

TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS

Response type	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
45 CFR 164.306 Justification	75,000	3	15/60	56,250
45 CFR 164.308 Security incident report	50	1	8	400
45 CFR 164.308 Contingency plan	60,000	1	8	480,000
45 CFR 164.310 Physical safeguard policies and procedures	500	1	10/60	83
45 CFR 164.314 Problem reports	10	1	1	10
Total				536,743

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,
Information Collection Clearance Officer.
 [FR Doc. 2016-05806 Filed 3-14-16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General
[OIG-1206-N]

Statement of Organization, Functions, and Delegations of Authority

AGENCY: Office of Inspector General (OIG), HHS.
ACTION: Notice.

SUMMARY: This notice replaces all language in Part A (Office of the Secretary) of the Statement of Organization, Functions, and Delegations of Authority for the Department of Health and Human Services (HHS), Office of Inspector General (OIG) (70 FR 20147, as amended April 18, 2005; as last amended at 73 FR 7568, dated February 8, 2008).

The statement of organization, functions, and delegations of authority conforms to and carries out the statutory requirements for operating OIG. The organizational changes reflected in this notice are primarily to realign the functions within OIG to better reflect the current work environment and priorities, and to more clearly delineate responsibilities for the various activities within OIG's offices. In addition, this notice removes all of Chapter A and establishes Chapter Q.

OIG was established by law as an independent and objective oversight unit of the Department to carry out the mission of preventing fraud and abuse and promoting economy, efficiency and effectiveness of HHS programs and operations. In furtherance of this mission, the organization:

- A. Conducts and supervises audits, investigations, evaluations and inspections relating to HHS programs and operations.
- B. Identifies systemic weaknesses giving rise to opportunities for fraud and abuse in HHS programs and operations and makes recommendations to prevent their recurrence.
- C. Leads and coordinates activities to prevent and detect fraud and abuse in HHS programs and operations.
- D. Detects wrongdoers and abusers of HHS programs and beneficiaries so appropriate remedies may be brought to bear, including imposing administrative sanctions against providers of health care under Medicare and Medicaid who commit certain prohibited acts.
- E. Keeps the Secretary and Congress fully and currently informed about problems and deficiencies in the administration of HHS programs and operations and about the need for and progress of corrective action.

In addition, OIG works with the Department of Justice (DOJ), on behalf of the Secretary, to operate the Health Care Fraud and Abuse Control Program. In accordance with authority enacted in its annual appropriations, OIG also provides protection services to the Secretary and conducts criminal investigations of violations of Federal child support provisions.

In support of its mission, OIG carries out and maintains an internal quality assurance system and a peer review system with other Offices of Inspectors General, including periodic quality assessment studies and quality control reviews, to provide reasonable assurance that applicable laws, regulations, policies, procedures, standards, and other requirements are followed, are effective, and are

functioning as intended in OIG operations.

Section Q, Office of Inspector General—Organization

There is at the head of OIG a statutory Inspector General, appointed by the President and confirmed by the Senate. This office consists of six organizational units:

- A. Immediate Office of the Inspector General (QA)
- B. Office of Management and Policy (QC)
- C. Office of Evaluation and Inspections (QE)
- D. Office of Counsel to the Inspector General (QG)
- E. Office of Audit Services (QH)
- F. Office of Investigations (QJ)

Section Q, Office of Inspector General—Functions

The component sections that follow describe the specific functions of the organization.

Section Q.00, Immediate Office of the Inspector General—Mission

The Immediate Office of the Inspector General is directly responsible for meeting the statutory mission of OIG as a whole and for promoting effective OIG internal quality assurance systems, including quality assessment studies and quality control reviews of OIG processes and products. The office also plans, conducts and participates in a variety of interagency cooperative projects and undertakings relating to fraud and abuse with the DOJ, the Centers for Medicare & Medicaid Services (CMS) and other governmental agencies, and is responsible for the reporting and legislative and regulatory review functions required by the Inspector General Act.

Section QA.10, Immediate Office of the Inspector General—Organization

The Immediate Office is comprised of the Inspector General, the Principal Deputy Inspector General, Chief of Staff,

several technical advisors, including the Chief Medical Officer, and staff.

Section QA.20, Immediate Office of the Inspector General—Functions

The Inspector General is appointed by the President, with the advice and consent of the Senate, and reports to and is under the general supervision of the Secretary or, to the extent such authority is delegated, the Deputy Secretary, but does not report to and is not subject to supervision by any other officer in the Department. In keeping with the independence conferred by the Inspector General Act, the Inspector General assumes and exercises, through line management, all functional authorities related to the administration and management of OIG and all mission-related authorities stated or implied in the law or delegated directly from the Secretary.

