NIH POLICY MANUAL

1825 - INFORMATION COLLECTION FROM THE PUBLIC
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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 1980 (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 provided in Appendix 1.

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The Paperwork Reduction Act of 1980 superseded and extended the Federal Reports Act of 1942, and encompasses Federal statistical programs, including the collection of data, authority over which was accorded to OMB under the Budget and Accounting Procedures Act of 1950.

C. References:

1. 44 U.S.C. Chapter 35, Public Law 96-511, Paperwork Reduction Act of 1980.

2. 5 CFR Part 1320, Controlling Paperwork Burden on the Public.

3. 45 CFR 46, Protection of Human Subjects.

4. NIH Manual Chapter 1730, Forms Management.

D. Responsibilities:

1. OFFICE OF MANAGEMENT AND BUDGET (OMB)

Within the OMB, the Office of Information and Regulatory Affairs, 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 Federal Information Locator System (FILS).

2. DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Section 3506 of the PRA requires that each Department Head designate a Senior Official reporting directly to the chief executive of the Department. The Senior Official has responsibility for independently assessing all departmental collections of information to ensure that they meet the requirements of 5 CFR Part 1320, the Privacy Act, statistical standards and directives, and any other information policy directives. Within HHS, that official responsible for this function is the Assistant Secretary for Management and Budget (ASMB, OS).

3. PUBLIC HEALTH SERVICE (PHS), OFFICE OF THE ASSISTANT SECRETARY FOR HEALTH (OASH)

The ASMB, HHS, has redelegated to the Assistant Secretary for Health (ASH), HHS, OMB clearance functions within the PHS. This includes ensuring compliance with clearance policies, standards, procedures, and instructions from the Department and OMB, as well as department-wide health statistical planning, policy, coordination, and standard setting functions under the PRA.

4. NATIONAL INSTITUTES OF HEALTH

a. NIH Project Clearance Officer (PCO), Office of Extramural Research (OER)

As required by PHS, NIH has an identified focal point for OMB clearance functions. The PCO is responsible for:

- interpreting the PRA and implementing regulations for the NIH;
- ensuring the quality and completeness of NIH request for OMB approval, and of the NIH portion of the HHS Information Collection Budget (ICB);
- developing and implementing NIH operating procedures;
- maintaining NIH records and inventories;
- keeping BIDs informed about information collection requirements and the policies and procedures associated with the clearance process; and
- responding for NIH to questions raised by PHS, HHS2, or OMB on information collection issues.

b. BID Project Clearance Liaisons (PCL)

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

- ensuring that projects presented for review by the PCO have followed appropriate review and approval procedures required by their components or by NIH;
- ensuring that projects have the official approval of the initiating component;
- maintaining BID records and inventories, and preparing the data submission for the ICB;
- providing guidance to individual staff, e.g., project officers, contracting officers, etc. concerning information collection requirements and the administrative aspects of the clearance process; and
- monitoring information collection projects along with project officers/contracting officers.

c. BID Staff Initiating Information Collection Activities

BID staff are responsible for:

- familiarizing themselves with the types of information collection activities which require OMB approval;
- coordinating with their PCL to ensure the proper preparation of materials to be submitted to OMB for review; 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.1).

E. Definitions:

The definitions in 5 CFR Part 1320 (Appendix 1 at 1320.7) apply to this chapter.

F. Policy for Collections of Information:

1. NIH-sponsored collections of information from ten or more persons, including "reporting", "recordkeeping", or "disclosure" requirements as defined by OMB's regulations, may be implemented only with a current and valid OMB control number, signifying OMB approval.

2. If the topics or particular items of information to be collected from the public are specified by the BID, OMB 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 BID 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.

3. The OMB has identified specific categories of activities, the items therein not generally considered "information," as defined by 5 CFR 1320.7(j); however, the OMB may determine that any specific item constitutes "information."

4. The OMB determines whether a collection of information is necessary for the proper performance of NIH's functions. (Information collections mandated by statute or court order are considered necessary.)

5. To obtain OMB approval, BIDs must demonstrate that:

- the proposed collection is appropriate to the mission of the BID;
- the proposed collection is designed in a way which imposes the least burden on respondents consistentwith the achievement of program objectives;
- the proposed collection does not duplicate information which is otherwise available;
- all reasonable steps have been taken to minimize the costs to the Government and to respondents of collecting, processing, and using the information;
- and the proposed collection has practical utility to the Federal Government.

6. 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.

7. Unless the agency is able to demonstrate that a collection of information is necessary to satisfy statutory requirements or other substantial need, OMB will not approve a collection of information:

- which requires respondents to report information to the agency more often than quarterly;
- which requires respondents to prepare a written response to an information collection request in fewer than 30 calendar days after receipt of the request;
- which requires respondents to submit more than an original and two copies of any document;
- which requires awardees to submit or maintain information other than that required under OMB Circulars A-102 or A-110;
- which provides for any payment or gift to respondents, other than

renumeration of contractors or grantees;

- which requires respondents to retain records other than health, medical or tax records for more than three years;
- which contains a statistical survey component that is not designed to produce results that can be generalized to the universe of study;
- unless the agency has taken all practicable steps to develop separate and simplified requirements for small businesses and other small entities;
- which requires respondents to submit personal, proprietary, trade secret, or other confidential information unless the agency can demonstrate that it has instituted procedures to protect its confidentiality to the extent permitted by law;
- which requires respondents to maintain or provide information in a format other than that in which the information is customarily maintained;
- which contains a statistical survey component in which a response rate of less than 75 percent is estimated;
- where the information collection activities involve programs which have been phased out or for which funds have not been budgeted;
- unless the agency has considered reducing the burden on respondents by use of automated collection techniques or other forms of information technology.

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. COVER MEMORANDUM -- A memorandum that is addressed to the Reports Clearance Officer (RCO), PHS, through the PCO, and through the BID PCL. It should briefly describe the nature of the information collection and why it is needed referencing its current or earlier OMB approvals, as appropriate.

