SMG 3297.9

FDA Staff Manual Guides, Volume III - General Administration

Information Resources Management - Privacy Program

Policy for Implementation of the Privacy Act and the FDA Privacy Program:

Accounting for Disclosures (Privacy Act)

Effective Date: September 16, 2015
Changed: May 2, 2023

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

Appendix A (References and Authorities)

1. Purpose

The purpose of this Staff Manual Guide (SMG) is to provide an overview of the policies and procedures that govern the Agency's satisfaction of the requirement to document certain disclosures of Privacy Act records.

2. References

- Privacy Act of 1974, 5 U.S.C. 552a
- FDA Regulations for the Protection of Privacy, 21 CFR Part 21
- HHS-OCIO Policy for Information Systems Security and Privacy (July 2014)

3. Background

The Privacy Act (5 U.S.C. 552a(c)) and related FDA regulations (21 CFR 21.71) require that the Agency maintain an accounting - essentially a log - of certain types of disclosures of records from a Privacy Act system of records. A Privacy Act "system of records" is a group of records under control of the Agency from which information is retrieved by the name of an individual or by some identifying number, symbol, or other identifying characteristic assigned to the individual (5 U.S.C. 552a(a)(5)). A system of records may extend across multiple physical and technical

locations, e.g., databases maintained by numerous offices or operated by a contractor on behalf of the FDA.

The Privacy Act authorizes disclosure of a record held in a system of records under certain conditions without prior written consent of the individual, sometimes known as a "non-consent disclosure." Unless such a disclosure is made to HHS personnel who have a need for the record in the performance of their duties, or, is required by the Freedom of Information Act (5 U.S.C. 552), the Agency is required to create and maintain an accounting of the disclosure (see 5 U.S.C. 552a(c)). Absent an exemption or other basis to deny access[1], the Act also requires the Agency to provide the subject individual access to the accounting (see 5 U.S.C. 552a(d)).

An accounting of disclosures allows individuals to learn to whom the FDA has disclosed records about them from an FDA system of records. It also provides a basis for advising prior and future recipients of records of any corrected or disputed record content, and to provide an audit chain for subsequent review of Food and Drug Administration (FDA) compliance with conditions of disclosure.

4. Policy

This SMG sets forth the policy for FDA to maintain an accounting concerning the disclosure of information contained in a Privacy Act System of Records. The Privacy Act requires agencies to maintain a record of the date, nature, and purpose of certain disclosures of records subject to the Privacy Act, i.e., records maintained in an FDA System of Records (5 U.S.C. 552a(c)). The accounting log must also record the name and address of the individual or agency to which the disclosure was made (id.). The Act requires agencies to maintain this log for five years, or the life of the record, whichever is longer (id.). System Owners[2] or others assigned with this responsibility will make this accounting available to the Office of the Senior Official for Privacy (SOP) upon request.

A. Assessing the Need to Maintain an Accounting of Disclosures

The table below summarizes when disclosure is authorized and when a record must be kept describing (that is, accounting for) the disclosure. However, the list of disclosures that will constitute "routine uses" will be different for different Systems of Records. For any specific system, the relevant system of records notice (SORN) will contain the definitive list of acceptable routine use disclosures for that system.

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[1] For example, the Agency may deny individuals access to law enforcement records and information compiled in reasonable anticipation of a civil action or proceeding. 5 U.S.C. 552a(j) and (k); 552a(d)(5). See other portions of this Guide for additional information about exemptions.

[2] "System Owner" refers to the official responsible for the overall procurement, development, integration, modification, or operation and maintenance of an information system. HHS-OCIO Policy for Information Systems Security and Privacy (July 2014), referencing National Institute for Standards and Technology (NIST) Special Publication (SP) 800-37, Guide for Applying the Risk Management Framework to Federal Information Systems: A Security Life Cycle Approach.

Disclosures of records after the removal of potential identifying content are not subject to the accounting requirement. Agency regulations provide that records held in a system of records may be disclosed to any person, without the consent of the subject individual, where the names and other identifying information are first deleted, and under circumstances in which the recipient is is unlikely to know the identity of the subject of the record. 21 CFR 21.70(a)(3). Any such disclosure must be carefully considered; the likelihood of identifying the subject individual will vary in each instance. Consult the Senior Official for Privacy for guidance.

