

Paperwork Reduction Act and Privacy

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Office of Operations

Office of Enterprise Management Services

Division of Information Governance



True or False?

The PRA is about Paper



FALSE

The PRA is about paperwork.

The PRA “is a law governing how federal agencies collect information from the American public.” ~digital.gov



Information Resource Management

Federal agencies play a critical role in collecting and managing information in order to promote openness, reduce burdens on the public, increase program efficiency and effectiveness, and improve the integrity, quality, and utility of information to all users within and outside the government.



What Else Does it Do?

It provides public protection...

44 USC 3512; 1320.6 Public protection:

(a) Notwithstanding any other provision of law, no person shall be subject to any penalty for failing to comply with a collection of information that is subject to the requirements of this part if:

- (1) The collection of information does not **display**, in accordance with [§ 1320.3\(f\)](#) and [§ 1320.5\(b\)\(1\)](#), a currently valid OMB control number assigned by the Director in accordance with the Act; or
- (2) The agency fails to **inform** the potential person who is to respond to the collection of information, in accordance with [§ 1320.5\(b\)\(2\)](#), that such person is not required to respond to the collection of information unless it displays a currently valid OMB control number.



Federal Food, Drug, & Cosmetic Act

21 U.S.C. 301 et seq.

Education

Research

Grants and awards – including BAAs

Paperwork Reduction Act

44 U.S.C. 3501 et seq.

Coordination of Federal information resource policies to ensure that the creation, collection, maintenance, use, dissemination, and disposition of information by or for the Federal Government is consistent with applicable laws, including laws relating to-

- (A) privacy and confidentiality, including section 552a of title 5;
- (B) security of information, including section 11332 of title 40 ¹; and
- (C) access to information, including section 552 of title 5;

*Nothing in any provision of the FFDCA shall be construed as authority to override the applicability of existing laws and statutes, including the PRA.

The Privacy Act of 1974

- 5 U.S.C. 552
- Privacy requirements can impact contracts, the ICR supporting statement, the design of paper and electronic forms, and involve special Federal Register publications and other lengthy processes.

Protection of Human Subjects

- 45 CFR 46; 21 CFR 50
- Compliance intended to protect the rights and safety of subjects pursuant to the Federal Food, Drug, and Cosmetic Act and sections 351 and 354-360F of the Public Health Service Act.

*Nothing in any provision of the FFDCA shall be construed as authority to override the applicability of existing laws and statutes, including the PRA.



Who Administers the PRA

Office of Management and Budget

OMB reviews agency information collection requests. FDA must receive OMB approval before collecting information. OMB has issued regulations and guidance to promote agency compliance with the PRA as well as policies and procedures to obtain approval for information collection. FDA also has internal processes to follow.



Before collecting information from the public, the PRA requires federal agencies to obtain OMB approval under the PRA. Therefore:

1. Determine whether there is approval for collection within existing inventory.
2. If not, determine whether exemption or flexibility may apply – plan accordingly.
3. If not, seek public comment on proposed collections (via publication in the *Federal Register*).
4. Submit proposed collections for review and approval by OMB.



Exemptions from OMB review and approval under the PRA

v.

Flexibilities under the PRA

Exemptions are limited; for example:

Facts or opinions obtained initially or in follow-on requests, from individuals (including individuals in control groups) under treatment or clinical examination in connection with research on or prophylaxis to prevent a clinical disorder, direct treatment of that disorder, or the interpretation of biological analyses of body fluids, tissues, or other specimens, or the identification or classification of such specimens.

Be mindful that the PRA Implementing Guidance states:

This category is limited to the collection of information with respect to medical research and treatment, and is limited to collections of information by or on behalf of bona fide medical and scientific personnel. This category does not include more general monitoring of health conditions through reports and electronic or other technological methods. Nor does this category include disclosures that medical personnel make to patients or other third-parties or members of the public outside of a clinical examination or treatment setting.



Generic clearance is best when you'll have multiple collections which:

- Request similar information,
- Have a low burden estimate,
- Don't raise substantive or policy issues, and
- Have details that won't be known until shortly before you collect data.

Generic IC not ideal when information collection is:

- Is “influential” or intended for broad dissemination
- Is needed for significant decisions, rulemaking, or Congressional testimony
- Is high burden
- Involves statistical sampling or tests, or other complex research or pre-/post evaluation designs
- Occurs on a regular or foreseeable, repeating schedule (e.g., routine monitoring or trend analysis)
- Is mandatory or required to receive a benefit



True or False?

The PRA does not apply if an information collection is voluntary.



FALSE

The PRA applies to any information collection conducted or sponsored by a Federal agency.



FALSE

The PRA applies to any information collection conducted or sponsored by a Federal agency regardless of form or format (on paper such as a form, orally in person or by telephone, via Internet), mandatory or voluntary (mandatory = regulation; voluntary = surveys, guidance, customer service evaluations, focus groups).

What is included in an Information Collection Request

The information collection request (ICR): package of documents submitted through HHS to OMB representing agency's discussion of the need for the information and representations of what is disseminated and collected from the public – the information exchange. This is what OMB reviews to grant approval of the information collection and the scope of collection is determined by supporting documentation.

Resources:

- <https://pra.digital.gov/additional-resources/> OMB's "A Guide to the Paperwork Reduction Act includes a complete collection of:
 - OMB Review criteria
 - Flexibilities memoranda
 - Q & A for Designing Surveys for Information Collection
- www.RegInfo.gov
- ICR Search capacity
- [Additional resources:](#)
- <https://www.usa.gov/statistics>
- Information Quality Act: Section 515 of the Treasury and General Government Appropriations Act for Fiscal Year 2001 (Public Law 106554)
- Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies
- Final Information Quality Bulletin for Peer Review
- Information Collection Budget Report



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