2. STANDARD FORM 83 (SF-83), Request for OMB Review -- This form and instructions have been developed by OMB. It requires identification of the sponsoring BID; 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 form and OMB instructions are provided at Illustration 2. Supplemental NIH instructions, are available from either the PCO or PCL. A supply of the SF-83 forms can be obtained from the PCO.

3. SUPPORTING STATEMENT FOR REQUEST FOR OMB APPROVAL
This is a double-spaced narrative prepared according to the

"Specific Instructions for Preparing a Supporting Statement for OMB Approval Under the Paperwork Reduction Act and 5 CFR 1320" described in Appendix 2. The supporting statement 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. Supplemental NIH instructions have also been developed and are available from the PCO to assist NIH staff in preparing the supporting statement.

4. ATTACHMENTS -- Back up materials are necessary to explain all aspects of the information collection activity. They should include the following:

- applicable section of statue and/or regulation authorizing the collection of information;
- data collection instruments such as forms, questionnaires, telephone interview guides, etc.;
- instructions to respondents for assembling and reporting information;
- introductory and follow-up letters to respondents, or scripts in the case or 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; and
- any additional back up material necessary to explain the purposes, approach, procedures and methodology of all aspects of the data collection whenever statistical methods are employed.

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 OMB requirements that are noted in this section.

1. PROTECTION OF THE 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 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 BID;
- 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. (See Section H.1.e.)

These preliminary explanations should be sufficient to serve as the basis for obtaining informed consent. There is no requirement under OMB 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 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, sex 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. Protection of Human Subjects

The PHS Act and other enactments have established special safeguards for biomedical or behavioral research projects involving human subjects which are carried out under the auspices of the Department. 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 Protection from Research Risks (OPRR), OER, OD, on 496-7005.

d. 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.

e. Requirements for Information Collections Involving Individually Identifiable Information, including Social Security Numbers.

Unless there are compelling reasons to the contrary PHS 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-d, 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.

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:

1. 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.

2. 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.)

3. The records must be under the control of the NIH or a BID, either by physical possession and in-house management or when the records are maintained under contract if the Privacy Act applies to the contract.

When these three conditions are met. the PHS component sponsoring the data collection must assure that the content, organization, use, location, protection, disposition, and conditions of access and disclosure

are accurately described in a notice of system of records. This notice must be published and reported in accordance with requirements of the Privacy Act before data is first collected or before any major changes are made in the system of records, its use or disclosures. (For further information contact the NIH Privacy Act Officer, Division of Management and Policy (DMP), 496-2832.)

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 individually identifiable information unless there is a firm legal basis for withholding information in the face of a subpoena, or court order, or other Federal, state, or locallegislation.

There are some statutes which protect data against disclosure, although their coverage is limited. Among these statutes are: 1) Section 308(d) of the Public Health Service Act, governing data collection in statistical, epidemiological and health services research and 2) Section 303 of the Public Health Service Act, one authorizing a grant of immunity against subpoena for research involving drug or alcohol abuse or mental health. Data collected for treatment of drug and alcohol abuse patients (as distinguished from research) is subject to special statutory restrictions on disclosure (Sections 523 and 527 of the Public

Health Service Act) which should be appropriately summarized for those providing information about themselves for such purposes.

When there is no legal basis for a promise of confidentiality other that 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.

f. The "Confidentiality of Information Clause" in Contracts

Where a collection of personality 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 individually identifiable information requires 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 as stated in Section H.1.e.

g. Confidentiality Protection

Section 163 of the Health Omnibus Programs Extension of 1988 (Public Law 100-607) entitled Miscellaneous Amendments appears to extend the confidentiality protection to all PHS research subjects, including participants in AIDS protocols. Section 301(d) of the Public Health Service Act now reads:

The Secretary may authorize persons engaged in biomedical behavioral, clinical, or other research (including research on mental health, including research on the use and effect of alcohol and other psychoactive drugs), to protect the privacy of individuals who are the subject of such research by withholding from all persons not connected with the conduct of such research the names or other identifying characteristics of such individuals. Persons so authorized to protect the privacy of such individuals may not be compelled in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings to identify such individuals.

When guidelines are developed to implement that confidentiality protection this section will be revised.

h. Special Requirements Concerning the Collection of Social Security Numbers

Under section 7 of the Privacy Act, no individual may be denied any government right, benefit, or privilege because the individual refuses to disclose his/her Social Security Number (SSN), unless a Federal statute requires it, or unless the practice was established by statute or regulation prior to

January 1, 1975.

If NIH requests an individual's SSN, it must inform the individual of the statute or other authority to solicit the SSN. In addition, the respondent must be informed about the uses which will be made of it, and whether his/her disclosure of the SSN is mandatory or voluntary. This information must appear on the public use report or information collection form itself, or on a separate form which can be retained by the individual.

2. RESPONDENT BURDEN

The Paperwork Reduction Act of 1980 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 in determining the extent of the burden (less than nine individuals).

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 requested 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 Management Officer, Records Management Branch (RMB), Division of Management and Policy, 496-2832.

g. Agency disclosure of estimated - BIDs shall disclose on each collection of information, as close to the current OMB control number as practicable, the estimate of the average burden hours per response. BIDs shall include with this estimate of burden a request that the public direct to the RCO. PHS and the Office of Information

and Regulatory Affairs any comments concerning the accuracy of the burden estimate and any suggestions for reducing the burden.

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 BID decisions which were based on similar data, or present problems which require the proposed data for resolution.

For purposes of OMB review and approval, sponsors should consider the practical utility of the expected results in furthering the mission of the sponsoring BID. 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 it demonstrates practical utility, (see 5 CFR 1320.7(o) in Appendix 1).

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;
- consultation with the RMB, DMP;
- 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 (FILS).

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 respond.

For OMB clearances, if respondents are drawn from the general population and are asked for no more than answe rs to survey questions, costs to respondents are calculated at the rate of $10 per hour. 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. In almost all instances of this kind, project sponsors should consult with representative respondents before making the cost estimate (consult with fewer than nine respondents).

