NIH Policy Manual

1825 - Information Collection From The Public

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Transmittal Notice

1. **Explanation of Material Transmitted:**
   This revised chapter contains an updated description of 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.
2. **Filing Instructions:**
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A. Purpose and Scope

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. This law 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) 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 (2) displaying a currently valid OMB control number and expiration date. The implementing OMB regulations (5 CFR Part 1320) are referenced with a URL below.

The provisions of this Chapter do not apply to other areas of authority under the Paperwork Reduction Act (or related laws), such as records management, automatic data processing, or telecommunication.

B. Background

The Paperwork Reduction Act of 1995 revised and reauthorized the Paperwork Reduction Act of 1980 and encompasses Federal statistical and information technology programs, including

the collection of data, authority over which was accorded to OMB under the Budget and Accounting Procedures Act of 1950. To further the goals of the Paperwork Reduction Act to have Federal agencies become more responsible and publicly accountable for reducing the burden of Federal paperwork on the public, the Senate and House of Representatives revised the act and it is now known as the Paperwork Reduction Act of 1995.

The Paperwork Reduction Act of 1995 significantly changes many aspects of Information Collection by the Federal government. The act, which went into effect October 1, 1995, requires agencies to plan for the development of new collections of information and the extension of ongoing collections well in advance of sending proposals to OMB. Agencies must:

- Seek public comment on proposed collections of information through "60-day notices" in the Federal Register;
- Certify to OMB that efforts have been made to reduce the burden of the collection on small businesses, local government and other small entities; and
- Have in place a process for independent review of information collection requests.

C. References

1. 44 U.S.C. Chapter 35, Public Law 104-13, Paperwork Reduction Act of 1995. http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=104_cong_public_laws&docid=f:publ13.104.pdf
2. 5 CFR Part 1320, Controlling Paperwork Burden on the Public http://www.access.gpo.gov/nara/cfr/waisidx_02/5cfr1320_02.html
3. Office of Management and Budget, Office of Information and Regulatory Affairs http://www.whitehouse.gov/omb/inforeg_infocoll/
4. The PRA of 1995: Implementing Guidance for OMB Review of Agency Information Collection, Preliminary Draft. June 2, 1999.*
   [* Document available in Project Clearance Branch, OD/OER/OPERA]
5. Guidance on Agency Survey and Statistical Information Collections, January 20, 2006 http://odoerdb2.od.nih.gov/oer/policies/project_clearance/omb_guidance_06.pdf
6. Standards and Guidelines for Statistical Surveys http://www.whitehouse.gov/omb/inforeg/statpolicy/standards_stat_surveys.pdf
7. 45 CFR 46, Protection of Human Subjects. http://www.access.gpo.gov/nara/cfr/waisidx_04/45cfr46_04.html
8. NIH Manual 1730, Forms Management
9. NIH Manual 1743, “Keeping and Destroying Records,” Appendix 1, NIH Records Control Schedule
10. Project Clearance Branch Website https://nih-extramural-intranet.od.nih.gov/d/nih/policies/project_clearance/pcb.htm
11. HHS/OCIO http://www.hhs.gov/ocio/policy/collection/index.html
12. 5 U.S.C. Section 552a, Public Law 93-579, Privacy Act of 1974, as amended http://www.usdoj.gov/opcl/privstat.htm

13. 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)http://www.law.cornell.edu/uscode/html/uscode44/usc_sup_01_44_10_36.html

D. Responsibilities

1. 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.
2. 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 (ORM).
   The OCIO, ORM 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.
3. NATIONAL INSTITUTES OF HEALTH (NIH)
   The National Institutes of Health (NIH), under the authority delegated by the Assistant Secretary on Resources and Technology (ASRT) shall:

   - ensure compliance with OMB and HHS regulations, policies, standards, procedures and instructions with regard to clearance of collections of information;
   - 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;
   - prepare and submit to HHS information collection request packages for submission to OMB;
   - provide HHS with certification that the proposed collection of information meets the standards set forth in the Act;
   - develop and approve notices for publication in the Federal Register;
   - manage the NIH burden reduction efforts; and
   - develop and manage the NIH Information Collection Budget.

a. As required by HHS, the NIH Deputy Director for Extramural Research (DDER) has an identified focal point for OMB clearance functions. The Project Clearance Branch (PCB) within the Office of Policy for Extramural Administration (OPERA), Office of Extramural Research (OER) is responsible for:

- interpreting the PRA and implementing regulations for the NIH;
- ensuring the quality and completeness of NIH requests for PRA approval;
- ensuring the quality and completeness of the NIH portion of the HHS Information Collection Budget (ICB);
- developing and implementing NIH operating procedures;
- maintaining NIH records and inventories;
- keeping ICs informed about information collection requirements and the policies and procedures associated with the clearance process;
- responding for NIH to questions raised by HHS or OMB on information collection issues.

OER/PCB responsibilities include addressing the following OMB requirements:

- *Independent review:* a paperwork review process "sufficiently independent of program responsibility"; in order to meet this requirement, all requests for PRA clearance must be cleared at the OER level prior to submission to HHS and OMB.
- *Need to develop new collections of information carefully:* OER to evaluate the need for each aspect of the information collection, estimate respondent burdens, and pilot-test the collection (where appropriate).
- *Informing the respondent:* OER to assess how respondents are informed of the reasons for the collection; how the information will be used; estimated burden; whether responses are voluntary, mandatory, or required for a benefit; and the necessity of a valid OMB control number.
- *Certification to OMB:* NIH to certify that the collection meets certain standards.
- *Federal Register notice:* NIH to provide citations of the Federal Register notice(s).
- *Planning for adequate time:* NIH to allow sufficient time for public comment prior to submission to HHS (at least 60 days) and for OMB review (from 30 to 60 days) after submission to OMB.

b. IC Project Clearance Liaisons (PCL)
Each NIH IC has a designee to act as its focal point for its PRA clearance functions https://extramural-intranet.nih.gov/node/3557. This designee (Project Clearance Liaison) is responsible for:

- providing guidance to individual staff, e.g., project officers, contracting officers, etc. concerning information collection requirements and the administrative aspects of the clearance process;

- informing the PCB about upcoming projects and potential problems or concerns about special data collection proposals;
- working closely with project officers and program staff on requests for OMB review, giving guidance and instructions for completing the cover memorandum (when necessary), Supporting Statement, Part I and II worksheets, and other relevant documentation;
- 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;
- 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;
- facilitating HHS 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;
- in concert with project officers (and contracting officers), monitoring information collection activities, giving advice and guidance concerning proposed potential changes;
- maintaining the complete and official file for each IC project and keeping accurate records on all IC projects;
- alerting project officers to upcoming expirations;
- 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; and
- preparing the annual Information Collection Budget (ICB) according to guidance from OMB, HHS, and the PCB (see Section K).

c. IC Staff Initiating Information Collection Activities

IC Project Officers and program staff are responsible for:

- familiarizing themselves with the types of information collection activities which require PRA approval;
- coordinating with their PCL to ensure the proper preparation of materials to be submitted to OMB for review;
- seeking public comment which requires the ICs to solicit comments through Federal Register notices. Requirements for public comment will vary depending on whether the information requirements are contained in current rules, proposed rules, or not in rules (5 CFR 1320.10 – 1320.12); and
- ensuring that no funds are expended for a collection of information until either OMB approval has been obtained or a clinical exemption granted (see Section I).

