

FDA STAFF MANUAL GUIDES, VOLUME III - GENERAL ADMINISTRATION

FDA OFFICIAL COUNCILS AND COMMITTEES

FDA PRIVACY COUNCIL

Effective Date: 09/16/2015
Certified as Current: 05/29/2025

1. Purpose
2. References
3. Policy
4. Responsibilities
5. Effective Date
6. History

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 5, Security and Privacy Controls for Information Systems and Organizations (September 2020)
- OMB M-24-04, Fiscal Year 2024 Guidance on Federal Information Security and Privacy Management Requirements
- OMB M-17-12, Preparing for and Responding to a Breach of Personally Identifiable Information
- HHS Policy for Preparing for and Responding to a Breach of PII (May 2020)
- SMG 3251.12 Information Security and Privacy Protection Policy (6/14/2024)

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 employed by FDA and 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/breach reporting and effective Agency responses to same;
- 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 annual and 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 if necessary invokes membership support and appropriate 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 laws and regulations;

3. Provide input to the Senior Official for Privacy (SOP) regarding FDA privacy policies, procedures and activities;
4. 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 role-based personally identifiable information (PII) training; and scheduling, advertising, and coordinating local administrative support.

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
Reissuance	05/22/2025	Throughout SMG	OC/OO/OMES/ODIG A/DIG/Privacy Branch	Cullen Cowley, Senior Official for Privacy (SOP) and Privacy Act Officer