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 PCO) 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.

For projects submitted for OMB review and approval, the RCO, PHS (and also Director, Division of Data Policy, OASH, PHS) makes the final PHS recommendation concerning NIH's justification for the studies and study designs proposed.

7. PRETESTS

An otherwise well designed survey may prove useless if respondents do not understand questions or instructions, or if planned procedures fail in operation. Therefore, a pretest of the survey procedures and instruments is strongly recommended, and the survey plan should include time and funds for this step. A pilot study may be necessary to determine whether the survey is practical, feasible or useful at all. The relative effectiveness and cost of alternative questionnaires, instructions, and operating procedures can be evaluated by means of a small pretest. While pretests or pilot tests of nine or fewer respondents may sometimes be sufficient for very limited purposes, most pretests will involve more than nine respondents to produce useful results and
consequently will require a submission for OMB approval.

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. Special Cases:

1. "CLINICAL EXEMPTION FROM OMB REVIEW AND APPROVAL

The OMB definition of "information" at 5 CFR 1320.7(j) (5) generally excludes facts and opinions obtained fromindividuals under treatment or clinical examination. 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.

The NIH Clinical Exemption Review Committee (CERC) consists of five members including the Clinical Exemption Coordinator (CEC), OEP, OER. The four non-OER members are NIH staff to include a physician, an epidemiologist, and an individual familiar with ethical concerns. Appointment terms are four years, with one non-OER member retiring each year. All appointments are made by the Deputy Director for Extramural Research (DDER).

Procedures for review of projects and definitions for clinical exemption are attached at Appendix 3.

All projects are expected to comply with the requirements under Section I.l of this chapter concerning the sensitivities and privacy of participants, the protection of human subjects, and the protection and disposition of records, with careful attention to the burden placed on participants. It is expected that projects will be technically sound and so documented, with data collection methodology and procedures appropriate to the intended use of the data. Projects (or portions thereof) not meeting the criteria for "clinical exemption" (exemption from OMB review and approval) may be initiated only upon OMB review and approval. The official file of CERC deliberations is maintained in OER.

In its reviews for clinical exemptions, CERC may comment on any aspects, meet with the PCO, suggest modifications, request additional information, and otherwise contribute toward improving projects to be conducted or sponsored by the NIH.

Information collection needs identified subsequent to CERC review (i.e., those over and above data collection reviewed and exempted) must be discussed with the Project Clearance Officer and the CEC of the CERC for a determination whether OMB or further CERC review is necessary.

Projects sponsors and PLCs are notified concerning the outcome of CERC reviews and are expected to monitor each exempted activity closely to ensure that projects are conducted as proposed and reviewed. Substantive changes to projects reviewed and exempted by CERC must be reported to the CEC.

2. EPIDEMIOLOGICAL CASE-CONTROL AND COHORT STUDIES

Requests for OMB approval of certain types of analytic epidemiological studies, e.g., of the relationship of potential risk factors to health outcomes, involve concepts which require special consideration and emphasis. Typically, these studies employ a prospective or historical cohort research design, or a case-control research design. In addition to the usual requirements, certain specialized information must be included in the Supporting Statement for these types of studies. The guidelines outlining this supplemental information are attached at Appendix 4.

J. Information Collection Requirements in Regulations:

The Paperwork Reduction Act of 1980 and implementing OMB regulations provide that all information collection requirements in regulations are subject to OMB review and approval. Explicit approval is required for each the regulatory section which contains information collection, record retention or other requirements, in addition to any approvals which may have been granted to forms or projects used to implement those requirements.

The requirements for OMB review and approval of information collection requirements in regulations applies at every stage of the rulemaking process; i.e.,

- Notices of Proposed Rulemaking (NPRM);
- Final Rules;
- existing regulations, the information collection requirements of which were not explicitly approved at the time the forms associated with them were cleared;and
- regulations promulgated before enactment of the Paperwork Reduction Act, which have never been submitted for review by OMB.

Most regulatory requirements subject to the Paperwork Reduction Act fall under one or more of five general categories: reporting, recordkeeping, disclosure, testing or auditing as described below:

Reporting: Information which must be provided to a Federal agency in order to comply with a statutory requirement or to obtain or retain a benefit. In general, sections of the regulations which direct the person or organization to take some action with regard to reporting are subject to approval. Such sections usually contain verbs such as provide, submit, include, furnish, etc., followed by a description of the general or specific information which is required. For example, the regulations for grant programs normally include one or more sections specifying the information which must be provided in grant applications. These specifications serve as the basis for the design of the application forms and instructions which are used to collect the information.

Since there is never a perfect correspondence between the regulatory language and the forms, and since both regulations and forms are subject to change, OMB has ruled that both must be approved. Approval may be requested for both the regulatory requirement and the form under one OMB number, or a separate approval may be requested for each.

Recordkeeping: Information which must be maintained by an individual or organization, usually for a stated period of time. The purpose of the recordkeeping may be to provide data for

reporting. (Frequently, however, there are no associated reporting requirements.) Recordkeeping requirements which require approval will usually include words and phrases such as maintain records, record, document, have written agreements, etc. An example of the recordkeeping requirements in regulations is the requirement for Institutional Review Board (IRB) and Institutional Animal Care and Use Committee (IACUC) minutes specified in the Protection of Human Subjects Regulations and the PHS Policy on the Human Care and Use of Laboratory Animals, respectively. Since there is usually no form used to implement recordkeeping requirements, the only way that OMB can assess the burden and practical utility of such requirements is through review of the regulatory language. Similarly, since there is no form on which to display the OMB number, the only way the public can be informed that the requirement has OMB approval is
through publication of the approval number in the Code of Federal Regulations.

Disclosure: Information which must be provided by an individual or organization to the general public or to designated third parties, rather than to a Federal agency directly. Disclosure is usually accomplished by means of labeling, posting, or other methods of notification, such as the informed consent statement required by the human subjects regulations.

