

FDA STAFF MANUAL GUIDES, VOLUME III - GENERAL ADMINISTRATION

FDA OFFICIAL COUNCILS AND COMMITTEES

FDA PRIVACY COUNCIL

Effective Date: September 16, 2015

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1. PURPOSE

The purpose of this Staff Manual Guide (SMG) is to provide an overview of the Food and Drug Administration's (FDA) Privacy Council.

2. REFERENCES

- Privacy Act of 1974, 5 U.S.C. 552a
- National Institute of Standards and Technology (NIST) Special Publication 800-53 rev 4, Appendix J (privacy controls) (April 2013)
- OMB M-14-04, Fiscal Year 2013 Reporting Instructions for the Federal Information Security Management Act and Agency Privacy Management
- OMB M-06-19, Reporting Incidents Involving Personally Identifiable Information and Incorporating the Cost for Security in Agency Information Technology Investments
- OMB M-06-15, Safeguarding Personally Identifiable Information
- HHS Privacy Incident Response Team (PIRT) Standard Operating Procedures (January 27, 2012)
- HHS-OCIO Policy for Information Systems Security and Privacy (as updated and issued in July 2014)

3. POLICY

A. Mission of the Privacy Council

The Privacy Council is established by the FDA's Senior Official for Privacy (SOP) with the support of the Agency's senior leadership. Council members will consist of individuals and organizations responsible for implementing federal privacy requirements and related HHS and FDA policies and procedures. The Council, with representatives from Agency Offices and Centers, will support the activities of the SOP, provide input to the SOP, and help to provide direction and strategy for the future implementation of privacy best practices and compliance driven activities within FDA.

B. Council Activities

Privacy Council members will be senior managers with responsibilities for establishing and implementing policies in various Centers and offices or their designees. Privacy Council members may delegate roles and responsibilities within their organizations.

Periodic meetings and/or teleconferences will be held at the discretion of the SOP.

The Privacy Council will:

- Leverage organizational expertise and authority to address privacy requirements and issues across FDA;
- Serve as a method to keep Council members apprised of privacy events and activities, new programs, and relevant legislative proposals;
- Support consistency and the uniform application of privacy policies and practices FDA-wide;
- Support consistent privacy incident reporting and effective Agency responses to incidents; and;
- Support publication and reporting requirements that are agency-wide in scope (e.g., Federal Information Security Management Act (FISMA) privacy reports, Systems of Records Notices (SORNs)), and
- Support SOP efforts to provide specialized or role-based training.

4. RESPONSIBILITIES

The following sets out the general roles and responsibilities for Agency personnel with regard to the Privacy Council. These roles and responsibilities are largely drawn from and intended to align with HHS policy.

A. FDA Senior Official for Privacy (SOP)

1. Chairs the Privacy Council;
2. Arranges and conducts meetings;
3. Advises the Privacy Council of privacy incidents and breaches and invokes Membership support and action to resolve such events;
4. Proposes or establishes working groups.

The staff of the SOP will:

1. Develop meeting agendas; receive agenda/topic requests and suggestions from Privacy Council members and representatives;
2. Coordinate meetings and/or teleconferences;
3. Provide meeting materials to Privacy Council members; and
4. Provide training to members, as needed.

B. Chief Information Security Officer (CISO, Information Security Services)

1. Attends Privacy Council meetings and contributes in a leadership capacity;
2. Designates staff to attend Privacy Council meetings on behalf of the CISO as needed; and
3. Informs member offices, distributes materials, and generally ensures Privacy Council awareness of security plans, policies, procedures, events and initiatives that relate to privacy activities.

C. Privacy Council Membership (Center/Office Representatives)

1. Attend meetings;
2. Maintain awareness, knowledge and expertise regarding privacy issues, policies, programs and procedures in support of federal, HHS and FDA privacy concerns;

3. Provide input to the Senior Official for Privacy (SOP) regarding FDA privacy policies, procedures and activities;
4. Review and support implementation of privacy directives, policies and procedures at FDA, including actions taken in response to privacy incidents and breaches;
5. Participate in and/or cooperates with privacy and security working groups for the formulation of privacy and security policies, procedures, publications and resource materials;
6. Serve as Center/Office Liaison and accountable management for privacy matters within their Center/Organization;
7. Delegate roles within their Center/Office to ensure efficiency and effectiveness of actions; and
8. Promote a culture of privacy across FDA by assisting the SOP in identifying organizational training needs; providing targeted personally identifiable information (PII) handler training; and scheduling, advertising, and coordinating local administrative support for same.

5. EFFECTIVE DATE

The effective date of this guide is September 16, 2015.

6. Document History - SMG 2010.15, FDA Privacy Council

STATUS (I, R, C)	DATE APPROVED	LOCATION OF CHANGE HISTORY	CONTACT	APPROVING OFFICIAL
Initial	09/16/2015	N/a	OC/OES/ DFOI/Privacy	Sarah Kotler, Director, DFOI