The Inspector General provides executive leadership to the organization and exercises general supervision over the personnel and functions of its major components. The Inspector General determines the budget needs of OIG, sets OIG policies and priorities, oversees OIG operations and provides reports to the Secretary and Congress. By statute, the Inspector General exercises general personnel authority, *e.g.*, selection, promotion, and assignment of employees, including members of the Senior Executive Service. The Inspector General delegates related authorities as appropriate. The Principal Deputy Inspector General assists the Inspector General in the management of OIG, and during the absence of the Inspector General, acts as the Inspector General. The Principal Deputy Inspector General supervises the Chief Counsel to the Inspector General, the Deputy Inspectors General, who head the major OIG components, as well as the Chief of Staff.

Section QC.00, Office of Management and Policy—Mission

The Office of Management and Policy (OMP) provides management, guidance, and resources in support of OIG.

Section QC.10, Office of Management and Policy—Organization

The office is directed by the Deputy Inspector General for Management and Policy, who, aided by Assistant Inspectors General, assures that OIG has the financial and administrative resources necessary to fulfill its mission. This office carries out its responsibilities through headquarters functions.

Section QC.20, Office of Management and Policy—Functions

The staffs within OMP are responsible for formulating and executing the budget, developing policy, managing information technology, human resources, executive resources, OIG procurement activities and OIG physical space. OMP also executes and maintains an internal quality assurance system, which includes quality control reviews of OMP processes and products to ensure that OIG policies and procedures are followed and function as intended. Additionally, the office leads OIG's congressional and regulatory functions; media and public communications; coordinates strategic planning and mandated Inspector General reporting, including Work Plans and Semi-Annual Reports to Congress; and responds to all requests made under the Freedom of Information Act.

Finally, the office leads and coordinates OIG's data analysis management and organizational performance management activities.

Section QE.00, Office of Evaluation and Inspections—Mission

The Office of Evaluation and Inspections (OEI) is responsible for conducting in-depth evaluations of HHS programs, operations, and processes to identify vulnerabilities and recommend corrective action; to prevent and detect fraud and abuse; and to promote efficiency and effectiveness in HHS programs and operations. OEI conducts its work in accordance with the Quality Standards for Inspection and Evaluation issued by the Council of the Inspectors General on Integrity and Efficiency.

Section QE.10, Office of Evaluation and Inspections—Organization

This office is directed by the Deputy Inspector General for OEI who, aided by Assistant Inspectors General, is responsible for carrying out OIG's responsibilities to evaluate the effectiveness and efficiency of HHS programs and operations. The office is comprised of headquarters and regional functions.

Section QE.20, Office of Evaluation and Inspections—Functions

OEI is responsible for conducting evaluations of HHS programs; conducting data and trend analysis; and recommending changes in programs, procedures, policies, regulations, and legislation. The Office develops evaluation policies, procedures, techniques and guidelines to be followed by all OEI staff in conducting evaluations. The office maintains an internal quality assurance program. OEI

also oversees the activities of State Medicaid Fraud Control Units (MFCUs) to ensure the MFCUs' compliance with Federal grant regulations, administrative rules, and performance standards for the purpose of certifying or recertifying the MFCUs annually.

The office also maintains automated data and management information systems used by all OEI employees, a quality assurance/peer review program and policy and procedure manuals.

Section QG.00, Office of Counsel to the Inspector General—Mission

In accordance with section 3(g) of the Inspector General Act (5 U.S.C. App. § 3(g)), the Office of Counsel to the Inspector General (OCIG) provides all legal advice to OIG and represents OIG in administrative litigation. OCIG proposes and litigates civil money penalty (CMP) and program exclusion cases within the jurisdiction of OIG. It coordinates False Claims Act matters involving HHS programs and resolves voluntary disclosure cases. OCIG develops guidance to assist providers in establishing compliance programs; monitors ongoing compliance of providers subject to integrity agreements; and promotes industry awareness through advisory opinions, fraud alerts, and special advisory bulletins.

Section QG.10, Office of Counsel to the Inspector General—Organization

The office is directed by the Chief Counsel to the Inspector General and aided by Assistant Inspectors General. The office carries out its responsibilities through headquarters functions.