Table for Disclosure of Records in Privacy Act Records Systems to Persons Other than the Subject Individual:

Conditions and/or Use for Disclosure of Records	**Accounting Required?**
1. Disclosure based on "Need to Know" Records may be disclosed to HHS or FDA officers or employees who have a need for the record in the performance of their duties in connection with the laws administered and enforced by the FDA or that govern the Agency. This exception authorizes the intra-Agency disclosure of a record for necessary, official purposes. 5 U.S.C. 522a(b)(1); 21 CFR 21.70(a)(4) and 21.71(a)(1) NOTE: Movement of records between personnel of different agencies (i.e., between agencies inside and outside of HHS) may in some instances be viewed as intra-Agency disclosures if that movement is in connection with an inter-agency support agreement, e.g., payroll records compiled in FDA transferred to another agency providing payroll services to the FDA. Office of Management and Budget's Privacy Act Implementation Guidelines, 40 Fed. Reg. 28,948 at 28,954 (July 9, 1975).	No accounting per 5 U.S.C. 552a(c)(1)

Conditions and/or Use for Disclosure of Records	**Accounting Required?**
2. Disclosure under the Freedom of Information Act (FOIA) The Privacy Act provides no authority to withhold information that must be released under the FOIA. FOIA requires the release of records and information unless one of the nine exemptions in the FOIA can be properly claimed as a basis for denying release. Unless a FOIA exemption applies, the requested information generally must be disclosed to any person under FDA's regulations at 21 CFR Part 20 after the names and other identifying information are first deleted, and under circumstances where the recipient is unlikely to know the identity of the subject of the record. 5 U.S.C. 522a(b)(2); 21 CFR 21.71(a)(2)	No accounting per 5 U.S.C. 522a (c)(1)
3. Disclosure for a "Routine Use" Records may be disclosed for a "routine use" if that routine use has been established and described in the Privacy Act System of Records Notice (SORN) published in the Federal Register. The list of disclosures that will constitute "routine uses" will be different for different Systems of Records. For any specific system, the relevant SORN will contain the definitive list of acceptable routine use disclosures for that system. 5 U.S.C. 522a(b)(3); 21 CFR 21.71(a)(3)	Yes
4. Disclosure to the Census Bureau Records may be disclosed to the Census Bureau pursuant to Title 13, for purposes of planning or carrying out a census or survey or related activity. 5 U.S.C. 522a(b)(4);21 CFR 21.71(a)(4)	Yes

Conditions and/or Use for Disclosure of Records	Accounting Required?
5. Disclosure for Statistical Research or Reporting Purposes Records may be disclosed to any person who has provided FDA with advance adequate written assurance that the record will be used solely for statistical research or reporting. The information disclosed or transferred must be stripped of individual identifiers. Agencies must ensure that the identity of the individual cannot reasonably be deduced either by combining various statistical records or by reference to public records or other available sources of information. Agencies are required to ensure that information disclosed for use as a statistical research or reporting record cannot reasonably be used in any way to make determinations about individuals. 5 U.S.C. 522a(b)(5); 21 CFR 21.71(a)(5)	Yes
6. Disclosure to the National Archives and Records Administration (NARA) Records may be transferred to NARA for preservation, and also disclosed to the NARA Archivist or his designee to permit a determination as to whether preservation is warranted. 5 U.S.C. 522a(b)(6); 21 CFR 21.71(a)(6)	Yes
7. Disclosure for Law Enforcement Purposes Records may be disclosed to an Agency or instrumentality of any government jurisdiction within or under the control of the United States for a civil or criminal law enforcement activity if the activity is authorized by law and the head of the Agency or instrumentality makes a written request to FDA or HHS specifying the particular portion of the record desired and the law enforcement activity for which the record is sought. 5 U.S.C. 522a(b)(7); 21 CFR 21.71(a)(7) A record may also be disclosed to a law enforcement Agency at the initiative of FDA when a violation of law is suspected, provided that such disclosure has been established in advance as a “routine use” within the relevant SORN. 5 U.S.C. 552a(b)(3); 21 CFR 21.71(a)(3)	Yes

Conditions and/or Use for Disclosure of Records	Accounting Required?
8. Disclosure under Emergency Health or Safety Circumstances Records may be disclosed to a person pursuant to a showing of compelling circumstances affecting the health or safety of an individual. FDA may disclose records when the time required to obtain consent of the individual to whom the records pertain might result in a delay which could impair the health or safety of an individual; as in the release of medical records on a patient undergoing emergency treatment. The individual whose records are disclosed need not necessarily be the individual whose health or safety is in peril. 5 U.S.C. 522a(b)(8); 21 CFR 21.71(a)(8)	Yes
9. Disclosure to Congress Records may be disclosed to the House or Senate, or any committee or subcommittee, joint committee, or joint subcommittee of Congress when the records relate to matters within its jurisdiction. Disclosure of a record is not authorized to a member of Congress acting in their individual capacities without the consent of the individual to whom the record pertains. 5 U.S.C. 522a(b)(9) and 21.71(a)(9)	Yes
10. Disclosure to the General Accountability Office Records may be disclosed to the Comptroller General, or any of his authorized representatives in the course of the performance of the duties of the General Accountability Office. 5 U.S.C. 522a(b)(10) and 21.71(a)(10)	Yes
11. Disclosure to a Court Records may be disclosed pursuant to a court order from a court of competent jurisdiction. 5 U.S.C. 522a(b)(11); 21 CFR 21.71(a)(11)	Yes