Testing: Procedures which must be carried out solely for the purpose of obtaining the information necessary to meet reporting, recordkeeping or disclosure requirements.

Audit: Information which must be maintained forexamination in periodic or unscheduled inspections.

The degree of specificity used to describe the information collection also determines if the regulatory section is subject to OMB approval; general directions such as the following are not usually subject to approval:

- Each applicant seeking a grant must submit an application at the time and in the form and manner that the Secretary may require.
- The applicant must maintain records and file with the Secretary those reports relating to the program that the Secretary may find necessary to carry out the purposes of the Act and these regulations.

Such general directions may be viewed as authorizing language for any forms subsequently specified by the program for recordkeeping or reporting. The

forms themselves require specific and separate OMB approval.

Information requirements specified in regulations are subject to HHS and OMB procedures governing the development and approval of regulations. Since procedures governing this type of submission are subject to change, NIH staff should consult with both the Division of Management Policy, OA, and the PCO. The following are general principles governing information requirements in regulations:

> NPRMs may be published in the Federal Register only after the information collection requirements in them have been submitted for OMB review and approval has been obtained. Staff should plan to submit appropriate documentation to the PCO, as soon as it is available, for forwarding to RCO, PHS at the time the NPRM is transmitted from NIH.
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> The preamble to the NPRM shall include the following: (a) the title of the information collection; (b) a brief description of the agency's need for and planned uses of the information, (c) a description of the likely respondents; (c) an estimate of the total and disaggregated reporting and recordkeeping burden that will result from each collection of information; and (d) an invitation to send comments on the burden estimate to the Office of Management and Budget and to the designated agency official.
>
> Final Rules may not be published in the Federal Register until the information collection requirements have been reviewed by OMB.
>
> Wherever possible, all information requirements in the regulations concerning a particular program should be cleared as a group. Changes in currently approved regulations should be treated as revisions to the existing clearance.
>
> An important consideration in requesting OMB approval for information requirements in regulations is the burden. Respondent burden imposed by the regulations per se must be determined apart from the burden associated with any forms used to implement the regulation. Generally, when the required information is collected by a form, the burden should be associated with the form.
>
> The components of a request for OMB review and approval are essentially the same as those for regular clearance requests (see Section G & H). Attachments would include sections of the regulations for which clearance is being requested, relevant

sections of the authorizing statute, and any other information deemed appropriate.

K. Forms, Including Application for Benefits, and Standard and NIH Forms:

To reduce the number of forms in use by Federal agencies, standardize certain information requirements, and simplify data collection, a number of "standard forms" and "optional forms" have been developed for government-wide use (e.g., SF-171; SF-83). Programs are encouraged to use standard forms wherever possible. If program needs can be satisfied by existing standard forms, no further OMB action is necessary, because all public use standard forms already have OMB approval. The NIH FMO, DMP, can assist staff in determining if an appropriate standard form is available. NIH must account for the burden imposed by its use of standard forms by reporting annually to the General Services Administration (GSA). Offices responsible for initiating or discontinuing use of a public use standard form should contact the FMO.

If a BID wants to deviate from an existing standard form, approval from both the GSA and OMB is required. The FMO will assist in developing the GSA clearance materials; the PCO will assist in developing the OMB materials. The GSA and OMB submissions are forwarded to PHS as a single package. Departmental and GSA approvals are required prior to OMB review. HHS, PHS, and NIH Forms.

When a standard form (or modification of a standard form) does not exist for the information collection needs, an HHS, PHS, or (most often) NIH form will have to be created or an existing form revised. Contact the NIH Forms Managements Officer for assistance and clearance (and see NIH Manual 1730) early in the planning stages.

Extramural Forms

Assistance related forms, such as applications, reporting instruments, and associated forms impacting on the review process, the extramural data system, and/or grants policy require coordination among the FMO, and the PCO, and input from the relevant standing NIH Staff Committees: Extramural Program Management Committee, Review Policy Committee, and Grants Management Advisory Committee. Individuals identifying the need for a new or revised extramural form are urged to contact the FMO and PCO in the earliest planning stages for technical assistance and advice concerning applicable clearance procedures. Extramural report forms (e.g., grant application forms) and instructions must also be approved by the Grants Policy Officer, OER, and the Director, Division of Grants and Contracts, ORM/OM, PHS, before being submitted through PHS and the Department to OMB. If the basic OMB-approved grant application or reporting forms are supplemented by requests for

additional program specific information, the BID responsible for the supplement must prepare and submit a separate OMB clearance request for that supplement; supplements clarifying or simplifying a basic OMB-approved information collection generally do not require additional OMB approval.

L. Information Collection Budget (ICB):

5 CFR 1320.10 requires that each agency develop and submit annually a comprehensive budget for all collections of information from the public to be conducted or sponsored by the agency in the succeeding 12 months. The ICB is expressed in the number of hours required of the public to comply with request and requirements for information.

Each BID PCL prepares a BID ICB in the spring of the fiscal year preceding the year to which it pertains. Working with project officers, PCLs identify all data collections, both new and ongoing, to be implemented or continued, respectively, and provide a brief project description and burden estimate for each.

These BID ICBs are submitted to the PCO, who develops a consolidated NIH ICB. Submissions are reviewed in OER for policy, planning and coordination concerns, and for their impact on respondent burden. When all issues have been satisfactorily resolved, the individual BID ICBs are aggregated into a consolidated NIH ICB, with a narrative description of NIH's data needs and plans for the future, and forwarded to PHS for subsequent inclusion in the HHS ICB, which is submitted to OMB.

The deadline for OMB receipt of the Department's ICB is approximately mid-July. In the following months, OMB holds hearings on the requests before completion of its review and transmittal of a passback, which gives a total information collection allowance of respondent burden hours for the Department for the fiscal year. This allowance is generally divided into two components: one for ongoing (continuing) projects, and one for new projects. The passback may disallow specific projects. It may also contain specific suggestions for eliminating or reducing respondent burden. In providing this passback detail, OMB is not committing itself to providing approval for any of the proposed (new) items contained in the ICB request. Such decisions will be based upon the merits of each individual request subsequently submitted for OMB review and approval.