IC staff whose functions include the management of projects requiring collections of information from the public should:

- familiarize themselves with the general requirements and guidelines of this Chapter and the requirements for all information collections. These two sections outline, respectively, administrative matters associated with OMB clearance and minimum standards/practices concerning all information collections;
- discuss their information collection projects with the PCL early in the planning stages. These discussions should clarify whether OMB review and approval is ultimately needed, and if so, determine when a request for OMB review should be submitted;
- work closely with the PCL to prepare: (a) draft OMB submissions which they submit to the PCL for review, and (b) final packages according to proper format (see PCB website:https://nih-extramural-intranet.od.nih.gov/d/nih/policies/project_clearance/pcb.htm)
- provide information/changes/revisions promptly to the PCL, as requested as a result of NIH, HHS, or OMB reviews;
- after OMB approval, notify contractor or other awardee (where relevant) of OMB approval number and expiration
- monitor the project (and contractor or awardee, as appropriate) to ensure that the activity is conducted as approved; that any OMB conditions are met; and that proposed changes are promptly discussed with the PCL.
- retain documents for 5 years after approval date.

E. Definitions

The definitions in 5 CFR Part 1320 (http://edocket.access.gpo.gov/cfr_2002/janqtr/pdf/5cfr1320.3.pdf) apply to this section. The following definitions should be especially noted.

Burden

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:

- reviewing instructions;
- developing, acquiring, installing, and utilizing technology and systems for the purpose of collecting, validating, and verifying information;
- developing, acquiring, installing and utilizing technology and systems for the purpose of disclosing and providing information;
- adjusting the existing ways to comply with any previously applicable instructions and requirements;
- training personnel to be able to respond to a collection of information;

- searching data sources;
- completing and reviewing the collection of information;
- transmitting or otherwise disclosing the information.

Collection of information

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.

Control number

Control number is the number assigned by OMB to a collection of information denoting that OMB has approved the collection.

Information

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.

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.

Person

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.

Personally Identifiable Information (PII)

Any information about an individual maintained by an agency, including, but not limited to, education, financial transactions, medical history, and criminal or employment history and information which can be used to distinguish or trace an individual's identity, such as their name, social security number, date and place of birth, mother’s maiden name, biometric records, etc., including any other personal information which is linked or linkable to an individual. (Defined in OMB Memorandum M-06-19, Reporting Incidents Involving

Personally Identifiable Information and Incorporating the Cost for Security in Agency Information Technology Investments).

Privacy Impact Assessment (PIA)

A methodology that provides information technology (IT) security professionals with a process for assessing whether appropriate privacy policies, procedures, and business practices–as well as applicable administrative, technical and physical security controls–have been implemented to ensure compliance with federal privacy regulations. (Defined in Secure One HHS Information Security Program Privacy Impact Assessment (PIA) Guide).

Sensitive Information:

Information is considered sensitive if the loss of confidentiality, integrity, or availability could be expected to have a serious, severe or catastrophic adverse effect on organizational operations, organizational assets, or individuals. Further, the loss of sensitive information confidentiality, integrity, or availability might: (i) cause a significant or severe degradation in mission capability to an extent and duration that the organization is unable to perform its primary functions; (ii) result in significant or major damage to organizational assets; (iii) result in significant or major financial loss; or (iv) result in significant, severe or catastrophic harm to individuals that may involve loss of life or serious life threatening injuries. (Defined in HHS Memorandum ISP-2007-005, "Departmental Standard for the Definition of Sensitive Information").

F. Policy for Collections of Information

1. Neither NIH nor any IC shall conduct or sponsor the collection of information unless, in advance of the initiation or revision of the collection of information:

    a. the agency has:

        - conducted a review to evaluate independently and fairly whether proposed collections of information should be approved;
        - evaluated public comments received after providing appropriate notice in the Federal Register and consulted with members of the public and affected agencies;
        - submitted to the Office of Management and Budget (OMB), as part of the clearance request, certifications that the proposed collections are necessary for the proper performance of agency functions; are not duplicative of other accessible information; reduce burden to the extent practicable; are written in plain terminology; are consistent and compatible with existing reporting practices; indicate how long records must be maintained; explain the nature and purposes of the collection; have been developed in an efficient and effective manner; use appropriate statistical survey methodology; and use information technology to reduce burden and improve quality;

- published a 30-day Federal Register notice at the time of the submission of the clearance request to OMB;

b. OMB has approved the proposed collection of information; and
c. the agency has received a control number and an expiration date to be displayed with the collection of information

2. If the topics or particular items of information to be collected from the public are specified by the IC, PRA approval is required regardless of the funding mechanism involved. That is, whether the information collection is to be carried out directly under an interagency agreement, grant, contract, or cooperative agreement, whether it is undertaken by IC staff directly or whether it is a recordkeeping or disclosure requirement in regulations, it is deemed to be Federally sponsored and, therefore, subject to OMB approval if the content and/or format of the public response is stated explicitly by the Federal sponsor. Reference: http://edocket.access.gpo.gov/cfr_2002/janqtr/pdf/5cfr1320.3.pdf. The OMB has identified specific categories of activities, the items therein not generally considered "information," as defined by 5 CFR 1320.3(h); however, the OMB may determine that any specific item constitutes "information."
Specific types of information include:

   - Request for information for transmission to the Federal government, such as grant application forms, written report forms, telephone surveys, and electronic data collections.
   - Recordkeeping requirements, which may involve compilation and maintenance of records, either alone or in conjunction with the reporting of information to the agency and/or some other person.
   - Third-party or public disclosure requirements, which may involve a requirement to disclose information to other members of the public directly or through publication in media such as newspapers or magazines, or to post the information on labels.
   - Information collections, recordkeeping requirements, and third-party disclosure requirements can be contained in or authorized by regulations as monitoring or enforcement tools. They can also appear in forms and their accompanying instructions.

3. The OMB determines whether a collection of information is necessary for the proper performance of NIH's functions by identifying a public law, US Code, Executive Order, Statute, court order or congressional mandate. In addition to these authorizing statutes, this link (http://www.law.cornell.edu/uscode/) will assist in identifying the legislative authority for the respective Institute or Center.
4. To obtain PRA approval of a collection of information, the IC shall demonstrate that it has taken every reasonable step to ensure that the proposed collection of information:

   a. Is the least burdensome necessary for the proper performance of the agency's functions to comply with legal requirements and achieve program objectives;

b. Is not duplicative of information otherwise accessible to the agency; and
c. Has practical utility. The agency shall also seek to minimize the cost to itself of collecting, processing, and using the information, but shall not do so by means of shifting disproportionate costs or burdens onto the public. Approval by OMB is granted on the basis of an assessment of the need for and intended uses of the information, as well as the adequacy of the methodology and all other aspects of the information collection plan.

