# NIH Policy Manual

## 1825 - Information Collection From The Public

**Issuing Office:** OD/OER/OPERA **Phone:** (301) 435-0949

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Transmittal Notice

1. **Explanation of Material Transmitted:** This revised chapter contains an updated description of Information Collection from the Public and outlines NIH's policies for the Office of Management and Budget (OMB) clearance requirements. The Chapter has been further revised to include modified requirements for implementing the 21st Century Cures Act (CCA) research exemptions within Section D, below, along with the need to update changes to NIH processes related to the definition of research and the removal of the Human Subjects Research and Clinical Exemptions section.
2. **Filing Instructions:**
   **Remove:** NIH Manual Chapter 1825 dated 12/10/2009
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- Content of this chapter, contact the issuing office listed above;
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### A. Purpose

This chapter sets forth NIH policies and procedures governing the collection of information from the public pursuant to 44 U.S.C. Chapter 35, the Paperwork Reduction Act of 1995 (PRA) as amended, and its implementing regulations (5 CFR Part 1320). This law generally provides that a Federal agency shall not collect or sponsor a collection of information on identical items from 10 or more public respondents without: (1) seeking public comment on the proposed collection, (2) obtaining approval from the Office of Management and Budget (OMB) for the data collection plans and instruments and for the information requirements in regulations; and (3) displaying a currently valid OMB control number and expiration date.

### B. Scope

This Manual Chapter is applicable to all NIH Institutes, Centers, and Offices (ICOs).

## C. Background

The Paperwork Reduction Act of 1995, among other things, provides that a Federal agency generally shall not collect or sponsor a collection of information on identical items from 10 or more public respondents without: (1) seeking public comment on the proposed collection, (2) obtaining approval from the Office of Management and Budget (OMB) for the data collection plans and instruments and for the information requirements in regulations; and (3) displaying a currently valid OMB control number and expiration date. Exceptions to these requirements exist. For example, Section 2035 of the 21st Century Cures Act, enacted December 13, 2016 (P.L. 114-255), amended Section 301 of the Public Health Service Act (42 U.S.C. § 241) by adding: "(g) The PRA shall not apply to the voluntary collection of information during the conduct of research by the National Institutes of Health.'" This exception along with others are described in this manual chapter.

## D. Definitions

For the purposes of this chapter, the following definitions apply:

1. **Research**
   A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.
2. **Burden (5 CFR 1320.3(b)(1))**
   Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a federal agency, including:

   a. reviewing instructions
   b. developing, acquiring, installing, and utilizing technology and systems for the purpose of collecting, validating, and verifying information
   c. developing, acquiring, installing, and utilizing technology and systems for the purpose of disclosing and providing information
   d. adjusting the existing ways to comply with any previously applicable instructions and requirements
   e. training personnel to be able to respond to a collection of information
   f. searching data sources
   g. completing and reviewing the collection of information
   h. transmitting or otherwise disclosing the information

3. **Information (5 CFR 1320.3(h))**
   Any statement of estimate of fact or opinion, regardless of form or format, whether in numerical, graphic, or narrative form, and whether oral or maintained on paper, electronic or other media.
4. **Conduct or Sponsor (5 CFR 1320.3(c))**
   A Federal agency is considered to "conduct or sponsor" a collection of information if the agency collects the information, causes another agency to collect the information,

contracts or enters into a cooperative agreement with a person to collect the information, or requires a person to provide information to another person, or in similar ways causes another agency, contractor, partner in a cooperative agreement, or person to obtain, solicit, or require the disclosure to third parties or the public of information by or for an agency.

5. **Collection of information** **(5 CFR 1320.3(c))**
   Collection of information means the obtaining, causing to be obtained, soliciting, or requiring the disclosure to an agency, third parties or the public of information by or for an agency by means of identical questions posed to, or identical reporting, recordkeeping, or disclosure requirements imposed on ten (10) or more persons, whether such collection of information is mandatory, voluntary, or required to obtain or retain a benefit. The term includes questions posed to agencies, instrumentalities, or employees of the United States, if the results are to be used for general statistical purposes. However, the definition excludes targeted investigations and audits.
6. **Information Collection Budget**
   Information Collection Budget is a management tool used by OMB and agency officials to measure and control the costs and burden of Federal information collections.
7. **Person** **(5 CFR 1320.3(k))**
   Person means, for the purposes of the control of paperwork burdens on the public, an individual, partnership, association, corporation (including government owned but contractor operated facilities), business trust, legal representative, organized group of individuals, State, territory, or local government or component thereof. The term excludes current employees of the Federal government for purposes of obtaining information about and within the scope of their employment.