If there is a possibility that project will be implemented, it is important to include it in the ICB. Projects that are not in the ICB are subject to the availability of burden hours within the ceiling approved by OMB for the Department and the allocations made to PHS and NIH. When a collection of information is proposed during the course of the year, which was not included in the annual budget, the PCL will generally need to make offsetting reductions in

other items in the BID budget.

Information collection activities ongoing without OMB approval should also be included in the ICB request. Information collections most frequently found in this category are regulatory (policy) requirements or administrative forms which were undiscovered or inadvertently overlooked in 1981 when the NIH identified activities requiring OMB approval subsequent to the enactment of the PRA. Whatever their purpose, such collections should be submitted for review and approval as soon as they are discovered. These previously unsanctioned ("bootlegged") activities are subject to the same potential disallowance or required burden reduction as is any other project.

M. The Review Process for Requests for OMB Approval, Interoffice Communications, and TimingForms:

1. THE REVIEW PROCESS

As noted under Responsibilities, Section D., all NIH projects originating in the BIDs must be reviewed by the PCO before being submitted for OMB review. It is generally recommended that NIH staff, working through their PCL, submit draft documents for preliminary review by the PCO. (See Section L. Procedures.) Satisfactory submissions are signed off by the PCO and PCL after receipt of the required number of copies. If PCO review indicates that the submission is not adequate for forwarding to PHS, the PCO 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 PHS are reviewed by the PHS RCO before they are forwarded to the ASH for signature. If the PHS RCO review indicates that the submission is not adequate for approval by the ASH, the reviewer may ask the PCO for information or, if the problems are major, may return the project with a memorandum explaining the issues. Proposals may be resubmitted as soon as the issues have been resolved. After approval by the ASH, the proposal is forwarded to the Department's Office of the Assistant Secretary for Management and Budget (ASMB) for review for Department policy concerns. Questions raised at this level are communicated to the PHS RCO which provides the required responses, calling on the PCO for additional information as necessary. Projects may be returned by the Department if issues cannot be resolved promptly. Satisfactory submissions are signed off by the Deputy Assistant Secretary for Management Analysis and Systems, ASMB, and forwarded to OMB. This review process within the Department

satisfies HHSAR requirements for ASMB approval of proposed information collections.

Departmental submissions to OMB are announced in the Federal Register 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 Department for resolution.

2. CHANNELS OF COMMUNICATION

NIH communications, both formal and informal, both to and from OMB are through PHS and the Department. Like-wise, communications from OMB are transmitted through the Department and PHS to the PCO.

The PCO will make all efforts to resolve issues that NIH staff brings to its attention. This includes requesting meetings/discussions with PHS or higher level staff. Under no circumstances should BID liaisons or staff directly contact PHS, the Department, or OMB about the substance or process of their clearance requests.

3. TIMING THE REQUEST FOR PROJECT REVIEW AND APPROVAL

OMB analysis and review in OMB may take up to 90 working days. Sixty days after OMB receives a request, it will notify the Department of either approval/disapproval or its 30-day extension of the review period. At a minimum, reviews by NIH, PHS, and the Department may each take one week. It should be noted that these are estimates for projects that are deemed satisfactory at each level of review. Projects requiring additional information, clarification, and/or complete revision take substantially longer.

There are no firm standards or guidelines for determining the stage in the development of a project at which a clearance request should be submitted. Because OMB approves or disapproves plans for information collection, staff are cautioned against entering into contract or other negotiations on projects that require clearance. If the Request for Proposals (RFP) prescribes the information collection plan, the information collection plan should be submitted for OMB review before the RFP is issued. If the RFP does not prescribe the information collection plan, then

prior to the signing of the contract, the Project Officer should submit a draft copy of the plan to the PCO so review at the NIH level can begin. If the contract allows the contractor to develop the survey plan, the plan should be submitted as soon as it is developed, even before survey forms or other documents are in final form.

a. Preliminary Clearance (Request for OMB Approval of a Concept)

Disapproval of a clearance request can be very costly. To guard against this, BIDs are strongly encouraged to seek preliminary clearance of large scale, costly, or complex data collection plans, especially if by contract. Preliminary clearance of the overall aim and design of a prospective study may be sought before a contract is negotiated. NIH recommends, but does not require, that such preliminary clearances be obtained. Preliminary clearance is also urged for program evaluations.

While a preliminary clearance does not guarantee final approval, it permits the project sponsors to develop the details of an information collection with some assurance that OMB considers the project or system an appropriate Federal activity and approves the general approach. Review of this type of request includes the need for and uses to be made of the data, along with a general description of the information collection plan, approach, methods, and schedule.

In seeking preliminary clearance, projects sponsors have the benefit of consultation with reviewers at the RCO, the Department, and OMB who can help them to anticipate and work out problems while changes are still easily accommodated and alert them to overlooked areas of coordination and consultation. At the same time, these reviewers become familiar with the objectives and design of the project, putting them in a position to expedite, upon request, the final review of the definitive data collection plans and final survey instruments.

All HHS contracts incorporate by reference the standard Paperwork Reduction Act clause which prohibits information collection without HHS and OMB approval. Contracting Officers are encouraged to clarify that this prohibition applies also to information collection devices which are not a contract requirement and that the Government will not reimburse the contractor for costs incurred in using information collection devices in violation of the Act or in processing information that may have been thus collected.

b. Emergency Review

OMB has established explicit criteria and procedures for emergency review.

Requests shall be accompanied by a written determination that the collection of information is:

> essential to the mission of the NIH; and
>
> (1) that public harm will result if normal clearance procedures are followed;
>
> OR
>
> (2) that an unanticipated event has occurred which will prevent or disrupt the collection of information or cause a statutory or judicial deadline to be missed if normal procedures are followed.
>
> All practicable steps must have been taken to consult with interested agencies and relevant members of the public in order to minimize the burden of the collection of information.
>
> NIH states the time period within which OMB should approve or

disapprove the collection of information.