5. Unless the IC is able to demonstrate, in its submission for PRA clearance, that such characteristic of the collection of information is necessary to satisfy statutory requirements or other substantial need, OMB will not approve a collection of information

    a. Requiring respondents to report information to the agency more often than quarterly;
    b. Requiring respondents to prepare a written response to a collection of information in fewer than 30 days after receipt of it;
    c. Requiring respondents to submit more than an original and two copies of any document;
    d. Requiring respondents to retain records, other than health, medical, government contract, grant-in-aid, or tax records, for more than three years;
    e. In connection with a statistical survey, that is not designed to produce valid and reliable results that can be generalized to the universe of study;
    f. Requiring the use of a statistical data classification that has not been reviewed and approved by OMB;
    g. That includes a pledge of confidentiality that is not supported by authority established in statute or regulation, that is not supported by disclosure and data security policies that are consistent with the pledge, or which unnecessarily impedes sharing of data with other agencies for compatible confidential use; or
    h. Requiring respondents to submit proprietary, trade secret, or other confidential information unless the agency can demonstrate that it has instituted procedures to protect the information's confidentiality to the extent permitted by law.

G. Components of a Request for OMB Review

To request OMB review and approval of an information collection, the initiator of the request must submit the following documents:

1. *Standard Forms, Part I and II*. These forms and instructions have been developed by OMB. They require identification of the sponsoring IC; a brief abstract of the proposed information collection; the amount and nature of the respondent burden; and other information for OMB management purposes. A copy of the forms and the instructions are provided on the PCB website https://nih-extramural-intranet.od.nih.gov/d/nih/policies/project_clearance/pcb.htm

2. *Supporting Statements A and B*. This is a double-spaced narrative prepared according to the "Information on Preparing a Package for Clearance" on the PCB website. The Supporting Statement A should provide: a narrative account of the purposes of the data collection; associated statutory and/or regulatory requirements; the intended uses of the results; a description of the approach, procedures and methodology for information collection, including measures to be taken to protect confidentiality; and an explanation of the basis for the estimate of respondent burden. Supporting Statement B should be addressed if the information collection involves statistical methods. Supplemental NIH instructions have also been developed and are available from the PCB to assist NIH staff in preparing the supporting statement. See PCB website: https://nih-extramural-intranet.od.nih.gov/d/nih/policies/project_clearance/pcb.htm
3. *60-Day Advance Federal Register Notice*. With the exception of Information Collection requirements contained in proposed rules, ICs must publish a 60-day advance notice in the Federal Register. A copy of this notice should be included as an attachment with the PRA information collection request. The notice must solicit public comment on the need for the information, its practical utility, the accuracy of the IC's burden estimate, and ways to minimize burden (including applications of information technology). The 60-day notice directs public comment to the IC. In preparing the 60-day notice, the IC should consult the templates and instructions on the PCB website https://nih-extramural-intranet.od.nih.gov/d/nih/policies/project_clearance/pcb.htm. For additional information on preparing the 60-day notice, consult the IC PCL or the PCB.
4. *Draft 30-Day Federal Register Notice*. The IC must include the draft 30-day notice in the information collection request package. At the end of the 60-day comment period, the IC should submit a 30-day Federal Register notice, notifying the public that the information collection request was submitted to OMB and requesting public comment be directed to OMB. The draft 30-day notice should be finalized at the end of the 60-day comment period to reflect whether any comments were received in response to the 60-day notice and any burden or other changes that resulted from the public comment period. Before HHS forwards the clearance request package to OMB, the PCB will notify the IC. Generally, upon notification, the IC will send the 30-day notice to the Federal Register for publication. The PCB web site: https://nih-extramural-intranet.od.nih.gov/d/nih/policies/project_clearance/pcb.htm contains the template and instructions for the 30-day notice. For additional information on preparing the 30-day notice, consult the IC PCL or the PCB.
5. *Cover Memorandum (Optional)*. At its option, the IC may include in the clearance package a cover memorandum to OMB. Occasions that might warrant a cover memo are special circumstances affecting the information collection request that the IC wishes to draw to OMB's attention (discussion of the status of previous conditions of approval). Cover memos should be addressed from the IC through the Chief, PCB and the Reports Clearance Officer, HHS to the NIH Desk Officer at OMB/OIRA.
6. *Attachments*. Backup materials are necessary to explain all aspects of the information collection activity. They should include the following:

    - data collection instruments such as forms, questionnaires, telephone interview guides, etc; each instrument submitted must display the agency identification

code (0925-XXXX or the current OMB number) in the upper right hand corner of the instrument or form together with the indication of the expiration date (month/year represented by "XX/XXXX"). The instruments and forms must also display at the top of the page the OMB Burden Statement. Examples are provided on the PCB web site:https://nih-extramural-intranet.od.nih.gov/d/nih/policies/project_clearance/pcb.htm

- instructions to respondents for assembling and reporting information;
- introductory and follow-up letters to respondents, or scripts in the case of telephone interviews, requesting participation and indicating whether or not responses are voluntary; explaining the purposes and procedures of the data collection and stating that the data collection is Federally sponsored;
- informed consent forms and Institutional Review Board (IRB) approvals
- any additional backup material necessary to explain the purposes, approach, procedures and methodology of all aspects of the data collection whenever statistical methods are employed.

7. *Additional Documentation*
   Some clearance requests will require additional documentation as in the examples below.

   - *Revisions with or without change*. When a clearance package requests renewal of an existing information collection, the IC should include a copy of any terms of clearance and an explanation of how the IC met any conditions OMB placed upon the original approval or on the subsequent renewal. When a clearance package contains revisions to an information collection previously submitted and/or approved, the IC should provide, in addition to the information required for a renewal, a clear explanation of the revisions in the body of the Supporting Statement in A.15 and highlight the revisions or provide a modification page.
   - *Reinstatements*. ICs should manage their paperwork transactions so that information collections whose approval period is nearing expiration do not lapse. However, when ICs wish to reinstate an information collection that has lapsed or reinstate a collection with periodicity, the IC should provide an explanation (in a cover memo to the HHS Reports Clearance Officer) with the reason for the reinstatement.
   - *Discontinuations*. When an information collection request will be discontinued, form OMB83-D, Paperwork Reduction Act - Collection Discontinuation Form, will be submitted to OMB.

For current procedures, please see the Project Clearance Branch web site: https://nih-extramural-intranet.od.nih.gov/d/nih/policies/project_clearance/pcb.htm.