Section QG.20, Office of Counsel to the Inspector General—Functions

The office provides legal advice to OIG on issues that arise in the exercise of OIG's responsibilities under the Inspector General Act of 1978. Such issues include the scope and exercise of the Inspector General's authorities and responsibilities; investigative techniques and procedures (including criminal procedure); the sufficiency and impact of legislative proposals affecting OIG and HHS; and the conduct and resolution of investigations, audits and inspections. The office evaluates the legal sufficiency of OIG findings and recommendations and develops formal legal opinions to support these findings and recommendations. The office provides legal advice on OIG internal administration and operations, including appropriations, delegations of authority, OIG regulations, personnel matters, the disclosure of information under the Freedom of Information Act,

and the safeguarding of information under the Privacy Act and serves as OIG's Deputy Ethics Officer. The office is responsible for the clearance and enforcement of subpoenas issued by OIG.

The office represents OIG in administrative litigation and related appeals. This includes representing OIG in personnel and Equal Employment Opportunity matters; and coordinating OIG's representation in Federal tort actions involving OIG employees.

The office also determines whether to propose or implement administrative sanctions, including CMPs and assessments within the jurisdiction of OIG. The office litigates and resolves all appealed or contested exclusions from participation in Federal health care programs under the Social Security Act. In coordination with DOJ, the office represents HHS in all False Claims Act cases, including qui tam cases, and is responsible for final approval of civil False Claims Act settlements for the Department, including the resolution of the program exclusion authorities that have been delegated to OIG.

The office, in conjunction with the Office of Investigations, coordinates resolution of all voluntary and mandatory disclosure under the OIG Provider Self-Disclosure Protocol, the contractor self-disclosure requirement and otherwise. The office develops and monitors corporate and individual integrity agreements adopted in connection with settlement agreements, conducts on-site reviews, and develops audit and investigative review standards for monitoring such integrity agreements in cooperation with other OIG components. The office resolves breaches of integrity agreements through the development of corrective action plans and through the imposition of sanctions.

Finally, the office issues advisory opinions to the health care industry and members of the public on whether a current or proposed activity would constitute grounds for the imposition of a sanction under the anti-kickback statute, the CMP law or the program exclusion authorities. The office develops procedures for submitting and processing requests for advisory opinions and for determining the fees that will be imposed. The office solicits and responds to proposals for new regulatory safe harbors to the anti-kickback statute, modifications to existing safe harbors, and new fraud alerts. The office consults with DOJ on proposed advisory opinions and safe harbors before issuance or publication. The office provides legal advice to the components of OIG, other HHS offices

and DOJ concerning matters involving the interpretation of the anti-kickback statute and other legal authorities, and assists those components or offices in analyzing the applicability of the anti-kickback statute to particular practices or activities under review.

Section QH.00, Office of Audit Services—Mission

The Office of Audit Services (OAS) is responsible for protecting the integrity of HHS operations and programs by conducting audits that identify and report ways to improve the economy, efficiency, and effectiveness of operations and services to beneficiaries of HHS programs, and help reduce fraud, waste, abuse, and mismanagement. OAS conducts audits and oversees audit work performed by others. It conducts its work in accordance with Government Auditing Standards and follows applicable legal, regulatory, and administrative requirements.

Section QH.10, Office of Audit Services—Organization

The office is directed by the Deputy Inspector General for Audit Services who, aided by Assistant Inspectors General, performs the functions designated in Section 3(d)(1)A of the Inspector General Act) for the position of Assistant Inspector General for Auditing. The office is comprised of headquarters and regional functions and also includes a designated Whistleblower Protection Ombudsman, and the functions thereof, as required by law (section 3(d)(1)C of the Inspector General Act).

Section QH.20, Office of Audit Services—Functions

OAS establishes audit priorities; performs audits; oversees the progress of audits; coordinates on bodies of work with stakeholders; recommends changes in program policies, regulations, and legislation to prevent fraud, waste, and abuse and improve programs and operations; and reports on the impact of audit work. The office develops audit policies, procedures, techniques, and guidelines to be followed by all OAS staff in conducting audits. OAS maintains an internal quality assurance program, conducts peer reviews of other OIGs and maintains automated data and management information systems used by all OAS employees. The office also provides oversight for audits of state and local governments, universities, and nonprofit organizations conducted by non-Federal auditors. The office provides education to agency employees about prohibitions on retaliation, and

the rights and remedies against retaliation, for protected disclosures, as required of the Whistleblower Protection Ombudsman.

