2) directs and manages the support and acquisition of HRSA network and desktop hardware, servers, wireless communication devices, and software licenses; (3) is responsible for the HRSA Data Center and the operation and maintenance of a complex, high-availability network infrastructure on which mission-critical applications are made available 24 hours per day, 7 days per week; (4) controls infrastructure

configuration management, installations and upgrades, security perimeter protection, and system resource access; (5) coordinates IT activities for Continuity of Operations Planning (COOP) Agency-wide including provisioning and maintaining IT infrastructure and hardware at designated COOP locations to support emergency and COOP requirements; (6) maintains workstation hardware and software configuration management controls; (7) the Chief Technology Officer (CTO), reporting to the IT OSS Division Director is responsible for assessing emerging technologies and the subsequent impact on current infrastructure restraints and program objectives; (8) coordinates and engages with all OIT Divisions and Branches to insure that advanced technology is being utilized to achieve program objectives through innovative technology use; and (9) provides leadership and establishes policy and provides oversight for Agency IT configuration management.

*Section RB5-30, Delegations of Authority*

All delegations of authority and re-delegations of authority made to HRSA officials that were in effect immediately prior to this reorganization, and that are consistent with this reorganization, shall continue in effect pending further re-delegation.

This reorganization is effective upon date of signature.

Dated: September 30, 2011.

**Mary K. Wakefield,**  
*Administrator.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**Submission for OMB Review; Comment Request; A Generic Submission for Theory Development and Validation (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 August 2, 2011

(76 FR 46307) and allowed 60-days for public comment. No public comment 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 Theory Development and Validation (NCI). *Type of Information Collection Request:* NEW. *Need and Use of Information Collection:* In order to carry out NCI's legislative mandate to conduct and support research with respect to the causes and prevention of cancer, it is beneficial for NCI, through initiatives in the Behavioral Research Program (BRP), to conduct and support behavioral research informed by and informing theory. Formative research in the area of theory development and validation would provide the basis for developing effective cancer prevention and control strategies, allow for a better understanding of theoretical constructs that influence decisions and actions related to cancer, and ultimately contribute to reducing the U.S. cancer burden. Data collections that result from this generic clearance would inform and clarify the use of theory in BRP-supported initiatives and funding announcements. Specifically, this research would allow NCI to conduct research to: (1) Identify psychological, biobehavioral, demographic, and individual difference predictors of cancer prevention and control behaviors and outcomes; (2) Develop and refine integrative theories; (3) Identify and observe theoretical and innovative trends in cancer prevention and control research; and (4) Determine feasibility and usefulness of collaborative and multidisciplinary approaches to cancer prevention and control. *Frequency of Response:* Will be determined by each project. *Affected Public:* Individuals or households; Businesses or other for profit; Not-for-profit institutions; Federal Government; State, Local, or Tribal Government. *Type of Respondents:* Members of the public including, but not limited to health professionals, physicians, and researchers. Table 1 outlines the estimated burden hours and cost required for a three-year approval of this generic submission.