H. Specific Requirements for Information Collections

The standards and recommended practices in this section may not be able to be applied uniformly or precisely in all situations (e.g., statistical surveys differ from administrative

forms). Project sponsors should be prepared to justify any significant departures from these standards. However, where projects require OMB review approval, project sponsors should pay particular attention to the specific PRA requirements that are noted in this section.

1. PROTECTION OF INDIVIDUALS

   All information collection must be carried out in ways which respect the sensitivities and privacy of the respondent public.

   Adequate safeguards to ensure this protection must be in place during the process of gathering the information and through all subsequent uses of the data. The level of these safeguards will depend on the risk or harm to the respondents if disclosure were to be made.

   a. Informing Respondents

      The first consideration in protecting the interests of respondents is the introductory statement informing them of the nature of the activity in which they are being asked to participate. This information may be provided by means of introductory letters, explanatory texts on the cover pages of questionnaires, and scripts read to respondents prior to telephone interviews. These introductory statements should be clear and straightforward. Because the free consent of the respondent is intimately connected to his or her understanding of the consequences of that consent, the explanation should be explicit and simple rather than formal and guarded. Easily understood language should be used. Thorough explanations should be available to any potential respondents.

      Each introductory statement must include:

      - the fact that the information collection is sponsored by an agency of the Federal Government, i.e., NIH or the particular IC;
      - the purposes of the information collection and the uses which will be made of the results;
      - whether providing the information is voluntary or mandatory. If responses are voluntary, respondents should also be assured that there will be no penalties if they decide not to respond either to the information collection as a whole or to any particular questions. For example, services in a health care facility will not be affected for clients who do not cooperate in a survey. If responses are mandatory, the statutory basis for the requirement and the penalties for non-response must also be explained; and
      - the extent to which individual responses will be kept confidential.

      These preliminary explanations should be sufficient to serve as the basis for obtaining informed consent. There is no requirement under PRA clearance procedures that the respondent sign an informed consent form for the collection of information. The individual's giving of information about himself or herself constitutes the consent. In some instances, a written consent may actually be inappropriate, as, for example, when survey procedures do not need to have the names of respondents recorded, or when the names are destroyed after a short time. Use of a written consent form in such instances may result in the creation of

a record that would not otherwise exist. If a consent form is used (e.g., because the collection of information is done in connection with procedures requiring a written consent under the human subjects regulations (45 CFR Part 46)), the explanations necessary to inform the respondent adequately, as described above, can be included in that form.

b. Sensitive Questions

Not only should respondents be fully informed about the circumstances of the information collection, but there should also be provision for respecting their right to decline to participate in the project as a whole or to refuse to answer particular questions which they may consider intrusive. For surveys involving face-to-face interviews, arrangements should be made to ensure privacy during the interview. Special attention should be given to the wording of questions and the handling of potentially sensitive topics.

Areas of particular sensitivity include religion, reproduction decisions, sexual behavior and attitudes, use of alcohol and drugs of abuse, psychological problems, and questions about a third party without that person's knowledge. Actual income may also be considered a sensitive issue. Questions touching on these sensitive areas must be justified in terms of their importance to the purposes of the data collection and the consequences of not including them.

c. Protecting Personal Privacy

(1) Personally Identifiable Information (PII) and Privacy Impact Assessment (PIA)

Personally Identifiable Information (PII)

PII is an individual identifier (such as name or driver’s license number or a link to that information) along with data that can be used to cause harm to the individual (like bank account number or medical records). PII can be an individual field, such as a social security number. PII does NOT include publicly available information that is lawfully made available to the general public from federal, state, or local government records.

PII has become a major topic across all government agencies. The Department of Health and Human Services (HHS) and the Office of Management and Budget (OMB) require implementation of stringent controls to protect the confidentiality, integrity and availability of Sensitive Information and Personally Identifiable Information (PII). Within the Supporting Statement A, section A.11, this must be explained in compliance with the Federal Information Security Management Act (FISMA), if applicable.

Unless there are compelling reasons to the contrary, HHS policy discourages the collection of information in such a way that individuals may be identified with the responses they have provided. There are, of course, important exceptions to this rule, notably applications for benefits and certain other administrative data collections, and some research projects. In situations where it is necessary to collect and retain individually identifiable data, all the principles stated in parts a and b, above, apply. Because respondents are being asked to take an additional risk when their answers can be linked with their names, more stringent procedural safeguards must be observed.

There are some statutes which protect data against disclosure, although their coverage is limited. Among these statutes are: Section 241(d) of Title 42 [42 USC 241(d)] governing data collection in statistical, epidemiological, behavioral, clinical and health services research. Data collected for treatment of drug and alcohol abuse patients (as distinguished from research) is subject to special statutory restrictions on disclosure (42 USC 290 dd-2) which should be appropriately summarized for those providing information about themselves for such purposes.

Privacy Impact Assessment (PIA)

PIA is an analysis tool designed to identify any privacy risks associated with information that is collected, processed, stored, and/or transmitted by an Information Technology (IT) system. The PIA describes what information is contained within an IT system, whether or not it contains personally identifiable information, how the information is used, and how it is protected. IT systems such as databases, websites, servers and software applications containing PII are subject to an extensive range of requirements derived from privacy legislation, OMB Memoranda, Departmental and NIH policy. NIH is responsible for providing proper protections for PII contained within its IT systems. A detailed breakdown of the legislation regarding PIAs can be found in the following resources:

NIH Manual 1745 - NIH Information Technology (IT) Privacy Program
NIH Manual 1745-1 - NIH Privacy Impact Assessments
NIH PIA Guide: http://oma.od.nih.gov/ms/privacy/NIHPIAGuide.doc
NIH PIA Training Presentation:
Color - http://oma.od.nih.gov/ms/privacy/Training2008.ppt
Black and White - http://oma.od.nih.gov/ms/privacy/Training2008bw.ppt
NIH Privacy Awareness Training: http://irtsectraining.nih.gov

(2) The Federal Privacy Act

More extensive procedures are required whenever a collection of information constitutes a system of records as defined in the Privacy Act. A Privacy Act system of records exists whenever the following three conditions are met:

- The records contain information about individuals, including the name or any other item of information, such as the Social Security Number, which uniquely identifies each individual.
- The records are actually retrieved by reference to the individual identifier. (The possibility of making such a retrieval is not sufficient; actual retrieval by identifier must occur or be planned.)
- The records must be under the control of the NIH or an IC, either by physical possession and in-house management or when the records are maintained under contract if the Privacy Act applies to the contract.