The PCO shall send forth a prescribed Federal Register notice prescribed which indicates that it is requesting emergency processing.

If OMB approves the collection of information, it will assign a control number valid for a maximum of 90 days after receipt of the emergency submission.

Components of such a request for OMB review are the same as those stated in Section G. with the exception of the cover memorandum. The cover memorandum for an emergency submission consists of a memorandum from a BID Director, or equivalent, to ASH setting forth the information stated above. If after emergency approval is granted, more time than 90 days is required for the information collection activity, a regular request for OMB review and approval must be submitted.

c. Expedited Review

Upon request, OMB may agree to act on a request for approval of a collection of information on an expedited schedule, even though that submission may not qualify for emergency processing.

Components of such a request for OMB review are the same as those stated in Section G. In addition, the NIH is required to publish as part of the Federal Register notice the time period within which it is requesting OMB to approve or disapprove the collection of information, and a copy of the collection of information, together with any related instructions, for which OMB

approval is being sought.

In this case, the memorandum explains the special circumstances and indicates the date by which OMB action is required. If PHS agrees with such a request, the project will receive prompt review at PHS and will be forwarded to the Department with a request for priority review at the Department level and at OMB. OMB approvals under expedited review may be granted for up to the maximum of three years.

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 compu ter-generated Notice of OMB Action. This notice contains the information from the submitted SF-83 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 Remarks section of the Notice of OMB Action may be supplemented by a letter attached to the Notice.

a. Approval Without Conditions: By law, such approvals are granted for not more than three years.

b. Approval With Conditions: OMB frequently specifies a due date for compliance. In some cases, approval may be granted for a short time, with extensions of approval dependent on evidence of compliance with the specified conditions. NIH will not forward subsequent requests for extension without written verification that the specified conditions have been met.

c. Disapproval: A brief explanation of the reasons for disapproval accompanies the Notice of OMB Action in these cases.

2. APPEALS

OMB disapprovals may be appealed of the BID disagrees with the reasons stated by the OMB reviewers and can produce

justifications different from or more strongly stated than those in the original supporting statement. These justifications should be explained in a memorandum requesting OMB reconsideration and signed by the OPDIV Agency Head, or equivalent designee. The review process is the same as that for regular requests for OMB review (see Section J.), beginning with the NIH PCO.

3. FINAL PRINTED FORMS

As soon as possible after approval, the PCO requests sets of final printed forms and all materials provided to respondents for forwarding to OMB through PHS and the Department. Final forms, must be exactly the same, in content and wording, as those approved by OMB. The OMB approval number and expiration date and other required information must appear on the front page of all data collection instruments, preferably in the upper right hand corner.

4. CHANGES TO APPROVED PROJECTS

a. No OMB Action

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 BID, in consultation with the PCL and the PCO. If necessary, advice will be sought from the PHS PCO on whether further OMB action is required.

b. Notifying OMB

Changes in burden, however minor, or a change in title must be reported to OMB, through the PCL and the PCO, although review by OMB is not normally required.

5. REVISIONS OF APPROVED PROJECTS

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, a new SF-83, 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 other circumstances other than those for which it was approved.

6. 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 PCL and the PCO), 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. If the date of the most recent OMB review was less than one year earlier, it may be possible to use a copy of that Supporting Statement with an addendum explaining the need for continued approval. Supporting Statements more than one year old should be replaced by a newly written Supporting Statement.

Requests for extensions must be sent in a timely manner, preferably 90-100 days before the expiration date. The PCO notifies PCLs concerning expiring projects at intervals before the actual date of expiration. Unacknowledged notices sent from the PCO result in expiration of approval, and no further data collection may take place.

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

Reinstatement requires a fill Request for OMB Review. If the approval expired within the past six months and if there are no material changes in the plan or forms, the most recently approved Supporting Statement, a new SF-83, and a memorandum explaining the need to resume data collection are generally sufficient. However, if there are significant changes, or if the approval expired more than six months before, a new Supporting Statement is required.

O. Procedures:

1. BID PROJECT OFFICERS AND PROGRAM STAFF

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

a. familiarize themselves with the general requirements and guidelines of this Chapter (Section F.) and the requirements for all information collections (Section H.). These two sections outline, respectively, administrative matters associated with OMB clearance and minimum standards/practices concerning all information collections;

b. discuss their information collection projects with 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;

c. work closely with PCL to prepare: (a) draft OMB
submissions which they submit to the PCL for review, and (b) final packages according to proper format (see Illustration 1);

d. provide information/changes/revisions promptly to PCL, as requested as a result of NIH, PHS, Department, or OMB reviews;

e. after OMB approval, notify contractor or other awardee (where relevant) of OMB approval number and expiration date and forward copies of

the survey instrument through the PCL to the PCO;

f. 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.

2. BID PROJECT CLEARANCE LIAISONS

PCLs in the BIDs are the focal point for OMB clearance functions in the BIDs. As such, they are expected to:

a. inform the PCO about upcoming projects, and on potential problems or concerns about special data collection proposals;

b. work closely with project officers and program staff on Requests for OMB Review, giving guidance and instructions for completing the cover memorandum, SF-83, and Supporting Statement;

c. review draft packages from NIH staff for administrative completeness; ensure that the minimum standards/practices for all information collections, as described in Section H., are addressed; provide comments and feedback to staff prior to forwarding final draft for PCO review;

d. following NIH Project Clearance Office review, work 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 (see Illustration 1);

e. facilitate PHS, Department, and OMB reviews by the 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;

f. ensure that OMB submission are complete and accurate and forwarded promptly when requested

by members of the public;

g. after OMB approval is obtained, review the OMB Action Sheet for the accuracy of the data items on the Action Sheet, notifying the PCO of any inaccuracies; notify project officers about the OMB action and discuss any OMB conditions with them to determine how they will be met; and check that the final forms, in content and wording, are the same as those approved by OMB, and that the proper OMB number is displayed; and forward final forms to the PCO as soon as practicable;

h. in concert with project officers (and contracting officers), monitor information collection activities, giving advice and guidance concerning proposed potential changes;

i. monitor the conduct of clinically exempt activities to ensure that they are conducted as proposed (see Section I.l);

j. alert project officers to upcoming expirations;

k. maintain the complete and official file for each BID project and keep accurate records on all BID projects;

l. in concert with the NIH Project Clearance Office keep staff apprised of NIH, PHS, 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

m. prepare the annual Information Collection Budget (ICB) according to guidance from OMB, HHS, PHS, and the PCO (see Section I.5).