Conditions and/or Use for Disclosure of Records	Accounting Required?
12. Disclosure to a Consumer Reporting Agency *Records may be disclosed to a consumer reporting agency in accordance with section 3711(e) of Title 31.* *5 U.S.C. 522a(b)(12); 21 CFR 21.71(a)(12)*	Yes

B. Documenting Accountings of Disclosures

The following chart would be an acceptable log of accountings of disclosures. It contains all the data elements required by the Privacy Act (5 U.S.C. § 552a(c), Accounting of Certain Disclosures) and FDA regulations (21 CFR 21.71, Disclosure of records in Privacy Act Record Systems; accounting required). Any other format that contains these data elements in a clear and complete fashion would also be acceptable.

Table for Privacy Act Accounting:

Date	Disclosed To	Records Disclosed	Purpose	Disclosed By	Comment
1/12/14	AUSA John Doe 222 Main St. City, State, zip	XXX documents for Dr. Jones; Generic Medical Center, 11/xx/xx-1/xx/xx (90 pages)	21 CFR 21.71 (a)(11): For further production to private litigants in lawsuit against the United States. Production is made pursuant to a court order.	Office of Resource Management; POC: H. Smith; disclosed through Judy Doe, OGC	

5. Responsibilities

The following sets out the general roles and responsibilities for Agency personnel with regard to Accounting for Disclosures. These roles and responsibilities are largely drawn from and intended to align with HHS policy[3] and the requirements of the Privacy Act and FDA's regulations at 21 CFR 21.

A. System Owner (for a Privacy Act system of records)

- Either:

[3] HHS-OCIO Policy for Information Systems Security and Privacy (July 2014)

- Create and maintain a log of applicable disclosures made from a Privacy Act System of Records, as described in the table above, or

- Ensure a log of applicable disclosures is being maintained by an authorized agency component (for example, Regulatory Counsel associated with the system or organization, a Center's FOIA/Privacy component, or a System Owner's designee).

- Provide a copy of the log of disclosures to DFOI/Privacy periodically or upon request of the SOP.

- In coordination with the staff of the Senior Official for Privacy, respond to requests for notification or access to disclosure accounting logs.

- Work with the staff of the Senior Official for Privacy to satisfy requirements to notify disclosure recipients of subsequent amendments or disputes of record accuracy, relevance, timeliness or completeness as described in the Privacy Act (5 U.S.C. 552a(d)) and FDA regulations (21 CFR 21.50-.54).

B. Privacy Act Coordinator and other Staff of the Senior Official for Privacy

- Support FDA-wide implementation of Privacy Act policies and procedures at the direction of the Senior Official for Privacy (SOP).

- Serve as Privacy Act subject matter experts and points of contact for FDA personnel.

- Coordinate Privacy Act compliance activities, including:

    - Periodic review of Privacy Act disclosure accounting logs;

    - Respond to requests by subject individuals for amendment of records pertaining to them (see 5 U.S.C. 552a(d)(2)).

    - Notification of previous record recipients identified in the disclosure accounting logs when the Agency has granted a request to amend a disclosed record in response to the subject individual's request for amendment;

    - The marking of disputed portions of a record in instances where the subject individual requested amendment of the record and the Agency denied the request, and notification of previous record recipients regarding the disputed information (see 5 U.S.C. 552a(c)(4), (d)(4)); and

- Processing requests made under the Privacy Act for notification of or access to disclosure accounting logs.

C. Senior Official for Privacy

- Administer FDA's Privacy Act program.
- Disseminate Privacy Act guidance within FDA and provide FDA permanent and contract employees with appropriate training and education regarding information privacy laws, regulations, policies, and procedures.
- Respond to questions from system owners and program management regarding the need to maintain an accounting.
- Consult Center and Office privacy contacts as needed and make final determinations on the accounting requirement for specific systems of records.
- Provide programmatic direction, aligning FDA's Privacy program with that recommended by the Department.

6. Effective Date.

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

7. Document History - SMG 3297.9, "Accounting for Disclosures (Privacy Act)"

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
Change	04/26/2023	Title; Appendix A	OEMS/DIG/Privacy	Tiffany Branch, Director, OEMS

Appendix A

References and Authorities

Statutes

- Privacy Act of 1974, as amended, 5 U.S.C. 552a

Regulations

- HHS Privacy Act Regulations, 45 CFR Part 5b
- FDA Public Information and Privacy Act Regulations, 21 CFR Parts 20 and 21

Other

- OMB Circular A-108, Federal Agency Responsibilities for Review, Reporting, and Publication Under the Privacy Act (2016)