The Privacy Act System of Records Notices most relevant to NIH information collection activities are: *09-25-0156 Records of Participants in Programs and Respondents in Surveys used to Evaluate Programs of the Public Health Service* (http://oma.od.nih.gov/ms/privacy/pa-files/0156.htm) and *09-25-0200 Clinical,*

Basic and Population-based Research Studies of the National Institutes of Health (http://oma.od.nih.gov/ms/privacy/pa-files/0200.htm).
For further information, contact the IC Privacy Coordinator at http://oma.od.nih.gov/about/contact/browse.asp?fa_id=3 or the NIH Privacy Act Officer, Office of Management Assessment (OMA), Division of Management Support (DMS) at 496-2832, or visit http://oma.od.nih.gov/ms/privacy.
Additional information may also be obtained from NIH Manual 2805 - NIH Web Page Privacy Policy: http://oma.od.nih.gov/manualchapters/management/2805/.
(3) The HIPAA Privacy Rule
The "Privacy Rule," a Federal regulation under the Health Insurance Portability and Accountability Act (HIPAA) of 1996 protects certain health information. The Privacy Rule was issued to protect the privacy of health information that identifies individuals who are living or deceased. The Privacy Rule (also known as *Standards for Privacy of Individually Identifiable Health Information*) is in Title 45 of the Code of Federal Regulations, Part 160 and Subparts A and E of Part 164. The full text of the Privacy Rule can be found at the HIPAA Privlacy Web site of the Office for Civil Rights (OCR): http://www.hhs.gov/ocr/hipaa.
The NIH is not a "covered entity" as defined in the HIPAA regulation, so the regulation is not applicable to NIH activities. However, many of the research activities carried out under NIH awards are performed at institutions and organizations that are covered by the HIPAA regulation. NIH staff are expected to be attentive to the requirement for HIPAA compliance in information collection activities.

d. Protecting Confidentiality
Inclusion in a system of records under the Privacy Act does not of itself provide sufficient protection to warrant assurance of full confidentiality to respondents. There should be no promise of total and absolute confidentiality for personally identifiable information (PII) unless there is a firm legal basis for withholding information in the face of a subpoena, or court order, or other Federal, state, or local legislation.
When there is no legal basis for a promise of confidentiality other than that offered by the Privacy Act, the introductory statement must be drafted in a way that fairly advises the respondent of the data disclosure possibilities, while at the same time being effective in soliciting the respondent's cooperation. The statement should not be labeled "assurance" or "guarantee" of confidentiality, but should be a realistic description of the limits of confidentiality. For example:
The information you provide will be kept confidential, and will not be disclosed to anyone but the researchers conducting this study, except as otherwise required by law.
Here the term "confidential" is not misleading because it is coupled with an explicit statement of its limits.
(1) There are some statutes which protect data against disclosure, although their coverage is limited. Among these statutes are: Section 241(d) of Title 42 [42 USC 241(d)] governing data collection in statistical, epidemiological, behavioral, clinical and health services research. Data collected for treatment of drug and

alcohol abuse patients (as distinguished from research) is subject to special statutory restrictions on disclosure (42 USC 290 dd-2) which should be appropriately summarized for those providing information about themselves for such purposes.

(2) Certificates of Confidentiality. Pursuant to (42 U.S.C. 241(d)), the Secretary of Health and Human Services may authorize persons engaged in biomedical, behavioral, clinical, or other research to protect the privacy of individuals who are the subjects of that research. This authority has been delegated to the National Institutes of Health (NIH).

Persons authorized by the NIH to protect the privacy of research subjects may not be compelled in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings to identify them by name or other identifying characteristic.

Certificates of Confidentiality are issued by the National Institutes of Health (NIH) to protect identifiable research information from forced disclosure. They allow the investigator and others who have access to research records to refuse to disclose identifying information on research participants in any civil, criminal, administrative, legislative, or other proceeding, whether at the federal, state, or local level. Certificates of Confidentiality may be granted for studies collecting information that, if disclosed, could have adverse consequences for subjects or damage their financial standing, employability, insurability, or reputation. By protecting researchers and institutions from being compelled to disclose information that would identify research subjects, Certificates of Confidentiality help achieve the research objectives and promote participation in studies by assuring confidentiality and privacy to participants. For more information, see: http://grants1.nih.gov/grants/policy/coc/index.htm.

(3) The "Confidentiality of Information Clause" in Contracts

Where a collection of personally identifiable data does not constitute a system of records as defined by the Privacy Act, the Confidentiality of Information (CI) Clause (Health and Human Services Acquisition Regulations [HHSAR] 352.224-70) provides a mechanism to protect subjects of studies under contracts. Consistent with HHSAR policy at 324.70 and the CI clause, release of personally identifiable information (PII)requires the subject's written permission, except as otherwise required by law. Again, there can generally be no guarantee of total and absolute confidentiality except for those specific projects which have authorizing immunity against a subpoena.

e. Protection of Human Subjects

Title 42 Section 289 of the United States Code (42 USC 289) and other enactments have established special safeguards for biomedical or behavioral research projects involving human subjects which are carried out under the auspices of HHS. Detailed definitions of what is subject to and what may be exempted from these rules, and descriptions of the reporting, recordkeeping and disclosure procedures which must be followed, where applicable, are contained in 45 CFR Part 46. Additional information is available from the Office for Human Research Protections (OHRP) by phone at 240-453-6900 or by e-mail at

ohrp@hhs.gov, http://www.hhs.gov/ohrp/ and from the NIH Office of Human Subjects Research, 301-402-3444 http://206.102.88.10/ohsrsite/.

f. Protection and Final Disposition of Records
Steps must be taken to protect the security of information during periods of data collection and use, and plans should be made for final proper disposition of the records when the information collection activities are completed.

2. RESPONDENT BURDEN
The Paperwork Reduction Act of 1995 and implementing OMB regulations require that information obtained from respondents be kept to a minimum. Project sponsors should consult with members of the respondent public (fewer than ten individuals) in determining the extent of the burden.
To keep the burden as low as possible, the following criteria should be considered:

a. Number of respondents
Whenever possible, a representative, scientifically selected sample, preferably a probability sample, should be used instead of total coverage for the potential respondent population. The sample should be of sufficient size to yield valid statistical results in accordance with good statistical practices and be generalized to larger populations.

b. Frequency of collection
If the information is to be reported periodically, the intervals should be spaced as far apart as possible. With very few exceptions, information collections that require respondents to report more often than quarterly will not be approved by OMB.

c. Availability or ready accessibility of data to respondents
This includes the preparatory effort which will be required of respondents, in addition to the time they will spend actually answering questions; whether they are likely to have reliable records readily at hand; and whether the time period involved will permit accurate recall (requests for information from prior periods or dates long past).
When the answers to questions can be provided only after a records search or after significant modifications in respondents' existing information systems, prospective respondents should be informed well in advance so they can prepare themselves to respond with a minimum of wasted motion. The time respondents spend in preparing their answers is considered part of the burden.

d. Relevance to the central question
All information items must be clearly related to the purpose of the proposed activity.
"Nice to Know" items not contributing to the purposes of the survey/form will not be approved by OMB.

e. Length of questionnaire/form
Project sponsors should guard against excessive detail and overly lengthy questionnaires, even if questions are considered relevant. Response time of more than one hour generally will not be approved by OMB except in the case of administrative forms such as applications.