## E. Policy

Compliance with the PRA is required before conducting or sponsoring a collection of information. Compliance with the PRA requires that that the ICO conducting or sponsoring a collection of information either (1) obtain an OMB approval number and include that number on the collection instrument or (2) determine that an exemption to the PRA applies. An ICO is considered to conduct or sponsor a collection of information if the ICO specifies the topics or items of information to be collected from the public are specified by the ICO, including through a contract, cooperative agreement, or Other Transaction. With respect to a grant, the ICO is considered to conduct or sponsor a collection of information if the recipient is collecting the information at the specific request of the ICO, or the terms and conditions of the grant require specific approval by the ICO of the collection of information or collection procedures.

**21st Century Cures Act Research Exemption**

Section 2035 of the 21st Century Cures Act, enacted December 13, 2016 (P.L. 114-255), amended Section 301 of the Public Health Service Act (42 U.S.C. § 241) by adding: "(g) The PRA shall not apply to the voluntary collection of information during the conduct of research by the National Institutes of Health." This new provision is explained below.
For the purposes of this policy, ICs must answer the following questions in order to use the

PRA Research Exemption, ICs must answer the following questions:

1. Will the program analyze the project outcomes in a systematic way?
2. Will the program publicize the results of your systematic analyses?

If the answer to both questions is **yes**, then the program is conducting NIH research and is exempt from the PRA requirements as outlined by 21st Century Cures Act. Refer to OER Implementation Process for ICOs as outlined in Appendix 2.

If the answer to one or both questions is **no**, then the exemption does not apply, and OMB approval is required. Refer to the OER Implementation Process for ICOs as outlined in Appendix 2.

## F. Roles and Responsibilities

PRA requirements are implemented throughout NIH where there are various roles and responsibilities that span across many functional areas within NIH and across Federal Government to include DHHS and OMB. This section is designed to outline those roles and responsibilities for each respective area.

**1. Office for Policy for Extramural Research Administration (OPERA)/Project Clearance Branch (PCB) are required to conduct the following activities:**

a. ensure compliance with OMB and HHS regulations, policies, standards, procedures, and instructions with regard to clearance of collections of information
b. Conduct independent review: sufficiently independent of program responsibility to ensure all requests are compliant with requirements of PRA prior to submission to HHS and OMB.
c. plan for the development of new collections of information and the extension of ongoing collections well in advance to allow for public comment, HHS certification and OMB review
d. prepare and submit to HHS information collection request packages for submission to OMB
e. provide HHS with certification that the proposed collection of information meets the standards set forth in the Act
f. review Request for Information (RFI) and Funding Opportunity Announcements (FOA)
g. develop and approve notices for publication in the Federal Register
h. manage the NIH burden reduction efforts
i. develop and manage the NIH Information Collection Budget; and
j. assess PRA clearance requirements for research vs administrative clearance points.
k. Facilitates HHS and OMB reviews by following up with appropriate staff during those reviews to ensure that any requests for information/changes are promptly forwarded and responsive to the concerns noted.

**2. Institutes, Centers, and Offices (ICOs):**

**Each NIH ICO has a designee to act as its focal point for its PRA clearance functions. This designee (Project Clearance Liaison) is responsible for:**

a. providing guidance on behalf of PCB to individual staff, e.g., project officers, contracting officers, etc. concerning information collection requirements and the administrative aspects of the clearance process
b. informing PCB about upcoming projects and potential problems or concerns about special data collection proposals.
c. working closely with project officers and program staff on requests for OMB review, giving guidance and instructions for completing the necessary documents (i.e., Supporting Statement A/B, instruments/surveys, and other relevant documentation
d. reviewing draft packages from NIH staff for administrative completeness; ensuring that the minimum standards/practices for all information collections are addressed; providing comments and feedback to staff prior to forwarding final draft for PCB review.
e. following PCB review, working with program staff to ensure that any identified concerns are addressed, that the additional information requested has been included in the final package and that the package is administratively correct.
f. facilitates PCB and OMB reviews by following up with appropriate staff during the course of those reviews to ensure that any requests for information/changes are promptly forwarded and responsive to the concerns noted.
g. in concert with project officers (and contracting officers), monitoring information collection activities, giving advice and guidance concerning proposed potential changes.
h. maintain the complete and official file for each ICO project and keep accurate records on all ICO projects.
i. alert project officer of upcoming expirations regarding submissions
j. in concert with the PCB, keeping staff apprised of NIH, HHS, and OMB requirements associated with the Paperwork Reduction Act to help ensure that NIH does not collect information without displaying a valid OMB control number.