P. Effective Date:

This policy is effective on date of release.

Q. Additional Information:

For further information on this chapter contact the Project Clearance Officer,

Office of Extramural Research, Building 31, Room 5B41, Telephone: 496-1963.

R. Additional Copies:

For copies of this manual chapter send a Form NIH 414-5 "Request for Manual Chapter" to the Printing and Reproduction Branch (P&RB), DTS, Building 31, Room B4BN09.

Appendices

Refer to Hardcopy Appendix 1
Refer to Hardcopy Appendix 2

APPENDIX 3. PROCEDURES FOR REVIEW OF PROJECTS AND DEFINITIONS FOR CLINICAL EXEMPTION

To have an information collection reviewed by the Clinical Exemption Review Committee a narrative summary must be written which contains the following information:

(1) A precis of the study:

Summarize study aims, and design criteria for selecting population and controls, types of information to be obtained, and methods of collection (interview, hospital or registry record, etc.).

(2) Subject Recruitment and Care:

Describe the way the study is represented to potential participants (as in a letter or interview); describe the study in relation to optimum treatment for the disorder under investigation.

(3) Relevant Documents:

Attach letters of invitation, consent forms, survey instruments(s), and other documents that may help the committee reach a sound decision.

(4) Confidentiality/Human Subjects:

Provide a brief statement indicating compliance with:

(a) The Privacy Act - if the Privacy Act does not apply, give the reasons for that determination and indicate how individually identifiable information

will be protected.

(b) Basic HHS Policy for Protection of Human Research Subjects (45 CFR 46) - if the project has already been reviewed by an Institutional Review Board (IRB), give the date of review, noting any changes mandated by the IRB. If not yet reviewed by an
IRB, state the arrangements (process) for that review.

Submit six copies each of the above information to the NIH Clinical Exemption Coordinator, OER.

EXCERPT FROM POLICIES AND PROCEDURES FOR INFORMATION COLLECTION FROM THE PUBLIC, DHHS, PHS

Facts or opinions, obtained initially or in follow-on requests, from individuals (including individuals in control groups) in treatment for a clinical disorder in connection with:

- research on or prophylaxis to prevent the clinical disorder;
  direct treatment of that disorder;
- he interpretation of biological analyses of body fluids, tissues or other specimens; or
- the identification or classification of such specimens.

Conduct of a study in a clinical setting does not by itself provide grounds for exemption. In addition, this exemption does not apply to standard health-related surveys (including those involving a health examination component -- e.g., the National Health and Nutrition Examination Survey) and epidemiologic studies.

Individuals receiving a vaccine or drug would be considered "patients in treatment" as long as data were collected for purposes of evaluating the vaccine or monitoring effects.

If the respondent individuals, because of age or physical condition, are unable to communicate for themselves, requests for information from proxies are also exempt. Note, however, that the exemption does not extend to next-of-kin or others responding for deceased individuals; or adjuncts, such as spouses, responding in addition to the subject individuals.

For purposes of making the determination as to whether or not a particular clinical data collection is exempt:

- Treatment of a disorder is defined as measures taken to stabilize, reduce or eliminate the severity or duration of the disorder, or to reduce the disability associated with it. Before treatment can begin, the clinician must diagnose the condition and then act to cure it, lessen its severity, shorten its course, reduce its impairments, or at least try to avoid its progression and worsening. Treatment includes direct somatic (e.g. medication) and psychosocial (e.g. counselling) therapies, as well as referral to another, more appropriate clinical setting.
- Prophylaxis to prevent a disorder refers to measures taken to reduce either the occurrence of new disorders, or the recurrence of active disorders in subjects who have a history of the illness but who are in remission at the time of study. Requests for information from patients in remission, however, are exempt only if the information is provided during the course of a clinical examination. Prophylactic measures include those targeted specifically for the subject, such as dietary fortification with niacin to prevent pellagra.

APPENDIX 4. SUPPLEMENTAL GUIDELINES FOR REQUEST FOR OMB APPROVAL OF EPIDEMIOLOGICAL COHORT AND CASE-CONTROL STUDIES

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE

SUPPLEMENTAL GUIDELINES FOR
REQUESTS FOR OMB APPROVAL OF EPIDEMIOLOGICAL
COHORT AND CASE-CONTROL STUDIES

Office of Health Planning and Evaluation
Division of Data Policy
January 1987

I. BACKGROUND

The Paperwork Reduction Act (P.L. 96-511) requires all Federal Agencies to obtain Office of Management and Budget (OMB) approval to conduct information collections involving identical items from ten or more respondents, whether for research, statistical, administrative, or other purposes. Policies and procedures pertaining to this requirement in the Public Health Service (PHS) have been published (U.S. Public Health Service, 1985).

Among the types of information collection requests submitted to OMB by PHS Agencies are analytic epidemiological studies of the relationship of potential risk factors to health outcomes. Most often conducted by the Centers for Disease Control and the National Institutes of Health, the studies typically employ a prospective or historical cohort design, or a case-control design.

Reviews of these types of OMB submissions have consistently raised questions or indicated the need for additional information relating to: 1) clarity of scientific purpose; 2) related studies; 3) detectable relative risks and their rationale, and 4) sample size and expected statistical power of the studies. Attempts to resolve these questions at such a late stage of study development have resulted in delays in obtaining OMB approval and, in some instances, to disapproval of the study as the review period expires.