f. Design of questionnaire/form
Clear design of the form and clearly-written instructions reduce the time respondents need to complete the form. Assistance is available from the NIH Forms Officer, (301) 496-8155http://oma.od.nih.gov/ms/forms/.

g. Agency disclosure of estimated burden
ICs shall disclose on the first page of each collection of information the estimated average burden hours per response. ICs shall include with this estimate of burden a request that the public direct to the NIH Project Clearance Branch any comments on accuracy of the burden estimate and any suggestions for reducing the burden. Effective October 1, 1995 the revised regulations implementing the new Paperwork Reduction Act add a new requirement to be included in the burden statement. The new requirement is that potential respondents must be informed of the fact that an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Samples of the required burden disclosure statements are available on the Project Clearance Branch web site:https://nih-extramural-intranet.od.nih.gov/d/nih/policies/project_clearance/pcb.htm

3. PRACTICAL UTILITY
Project sponsors should consider the positive needs for the information and the negative consequences of not having this information available. Special emphasis should be placed on the practical utility of the expected results in furthering the mission of the sponsoring agency. Sponsors should focus on past IC decisions which were based on similar data, or present problems which require the proposed data for resolution.
For purposes of PRA review and approval, sponsors should consider the practical utility of the expected results in furthering the mission of the sponsoring IC. Uses such as "needed to make management decisions" do not satisfy OMB's definition of practical utility. OMB will not approve an information collection request unless the agency has demonstrated the practical utility of the collection [see 5 CFR 1320.5.(d)(iii)] http://edocket.access.gpo.gov/cfr_2002/janqtr/pdf/5cfr1320.5.pdf.
4. AVOIDING DUPLICATION
NIH sponsors of proposed information collection activities are to take appropriate steps early in the development stage to ensure that the information collection being proposed has been assessed for duplication and overlap. Those planning surveys should document that all or part of the information needed is not available from some other source or could not be appropriately obtained by adding questions to an existing survey by another agency. Depending on the particular activity, one or more of the following is appropriate:

- literature search;
- consultation with staff in other agencies who are working in related program areas;
- discussions, meetings, and seminars documenting efforts to identify similar data collections by organizations and individuals prominent in the particular area; and

- computer search of on-going Federal data collection activities, e.g., www.reginfo.gov; www.fedstats.gov.

5. COSTS TO THE GOVERNMENT AND TO RESPONDENTS

Federal costs for data collection activities should be commensurate with the expected and requisite quality of the information to be obtained.

With respect to respondents' costs to Federal information collection requests or requirements, costs are based on the expenditure of the time necessary to read instructions, consult and assemble records and to complete the response.

For PRA clearances, if respondents are drawn from the general population and are asked for no more than answers to survey questions, costs to respondents are calculated at the current average hourly rate for employees based on the Department of Labor published standards: http://www.bls.gov/bls/blswage.htm.

In the case of information collections which make more complex demands on respondents, such as information requirements in regulations, the cost to respondents is more difficult to estimate. In almost all instances of this kind, project sponsors should consult with representative respondents before making the cost estimate (consult with fewer than ten respondents).

Capital, Maintenance and Operating costs. The cost estimate should be split into two components: (a) a total capital and start-up cost component (annualized over its expected useful life) and (b) a total operation and maintenance and purchase of services component. The estimates should take into account costs associated with generating, maintaining, and disclosing or providing the information. Include descriptions of methods used to estimate major cost factors including system and technology acquisition, expected useful life of capital equipment, the discount rate(s), and the time period over which costs will be incurred. Capital and start-up costs include, among other items, preparations for collecting information such as purchasing computers and software; monitoring, sampling, drilling and testing equipment; and record storage facilities.

If cost estimates are expected to vary widely, agencies should present ranges of cost burdens and explain the reasons for the variance. The cost of purchasing or contracting out information collection services should be a part of this cost burden estimate. In developing cost burden estimates, agencies may consult with a sample of respondents (fewer than ten), utilize the 60-day pre-PRA submission public comment process and use existing economic or regulatory impact analysis associated with the rulemaking containing the information collection, as appropriate.

6. METHODOLOGY

Many information collections proposed by NIH are either surveys per se or otherwise employ survey procedures and statistical methods within broader research designs. It is expected that all NIH information collection projects are to be technically sound, with data collection methodology and procedures appropriate to the intended uses of the information. Technical assistance is available from the National Center for Health Statistics on both the study design and the framing of the questions in the questionnaire. NIH staff are urged to use this resource (as arranged through the NIH PCB) as well as those within the NIH to ensure that all aspects of the study (target population, sampling,

frequency and timing, method of data collection, consideration of error, data analysis plan, pretests, follow-up, quality control, plans for presentation of the results) have been addressed and reviewed for adequacy.
OMB review makes the final recommendation concerning NIH's justification for the studies and study designs proposed.

7. PRETESTS
Agencies should always consider conducting pretests (small trials of the measurement process) or pilot studies (larger trials yielding statistical information) when planning for a new information collection or changing methods and procedures for an ongoing survey. These kinds of tests may provide critical information necessary to ensure the quality of the data and smoothness of operations needed in the full-scale information collection. They can provide essential information to the agency and result in higher data quality than would have been achieved without them and may be the only vehicle for measuring the effects of different changes an agency is considering implementing. Thus, agencies will need to weigh the importance and use of pretests against the time and resources needed to conduct them. Pilot studies can be useful when there are a number of issues the agency needs more information. See Guidance on Agency Survey and Statistical Information Collection, January 20, 2006, item #22.
http://odoerdb2.od.nih.gov/oer/policies/project_clearance/omb_guidance_06.pdf
Generally, a request for clearance of a pretest is submitted separately from the request for clearance for the main project; but a proposed test or set of tests may be submitted for approval in combination with the main project approval request.

I. Clinical Exemption from OMB Review and Approval

The OMB definition of "information" at 5 CFR 1320.3(h)(5) generally excludes facts and opinions obtained from individuals (including control subjects) under treatment or clinical examination for a disorder or medical condition, including prevention of a disorder. Therefore, collections of information from such individuals do not require OMB review and approval. However, they do require approval from the NIH Clinical Exemption Review Committee. NIH monitors closely the application of these interpretations, and procedures have been developed at NIH for determining conformance to the stated OMB criteria.

Requests for clinical exemption are to be submitted to the PCB website: https://nih-extramural-intranet.od.nih.gov/d/nih/policies/project_clearance/pcb.htm. Requests are to provide the required information and supporting materials.

J. Information Collection Regulations Which Impose Information Collection Requirements

Proposed and Final Rules

1. *Proposed Rules*. 5 CFR Part 1320.11 requires that, when an information collection is contained in a proposed regulation, HHS must submit to OMB a PRA package for the information collection on or before the day on which the Notice of Proposed Rule Making (NPRM) is published in the Federal Register. Therefore, the NIH must submit

the information clearance package to HHS before NPRM publication in the Federal Register. HHS will coordinate with the NIH so that publication in the Federal Register coincides with OMB receipt of the clearance package.

