statistical or epidemiological activities, where such activities of CDC are not duplicative of other activities of the Department, and when the Director, CDC, determines that the authority to give assurances of confidentiality based upon Section 308(d) is necessary for the successful conduct of these statistical and epidemiological activities.

Whenever CDC requests information under an assurance of confidentiality, it informs the person or agency supplying the information as to the uses to be made of it. The first clause of Section 308(d) guarantees that thereafter CDC will be limited to those uses so specified to the supplier. Moreover, the information obtained may be used only by staff of CDC, or its qualified agents, in the pursuit of such stated purposes, and by them *only* in activities *directly* aimed at achieving those specific purposes.

The second clause states that CDC may never release identifiable information without the advance, explicit approval of the person or establishment supplying the information or by the person or establishment described in the information.

2.2 Privacy Act of 1974 (5 U.S.C. 552a)

This Act also provides for the confidential treatment of records of individuals which are maintained by a Federal agency according to either the individual's name or some other identifier. (Deceased individuals are not covered by the Privacy Act.) This law also requires that such records in CDC are to be protected from uses other than those purposes for which they were collected. It further requires agencies to:

1. Collect only that information necessary to perform agency functions;
2. Publish descriptions of existing data systems (called "systems of records") so that the public can learn what records are maintained by the agency;
3. Inform individuals at the time of data collection as to the legislative authority under which it is requested, whether the request is mandatory or voluntary, the consequences, if any, of nonresponse, and the purposes and uses to be made of the data;
4. Maintain no records on how an individual exercises rights under the first amendment except with special legal authorization;
5. With certain exceptions, permit individuals to examine records maintained about themselves and to challenge the accuracy of those records;
6. Establish rules of conduct governing persons involved in collecting and maintaining records; and
7. Establish appropriate administrative, technical, and physical safeguards to protect records.

Employees of agencies and their contractors subject to the Act who willfully disclose personal information contrary to the law, or who fail to give notice of a system of records, may be fined up to $5,000, and the agency may be sued for damages. Finally, the Act places severe restrictions on the use of an individual's Social Security number, with the effect that CDC is virtually precluded from using Social Security numbers in most of its statistical activities.

Regulations (45 CFR Part 5b) have been published by the Department of Health and Human Services (HHS) providing for implementation of the Privacy Act within this Department. Additional guidelines are in HHS General Administration Manual Part 45 and PHS supplementary chapters PHS.hf: 45-10 through 45-19. The CDC rules of conduct under the Privacy Act are set forth in Appendix I to the Manual Guide—General Administration No. CDC-63, Privacy Act. All employees are bound to comply with these regulations.

2.3 Federal Law Governing Federal Employees' Behavior (18 U.S.C. 1905)

This law includes the following provision, which is also relevant to the maintenance of confidentiality for CDC records:

> **Disclosure of Confidential Information**
>
> Whoever, being an officer or employee of the United States or any department or agency thereof, publishes, divulges, discloses or makes known in any manner or to any extent not authorized by law any information coming to him in the course of his employment or official duties or by reason of any examination or investigation made by, or return, report or record made to or filed with, such department or agency or officer or employee thereof, which information relates to trade secrets, processes, operations, style of work, or apparatus, or to the identity, confidential statistical data, amount or source of any income, profits, losses, or expenditures of any person, firm, partnership, corporation or association; or permits any income return or copy thereof or any book containing any abstract or particulars thereof to be seen or examined by any person except as provided by law; shall be fined not more than $1,000 or imprisoned not more than one year, or both; and shall be removed from office or employment.

2.4 Freedom of Information Act (5 U.S.C. 552)

First passed in 1967 and amended in 1974, this Act requires Federal agencies to make their records available to persons who request them. Some have speculated that this law undoes the privacy protection required under the laws just cited. However, such a view is mistaken, since several kinds of records are specifically exempted from the disclosure requirements of the Freedom of Information Act (FOIA). Two exclusions provided in Sec-

tion 552(b) of the Act are of special relevance: Subsection (6) exempts "personal and medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of personal privacy," and Subsection (3) provides that matters "specifically exempted from disclosure by statute" are also excluded from the disclosure requirement. Thus no records that are protected from disclosure are required by the Freedom of Information Act to be released by anyone.