Review of this experience indicates that the relevant information is an essential component of sound research design, and in most instances has already been developed by PHS investigators in the planning of the studies. Therefore, the routine inclusion of this information in requests for OMB approval should assist in facilitating the review process. Accordingly, the following guidelines have been developed to outline supplemental information which should be included in the supporting statement of information collection requests for OMB approval of epidemiological cohort and case-control studies.

II. PURPOSE

The purpose of these data policy guidelines is to describe general requirements for supplemental information on scientific purpose, related studies, smallest detectable
relative risk, assumptions, sample size determination, and expected statistical power which should be included in requests for OMB approval to conduct epidemiological cohort and case-control studies.

The guidelines are intended for preparers and reviewers of these types of OMB submissions. Preparers of OMB submissions who are unfamiliar with the theory and procedures for sample size determination and statistical power in epidemiological studies are encouraged to consult with program staff possessing appropriate expertise at an early state of study development.

It is recognized that the design and analysis requirements for any particular study will be more complex than the guidelines described in this paper and that the guidelines will not apply in every case. Further, these guidelines apply only to information on scientific purpose, detectable relative risk, sample size, and statistical power as special problems in OMB clearance of analytic epidemiological studies. As such, they are intended to supplement existing, best practice requirements for scientific, technical, and methodological soundness of requests for OMB approval.

Finally, it is emphasized that these guidelines are working guidelines which will be evaluated after a trial period and modified as necessary.

III. DETECTABLE DIFFERENCES, SAMPLE SIZE DETERMINATION,

AND EXPECTED STATISTICAL POWER

A fundamental step in the planning of a study is the determination of the number of subjects or respondents needed. An adequate number of subjects must be included to meet the research objectives. In order to calculate the required sample size in the simplest case, several factors must be considered (Mausner and Kramer, 1985):

1) the size of the difference one is interested in detecting (e.g., an odds ratio of 2 in a case-control study;

2) the frequency of the outcome or exposure in the control group e.g., the prevalence of exposure to the risk factor of interest among controls in a case-control study, or the incidence of the disease among the nonexposed in a cohort study (Schlesselman, 1982). When the focus of the study is on continuous variables as outcomes, the relevant variances should be considered.

3) the level of Type I error (a) or the significance level. The significance level is the probability of finding a statistically significant difference when none truly exists.

It represents the probability that observed significant results may have occurred by chance. Significance levels of 0.05 or smaller are commonly chosen to minimize the probability that the observed results occurred because of sampling fluctuations. If many associations are to be tested in a single analysis, as would occur in initial exploration of a large data set, the cumulative probability of making at least one Type I error is increased;

4) the value of Type II error (b). Type II error refers to the probability of failing to detect a significant difference when one in fact exists. (1-b) is referred to as the statistical power of the study. Statistical power is the probability of rejecting the null hypothesis when it is, in fact, false.

In choosing a and b, the investigator must weigh the relative disadvantage of falsely rejecting the null hypothesis against failing to detect an effect that truly exists.

Experts in experimental design have developed procedures which permit investigators to use previously developed tables and formulae to determine the sample size required under various assumptions concerning the acceptable level of error, the value of relevant parameters, and the variability of the observations (Cohen, 1977; Fleiss, 1981; Schlesselman, 1982).

In many instances in epidemiology, the investigator has a set, relatively inflexible sample size available for study, and will need to estimate, given certain specifications, what is the least significant relative risk that would be detectable by the study (Walter, 1977), or alternatively, what are the ranges of statistical power for differences of interest for the given sample size under various assumptions and study conditions. Such an analysis will assist in determining whether it would be worthwhile, scientifically, to carry out the study at all.

IV. GUIDELINES FOR REQUESTS FOR OMB APPROVAL

1. Requests for OMB approval to conduct epidemiological cohort and case-control studies should include a clear description of the scientific purpose of the study and an identification of previous and ongoing related studies. This information should be included in Section A of the Supporting Statement: Justification.

2. Requests for OMB approval to conduct epidemiological cohort and case-control studies should include a complete discussion of detectable differences, sample size, and expected statistical power analysis which takes into consideration the four factors described in III above as well as other relevant factors and study conditions, such as disease latency period, follow-up period, multiple outcomes, multiple controls, matching, etc.

Typically, epidemiologic studies provide estimates of the relative risk (RR) an individual has of contracting a disease if exposed to a substance compared with that of a non-exposed person. The following paragraphs describe sample size considerations necessary to estimate a relative risk. If the parameter of interest is something other than a relative risk, the relevant considerations are analogous.

a. The magnitude of the RR deemed important to detect and the reason for the choice should be described. When available, information about the normal risk (e.g., national disease rates) and the size of the population that may be exposed to the agent under study should be provided.

b. The expected statistical power of the proposed study to detect risks of the magnitude deemed important should be presented. These calculations will be dependent on the study design and

methods of analysis and should be derived under several reasonable assumptions concerning the exposure or outcome probabilities. For example, if a case control study continues prior research, power calculations assuming the previously observed exposure rates would be desirable.

c. An expected statistical power curve or table should be presented for a range of relative risks of interest under various alternative assumptions and conditions, i.e., if a relative risk of 4 is deemed important to detect, then, for example, the expected power to detect relative risks of 2, 3, 4, 5, 6, and 10 should be given in a table.

d. The choice of sample size should be related to the expected accuracy of the final relative risk estimates and the statistical power of the study.

e. The discussion of detectable differences and their rationale, and of sample size and statistical power, should be included in Section B of the Supporting Statement: Collection of Information Employing Statistical Methods with additional material and tables as necessary included in an appendix.

f. The discussion of sample size and statistical power should be presented at no less a level of detail than that customarily presented in research protocols.

V. REFERENCES

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Refer to Hardcopy Illustration 1
Refer to Hardcopy Illustration 2