The information PRA package must contain a copy of the proposed rule and its preamble. The preamble to the NPRM must include notification that HHS has requested OMB review of the information collection and direct that comments be sent to the OMB reviewer. Publishing this notification in the NPRM satisfies the requirement for public notice.

Consult OMB's Guidance on Agency Survey and Statistical Information Collections for information on the OMB review period and potential OMB actions. http://odoerdb2.od.nih.gov/oer/policies/project_clearance/omb_guidance_06.pdf

2. *Final Rules*. If the information collection contained in an NPRM is identical to the one to be included in the final rule, the IC need not resubmit a PRA clearance package during the final stage of rulemaking. If modifications have been made to the information collection between the NPRM and final stages, the IC must resubmit the clearance package for PRA approval. Resubmission must occur on or before the date of publication of the final rule.

   Consult OMB's Guidance on Agency Survey and Statistical Information Collections for information on the OMB review period and potential OMB actions for final rules. http://odoerdb2.od.nih.gov/oer/policies/project_clearance/omb_guidance_06.pdf

K. Information Collection Budget (ICB)

Under the Paperwork Reduction Act of 1995 (PRA), the Office of Management and Budget (OMB) prepares an annual report to keep Congress and the public informed of major activities under the PRA. This report, the ICB, describes Federal efforts to improve the quality of services delivered to the public by improving the efficiency and effectiveness of Federal information collections. It also highlights agencies' efforts to reduce the time the public spends on federal information collections and promotes further reductions by giving agencies examples of practical approaches that other agencies have used successfully.

The Paperwork Reduction Act of 1995 requires that the Director of the Office of Management and Budget

- "Set annual agency goals to reduce information collection burdens imposed on the public that represent the maximum opportunity in each agency..." (44 U.S.C. 3505(a)(1)).
- "[report annually on] a summary of accomplishments and planned initiatives to reduce collection of information burden" (44 U.S.C. 3514(a)(2)(A)(I)).
- "[report annually on] a list of any increase in the collection of information burden, including the authority for each such collection." (44 U.S.C. 3514(a)(2)(A)(iii)).

To meet these responsibilities, OMB requires each government agency to prepare an annual Information Collection Budget (ICB). The ICB is an annual accounting of the previous year's accomplishments and the presentation of a plan for burden reduction in the current year. OMB compiles the agencies' reports into a single government-wide total and compares each year with the information collection burden baseline developed in fiscal year 1995.

Each year, approximately two months after the end of the fiscal year, OMB issues a Data Call describing the ICB, the types of information required, and the format for reporting that information. HHS notifies NIH when OMB publishes the ICB Data Call and provides instructions for ICB submission. HHS will prepare the annual ICB based upon data supplied by NIH.

A memo from the PCB will describe what is needed from each IC for a collaborative effort of this report.

The ICs must develop an information collection burden management plan and maintain records sufficient for developing the annual ICB. At a minimum, the ICs must be able to provide:

1. The total information collection burden in hours and number of collections for the previous year, and the burden reduction goals for the current year.
2. The most significant burden reduction accomplishments from the previous year.
3. The most significant planned burden reduction initiatives for the current year.

If an IC's total information collection burden will increase for the current year, the IC must provide the primary statutes and/or regulations that cause the increase.

L. The Review Process for Requests for PRA/OMB Approval, Interoffice Communications, and Timing

1. THE REVIEW PROCESS
   As noted under Responsibilities, Section D, all NIH projects originating in the ICs must be reviewed by the PCB before being forwarded to HHS and OMB for PRA review. Additionally, the NIH Privacy Act Officer must review the proposed submissions to determine the applicability of the Privacy Act.
   It is generally recommended that NIH staff, working through their PCL, submit draft documents (to include supporting statements and/or survey tools) for preliminary review by the PCB. Satisfactory submissions are signed off by the PCB and PCL after receipt of the required electronic documentation. If PCB review indicates that the submission is not adequate for forwarding to HHS, the PCB may ask the PCL for more information, clarification of issues, or complete revision.
   The review process at each successive level operates similarly. All projects originating in NIH are reviewed by the HHS Reports Clearance Officer (RCO) before they are forwarded to OMB. If the RCO review indicates that the submission is not adequate for forwarding, the reviewer may ask the PCB for information or, if the problems are

major, may return the project with a requirement for further explanation. Proposals may be resubmitted as soon as the issues have been resolved. After approval by HHS, the proposal is forwarded to OMB. Departmental submissions to OMB are announced in the Federal Register (30-day FRN) and, upon request, are available to the public. Comments from the public are made directly to OMB. Questions raised by OMB desk officers are transmitted to the PCB for resolution.

2. CHANNELS OF COMMUNICATION
   NIH communications, both formal and informal, both to and from OMB are to be made through the Project Clearance Branch, OER/OPERA. The PCB will make all efforts to resolve issues that NIH staff brings to its attention. This includes requesting meetings/discussions with HHS or OMB. Under no circumstances should IC liaisons or staff directly contact HHS or OMB about the substance or process of their clearance requests.
3. TIMING THE REQUEST FOR PROJECT REVIEW AND APPROVAL
   The PRA of 1995 and the OMB Implementing Regulations require an extended period to allow for adequate public input on proposed information collections. The initial step involves preparing the documents followed by the 60-day Federal Register Notice. After any comments received during the 60 day period are addressed in the Supporting Statement, section A.8, the request can then be forwarded to HHS for review.
   Prior to HHS submitting the request to OMB, the IC must first publish a 30-day Federal Register Notice requesting that further comments from the public be directed to OMB. At the conclusion of the 30 day comment period, OMB has an additional 30 days to take action. OMB may approve the request, require modifications, enter into discussions with NIH to resolve areas of uncertainty, request the agency to withdraw the request or disapprove the request. Approval may be made with specific terms of clearance, which incorporate the response of the IC to OMB questions or restrict the information collection to comply with OMB standards.
   The overall time for obtaining PRA clearance, including preparation of documents, is generally 6-9 months. Staff must anticipate a long delay in initiating any information collection request.

M. Special Circumstances

1. EMERGENCY REVIEW

   An IC may only seek emergency clearances when compelling circumstances arise that could not have been foreseen. Failure to plan ahead is not an adequate reason to declare an emergency. The IC must provide a full explanation of the emergency situation in the Supporting Statement.

   The Guidance on Agency Survey and Statistical Information Collections, January 20, 2006, item #9 cites the following conditions governing emergencies:

   When the collection of information

- is needed prior to the expiration of time periods established under 5 CFR 1320; and
- is essential to the mission of the agency; and

When the agency cannot reasonably comply with the normal clearance procedures under 5 CFR 1320 because

- public harm is reasonably likely to result if normal clearance procedures are followed;
- an unanticipated event, e.g., natural disaster, has occurred; or
- the use of normal clearance procedures is reasonably likely to prevent or disrupt the collection of information or is reasonably likely to cause a statutory or court ordered deadline to be missed (e.g., Congressional deadlines).