**3. NIH Privacy Act Officer or ICO Privacy Coordinator by proxy**

Conducts a Privacy assessment of proposed and modified collections of information to determine the following:

a. whether a System of Records Notice is needed and can be identified.
b. whether there is an existing Privacy Act Memo or if a new one is needed.
c. whether a Privacy Impact Assessment (PIA) needs to be completed.

**4. Department of Health and Human Services (HHS)**

Section 3506 of the PRA requires that each Department Head designate a Chief Information Officer (CIO) reporting directly to the Department Head. The CIO retains responsibility for carrying out the responsibilities of the agency under the Act in accordance with the requirements of 5 CFR Part 1320, the Privacy Act, E-/Gov and FISMA Acts, statistical standards and directives, and any other information policy directives. Within HHS, that official responsible for this function is the HHS Reports Clearance Officer located in the Office of the Chief Information Officer (OCIO), Office of Resource Management.

The OCIO and the Office of Resource Management carries out the clearance functions for all of DHHS agencies. This includes ensuring compliance with clearance policies, standards, procedures, and instructions from HHS and OMB, as well as department-wide health statistical planning, policy, coordination, and standard setting functions under the PRA.

**5. Office of Management and Budget (OMB)**

Within the OMB, the Office of Information and Regulatory Affairs (OIRA), established by Public Law 96-511, has responsibility for the paperwork control function, review, and approval of proposed information collections from the public, reduction of paperwork burden, Federal statistical activities, and the duplication of available information.