Regulations (45 CFR Part 5) have been published by HHS implementing the Freedom of Information Act.

3. INDIVIDUAL EMPLOYEE'S RESPONSIBILITIES

As an employee of CDC, you are required to maintain and protect at all times the confidential records that may come into your presence or under your control. To assure that all CDC employees are aware of this responsibility and the penalties for failing to comply, each person, on entering employment in CDC, is given a Nondisclosure Agreement to read and sign (CDC 0.979, Appendix C).

4. ASSURANCES OF CONFIDENTIALITY

Whenever CDC requests data concerning an individual or an establishment, it is obligated to provide certain information and assurances to the supplier of information. While this is considered a moral obligation by CDC, it is also stated or implied in both the Public Health Service Act and the Privacy Act of 1974. The Public Health Service Act, in Section 308(d), states that information may not "be used for any purpose other than the purpose for which it was supplied"; therefore, such purposes must be explained to the supplier of information before obtaining the information. The Privacy Act of 1974 states in Section(e)(3) that the agency shall:

> Inform each individual whom it asks to supply information, on the form which it uses to collect the information or on a separate form that can be retained by the individual . . .
>
> A. the authority (whether granted by statute, or by executive order of the President) which authorizes the solicitation of the information and whether disclosure of such information is mandatory or voluntary;
>
> B. the principal purpose or purposes for which the information is intended to be used;
>
> C. the routine uses which may be made of the information, as published pursuant to paragraph (4)(D) of this subsection; and
>
> D. the effects on him, if any, of not providing all or any part of the requested information.

Such information must be consistent with the information in the description of the system of records published in the *Federal Register*. If any release of any identifiable information is to be made, then the law requires that consent be obtained in advance for that specific release. The Public Health Service Act, Section 308(d)(1), states that "such information may not be published or released in other form if the particular establishment or person supplying the information or described in it is identifiable unless such establishment or person has consented (as determined under regulations of the Secretary) to its publication or release in other form." The Privacy Act states that, with certain exceptions, an individual's record may not be disclosed "except pursuant to a written request by, or with the prior written consent of, the individual to whom the record pertains."

4.1 Policy Implementation

No CDC employee may give assurance of confidentiality under this authority to any individual or institution without specific approval of the Director, CDC. The Director, CDC, is responsible for determining that the following considerations are fully examined before giving assurance of confidentiality:

1. Extent to which the assurance of confidentiality is important to protection of the individual or institution.
2. Extent to which the individual or establishment will not furnish or permit access to it unless an assurance of confidentiality is given.
3. Extent to which the information cannot be obtained with the same degree of reliability from sources that do not require an assurance.
4. Extent to which the information is essential to the success of the particular statistical or epidemiological project and is not duplicative of other information-gathering activities of the Department.
5. Extent to which the giving of the assurance of confidentiality will restrain CDC from carrying out any of its responsibility.
6. Extent to which the advantages of assuring confidentiality outweigh the disadvantages of doing so.

The Director, Center/Institute/Office, is responsible for the following:

1. Ensuring that personnel in the organizational component have knowledge of and comply with established policies and procedures.
2. Informing staff members (either directly or through appropriate channels) that unauthorized disclosures of information obtained under an assurance of confidentiality may result in disciplinary action.

Each CDC employee will be asked to sign a Nondisclosure Agreement (See Section 3. Individual Employee's Responsibilities and Appendix C). In addition, each employee must at all times follow the principles and obey the laws, rules, and regulations that are cited or referenced in this manual. Additional copies of the manual will be available from the Office of Program Planning and Evaluation (OPPE), Office of the Director, CDC.

Preliminary information and guidance on obtaining an assurance of confidentiality may be obtained from the Director, OPPE/CDC.

Program officials requesting data which require an assurance of confidentiality will prepare a request to use Sections 304 and 306 authority of the PHS Act (CDC 0.970, See Appendix D) for signature of the Director, Center/Institute/Office, and forward seven copies to OPPE/CDC. The statement will contain the following information:

1. Programmatic purpose(s) for the conduct of the project, the type of data to be collected, and the uses which may be made of the information collected.
2. Justification giving detailed consideration to all of the issues outlined under Section 4.1 page 7 of this manual that must be met before the assurance of confidentiality is given.