Section QJ.00, Office of Investigations—Mission

The Office of Investigations (OI) is granted full statutory law enforcement authority under the Homeland Security Act of 2003 (Pub. L. 107–296). OI is responsible for protecting the integrity of the programs administered and/or funded by HHS by conducting criminal, civil and administrative investigations of fraud and misconduct related to HHS programs, operations and employees. The office serves as OIG's liaison to the DOJ on all matters relating to investigations of HHS programs and personnel, and reports to the Attorney General when there are reasonable grounds to believe Federal criminal law has been violated. OI serves as a liaison to the CMS, State licensing boards, and other outside organizations and entities with regard to exclusion, compliance, and enforcement activities.

Section QJ.10, Office of Investigations—Organization

The office is directed by the Deputy Inspector General for Investigations, aided by Assistant Inspectors General, and performs the functions designated in the law (section 3(d)(1)B of the Inspector General Act) for the position of Assistant Inspector General for Investigations. The office is comprised of headquarters and regional functions.

Section QJ.20, Office of Investigations—Functions

OI conducts criminal, civil, and administrative investigations of allegations of fraud, waste, abuse, mismanagement, and violations of standards of conduct within the jurisdiction of OIG. OI establishes investigative priorities, evaluates the progress of investigations, and reports findings to the Inspector General. The office develops and implements investigative techniques, programs, guidelines, and policies; manages OI's quality assurance/peer review program and conducts peer reviews of other OIGs. OI also carries out and maintains an internal quality assurance system. The system includes quality assessment studies and quality control reviews of OI processes and products to ensure that policies and procedures are followed effectively, and are functioning as intended. The office effectuates mandatory and permissive exclusions from participation in Federal health care programs under the Social Security Act; decides on all requests for reinstatement

from, or waiver of, exclusions; and participates in developing standards governing the imposition of these exclusion authorities. The office also oversees OIG's suspension and debarment referral program. OI implements policies and procedures and plans, develops, implements and evaluates all levels of training for OI employees. The staff provides for the personal protection of the Secretary and other Department officials, as needed, and all emergency operations preparedness and response. OI coordinates the adoption of advanced digital forensic acquisition and examination and information security technologies to assist in the investigation, prevention and detection of fraud and abuse; maintains an automated data and management information system used by all OI employees; provides technical expertise on computer applications for investigations; and coordinates and approves investigative computer matches with other agencies.

In addition, the office operates a toll-free hotline to permit individuals to report suspected fraud, waste and abuse within HHS programs.

Dated: March 9, 2016.

Daniel R. Levinson,
Inspector General.

[FR Doc. 2016-05714 Filed 3-14-16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel Cell Biology Topics.

Date: March 31, 2016.

Time: 1:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Elena Smirnova, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5187, MSC 7840, Bethesda, MD 20892, 301-435-1236, smirnov@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel PAR Panel: Translational Research in Pediatric and Obstetric Pharmacology and Therapeutics.

Date: April 6, 2016.

Time: 11:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Elaine Sierra-Rivera, Ph.D., Scientific Review Officer, EMNR IRG, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6182 MSC 7892, Bethesda, MD 20892, 301-435-2514, riverase@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Member Conflict: Child Psychopathology, Emotion, Learning and Memory.

Date: April 6, 2016.

Time: 1:30 p.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Biao Tian, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3089B, MSC 7848, Bethesda, MD 20892, (301) 402-4411, tianbi@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Member Conflict: Endocrinology and Reproduction.

Date: April 6, 2016.

Time: 12:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Michael Knecht, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6176, MSC 7892, Bethesda, MD 20892, (301) 435-1046, knechtm@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Urologic and Urogynecologic Small Business Applications.

Date: April 7-8, 2016.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Ryan G. Morris, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of

Health, 6701 Rockledge Drive, Room 4205, MSC 7814, Bethesda, MD 20892, 301-435-1501, morrisr@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel, PAR15-360 Mycobacterial Induced Immunity in HIV-Infected and Uninfected Individuals.

Date: April 7, 2016.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Jingsheng Tuo, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5207, Bethesda, MD 20892, 301-451-8754, tuo@nei.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Member Conflict: Biological Chemistry and Macromolecular Biophysics.

Date: April 7, 2016.

Time: 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Michael Eissenstat, Ph.D., Scientific Review Officer, BCMB IRG, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4166, Bethesda, MD 20892, 301-435-1722, eissenstatm@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Topics in Virology.

Date: April 7, 2016.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Marci Scidmore, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3192, MSC 7808, Bethesda, MD 20892, 301-435-1149, marci.scidmore@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Fellowship: Infectious Diseases and Microbiology.

Date: April 7, 2016.

Time: 1:00 p.m. to 2:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Neerja Kaushik-Basu, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3198, MSC 7808, Bethesda, MD 20892, (301) 435-2306, kaushikbasun@csr.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)