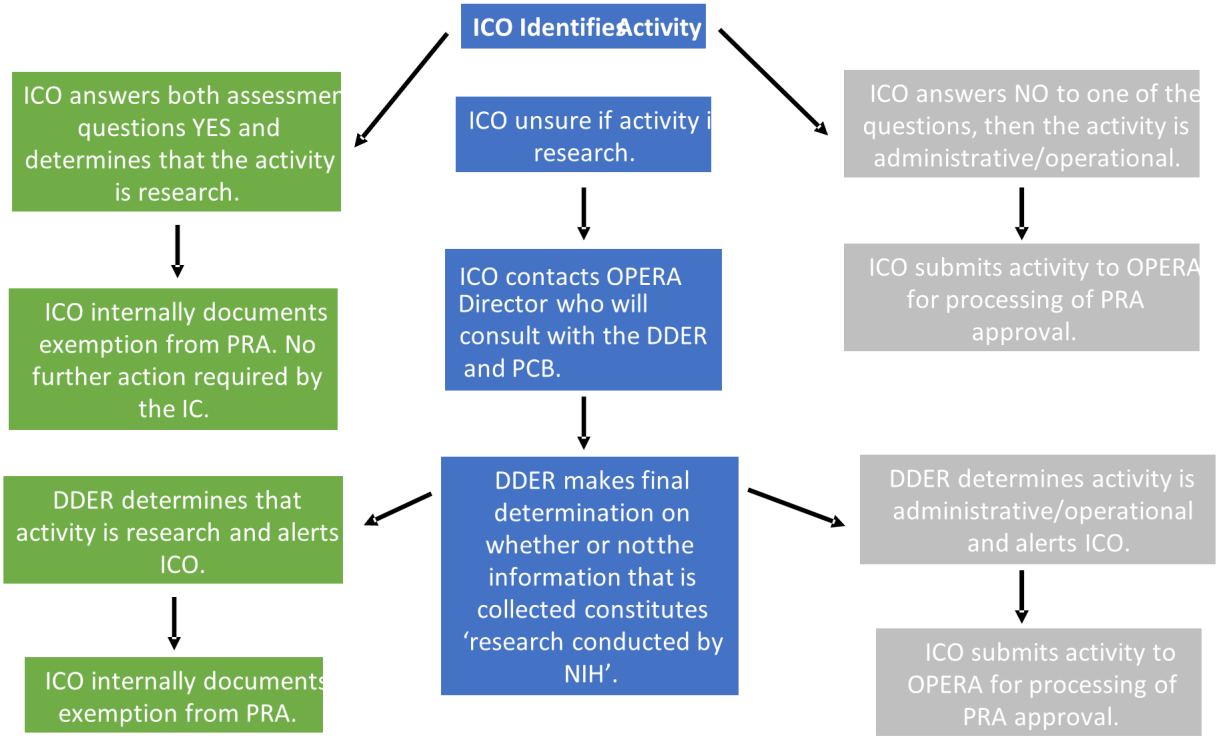
## G. References


1. **21st Century Cures Act Section 2035, enacted December 13, 2016 (P.L. 114-255), amends Section 301 of the Public Health Service Act (42 U.S.C. § 241)**
2. **5 CFR Part 1320, Controlling Paperwork Burden on the Public**
3. **Office of Management and Budget, Office of Information and Regulatory Affairs, "A Guide to Paperwork Reduction Act**
4. **Federal Collection of Information**
5. **Manual Chapter 1730: Forms Management**
6. **Manual Chapter 1743: Managing Federal Records, Appendix 1, NIH Records Control Schedule**
7. **Project Clearance Branch Intranet**
8. **HHS Office of the Chief Information Officer**
9. **5 U.S.C. Section 552a, Public Law 93-579, Privacy Act of 1974**
10. **44 U.S.C. Chapter 36, Public Law 107-347, E-Government Act of 2002 (see Title II, Section 208 for Federal Information Security Management Act privacy provisions**

## Appendix 1: What Does Not Count as Information Under the PRA (5 CFR 1320.3(h))

- Affidavits, oaths, affirmations, certifications, receipts, changes of address, consents, or acknowledgments, provided that they entail no burden other than that necessary to identify the respondent, the date, the respondent's address, and the nature of the instrument. (By contrast, a certification would likely involve the collecting of "information" if it were conducted as a substitute for a collection of information, to collect evidence of, or to monitor compliance with regulatory standards)
- Samples of products or of any other physical objects. (This category includes requests for information that is already available in a form suitable for distribution and is provided in that form to all requesters)
- Facts or opinions obtained through direct observation by an employee or agent of the sponsoring Agency or through non-standardized oral communication in connection with such direct observations.
- Facts or opinions submitted in response to general solicitations of comments from the public, published in the Federal Register or other publications, provided that no person is required to supply specific information pertaining to the respondent, other than that necessary for self-identification, as a condition to the Agency's full consideration of the comment
- Facts or opinions obtained initially or in follow-up 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. This includes medical records established because of this type of action.
- A request for facts or opinions addressed to a single person.
- Examinations designed to test the aptitude, abilities, or knowledge of the persons tested and the collection of information for identification or classification in connection with such examinations.
- Facts or opinions obtained or solicited at, or in connection with, public hearings or meetings
- Facts or opinions obtained or solicited through non-standardized follow-up questions designed to clarify responses to approved collections of information.

## Appendix 2: OER 21st Century Cures Act Implementation Process Flowchart




**Companion Document to Support OER Implementation Process Flowchart (shown above)**

- ICO Identifies Activity
    - ICO answers both assessment questions YES and determines that the activity is research.
        - ICO internally documents exemption from PRA. No further action required by ICO.
    - ICO answers NO to one of the questions, then the activity is administrative/operational.
        - ICO submits activity to OPERA for processing of PRA approval.

- ICO unsure if activity is research.
    - ICO contacts the OPERA Director.

        - OPERA will consult with DDER and PCB and makes final determination on whether or not the information that is collected constitutes 'research conducted by NIH'
            - OPERA Director determines that the activity is research and alerts ICO.
                - ICO internally documents exemption from PRA.
            - OPERA determines activity is administration/operational and alerts ICO.
    - ICO submits activity to OPERA for processing of PRA approval.

The policy requires ICOs to do the following when PRA applies:

- submit a collection package that has been approved by the ICO prior to submitting it to OPERA/PCB or PRA Officer
- publish the 60-day notice in the FRN
- evaluate comments and revise (or not) accordingly
- publish 30-day notice in the FRN
- submit final package submission to OMB through OPERA/PCB for final review and approval
- OMB has approved the proposed collection of information; and
- the agency has received a control number and an expiration date to be displayed with the collection of information