ICs should consult with the PCB regarding the process to be followed when requesting an emergency clearance.

2. GENERIC CLEARANCE

A generic clearance is a plan for conducting more than one collection of information using very similar methods. The review of this plan occurs in two stages: (1) a full PRA review of the generic clearance ICR, which includes the general approach and methodology, at least once every three years, and (2) an expedited review of the individual collections that fall within the scope of the generic clearance. A generic clearance is considered only when the agency is able to demonstrate that there is a need for multiple, similar collections, but that the specifics of each collection cannot be determined until shortly before the data are to be collected.

The Guidance on Agency Survey and Statistical Information Collections, January 20, 2006, item #8 identifies the following collections that are appropriate for consideration as generic:

- methodological tests,
- focus groups,
- other pretesting activities,
- many customer satisfaction surveys.

Each collection under the generic clearance must be well defined in the overarching ICR approved by OMB in terms of its sample or respondent pool and research methodology, and each individual collection should clearly fit within the overall plan. Individual collections should not raise any substantive or policy issues or go beyond the methods specified in the generic ICR. Any individual collection that would require policy or methodological review is inappropriate for expedited review under the generic clearance and must go through the full PRA process.

The ICs should follow the guidance on the PCB website https://nih-extramural-intranet.od.nih.gov/d/nih/policies/project_clearance/pcb.htm for submission of generic clearances. The overall time for obtaining PRA clearance for the full generic ICR is 6-9 months; an expedited review of individual collections takes approximately 4-6 weeks.

N. After OMB Action

1. NOTICE OF OMB ACTIONS

Formal notification of final OMB action on a Request for Review is transmitted by OMB in the form of a computer-generated Notice of Action. This notice contains the information from the submitted PRA ICR plus any remarks the OMB reviewers wish to make as conditions of approval or reasons for disapproval. If OMB's comments are extensive, the brief statements in the Terms of Clearance of the Notice of Action (NOA) may be supplemented by a letter attached to the NOA.

a. Approval: By law, such approvals are granted for up to three years.
b. Approval with Terms of Clearance: OMB may respond with a Terms of Clearance which specify conditions of approval.
c. Disapproval: A brief explanation of the reasons for disapproval accompanies the Notice of Action in these cases. In most cases, if OMB intends to disapprove a request, the PCB will be contacted and the potential reasons for disapproval will be explained. The ICs will have the option to withdraw their request or to negotiate with OMB via the PCB. During negotiations, whenever possible the ICs should produce justifications different from or more strongly stated than those in the original supporting statement.

   If a notice of disapproval is issued, the IC must begin the PRA review process from the beginning, addressing in their revisions any comments OMB listed in the Notice of Action.

2. CHANGES TO APPROVED PROJECTS

Non-substantive changes which alter only the format of approved data collections, or minor modifications in wording that do not affect substance or burden, may be made by the IC, in consultation with the PCL and the PCB, to OMB. In addition, changes in burden, however minor, or a change in title must also be reported to OMB. A justification is submitted to OMB (through the PCB) from the IC.

* A change is considered substantive any time new respondents are added to a collection or a new instrument is being used and will require a revision of the full ICR.

3. REVISIONS OF APPROVED PROJECTS THAT REQUIRE OMB APPROVAL

Any material or substantive change in the information collection, burden estimate, or use for the information must be submitted for OMB review. Generally, the most recently approved Supporting Statement and a memorandum describing the proposed changes and their purpose are sufficient. However, if the change is a fundamental modification of the basic study design, the Supporting Statement must be rewritten. Also, full justification (with OMB review) is required when it is proposed to use a questionnaire or form in circumstances other than those for which it was approved.

4. EXTENSION OF THE EXPIRATION DATE OF CURRENTLY APPROVED INFORMATION COLLECTIONS WITHOUT ANY CHANGE IN THE SUBSTANCE OR METHOD OF COLLECTION

    a. 3-Month Extensions

    The expiration date of a currently approved project may be extended for up to 90 days upon simple request to OMB (through the PCL and PCB), with an explanation of the need for a longer period of approval. No other changes, for example, in the method of collection or the burden, are permitted during such an extension. Three-month extensions, thus, are reported to, and recorded, but not reviewed by OMB. Only one three-month extension may be reported to OMB for any given project.

    b. Extensions of more than three months

    Extensions of more than three months require the submission of a full Request for OMB Review.

5. REINSTATEMENT OF A PREVIOUSLY APPROVED COLLECTION FOR WHICH APPROVAL HAS EXPIRED

    Reinstatement requires a full Request for OMB Review

O. Records Retention and Disposal

All records (e-mail and non-e-mail) pertaining to this chapter must be retained and disposed of under the authority of NIH Manual 1743,"Keeping and Destroying Records", Appendix 1, "NIH Records Control Schedule," Section 4000 Grants and Awards (all that apply), Section 1100-General Administration, Item L. Patents Inventions and Licensing (and any other items that apply), and Section 2600 Procurement, Property and Supply Management (all that apply). Refer to the NIH Manual for specific instructions.

NIH e-mail messages. NIH e-mail messages (messages, including attachments, that are created on NIH computer systems or transmitted over NIH networks) that are evidence of the activities of the agency or have informational value are considered Federal records. These records must be maintained in accordance with current NIH Records Management guidelines.

Contact your IC Records Officer for additional information.

All e-mail messages are considered Government property, and, if requested for a legitimate Government purpose, must be provided to the requester. Employees' supervisors, NIH staff conducting official reviews or investigations, and the Office of Inspector General may request access to or copies of the e-mail messages. E-mail messages must also be provided to Congressional oversight committees if requested and are subject to Freedom of Information Act requests. Since most e-mail systems have back-up files that are retained for significant periods of time, e-mail messages and attachments are likely to be retrievable from a back-up file after they have been deleted from an individual's computer. The back-up files are subject to the same requests as the original messages.

P. Internal Controls

The purpose of this manual issuance is to provide policies and procedures governing the collection of information from the public.

1. **Office Responsible for Reviewing Internal Controls Relative to this Chapter:** Office of Extramural Research, Office of Policy for Extramural Research Administration, Project Clearance Branch
2. **Frequency of Review:** Every five years.
3. **Method of Review:** The Project Clearance Branch evaluates input from users based on e-mail, telephone calls, meetings and memoranda, and makes appropriate changes as needed.
4. **Review Reports are sent to:** Deputy Director for Extramural Research (DDER) and Deputy Director for Management (DDM)

Q. Effective Date

This policy is effective on date of release.

R. Additional Information

For further information on this chapter contact the Project Clearance Branch, Office of Policy for Extramural Research Administration, Office of Extramural Research, Rockledge 1, 6705 Rockledge Drive, Suite 350, Bethesda, MD 20892-7974, phone: (301) 594-7949.