OPPE/CDC staff will maintain communication with NCHS to ensure that the information is not being gathered by another Department agency under confidentiality protection of Section 308 of the Public Health Service Act, as amended. If the information is being gathered, OPPE/CDC will notify the originator. If the information is not being gathered, OPPE/CDC will coordinate the CDC processing of the request.

The request will be reviewed by the Confidentiality Review Group which will recommend approval or disapproval to the Director, CDC. The membership of the Confidentiality Review Group (appointed by Director, CDC) will include:

- Director, OPPE/CDC (Chairperson),
- A program medical epidemiologist,
- A program statistician,
- CDC Ethics Advisory Committee representatives,
- Legal Advisor to CDC,
- CDC Freedom of Information Officer, and
- CDC Privacy Act Officer.

The group will review the request according to the criteria outlined under Section 4.1 page 7 of this manual. The Director, CDC, will:

1. Review the recommendations and authorize approval or disapproval, and
2. Notify the initiating organization by returning the signed copy of the request form or advise other action.

When the assurance of confidentiality is signed, OPPE/CDC staff will also notify the following to ensure that proper safeguards for handling confidential data will be implemented:

- ADP Security Officer
- CDC Freedom of Information Officer
- Human Subjects Review Coordinator
- CDC Legal Advisor
- CDC Privacy Act Officer
- Project Clearance Officer
- CDC Records Officer
- Director, Procurement and Grants Office

The CDC Ethics Advisory Committee will periodically review applications for use of this authority and decisions which were made on those applications for the purpose of identifying and making recommendations on any ethical problems which emerge.

The safeguards will be implemented in accordance with the procedures for handling and destroying data in the following:

"CDC Staff Manual on Confidentiality."
"Department ADP Systems Manual," Part 6 (for computerized records).
"General Administration Manual," HHS and PHS Chapters 45-13, and Appendix PHS.hf: 45-19-B (for nonautomated records).
CDC Records Control Schedule and the General Services Administration General Records Schedule.

Requests for disclosure received by the Center/Institute/Office must be reviewed with the Director, OPPE/CDC, and the Legal Advisor to CDC.

4.2 Procedures

Whenever data are to be collected directly from individuals or establishments by an employee, agent, or contractor of CDC, and where confidentiality has been authorized, the following rules governing assurances and information are to be met:

1. Print on the questionnaire in a clearly visible location and in clearly visible letters the following notice (or words to this effect) of the confi-

dential treatment to be accorded the information on the questionnaire by anyone who may see it:

Confidential Information

Information contained on this form which would permit identification of any individual or establishment has been collected with a guarantee that it will be held in strict confidence, will be used only for purposes stated in this study, and will not be disclosed or released without the consent of the individual or the establishment in accordance with Section 308(d) of the Public Health Service Act (42 U.S.C. 242m).

2. On a letter or other form that can be retained by the individual or the establishment, or on the questionnaire form itself if it is a self-administered questionnaire, inform in clear and simple terms each individual or establishment asked to supply information:

   a. That the collection of the information is authorized by Section 306 of the Public Health Service Act (42 U.S.C. 242k);
   b. Of the purpose or purposes for which the information is to be used, clearly stating that the records will be used solely for epidemiological or statistical research and reporting purposes;
   c. Of the routine uses that may be made of the information, including all disclosures specified in the *Federal Register* for this system of records which may be applicable to this project;
   d. That participation is voluntary and there are no penalties for declining to participate in whole or in part; and
   e. That no information collected under the authority of Section 306 of the Public Health Service Act (42 U.S.C. 242k) may be used for any purpose other than the purpose for which it was supplied, and such information may not be published or released in other form if the individual or establishment is identifiable unless the individual or establishment supplying the information or described in it has consented to such release.

Whenever CDC arranges to purchase or otherwise obtain from another organization data that contain identifiers of individuals or establishments, and where confidentiality has been authorized, it will provide to the supplier the information specified in the previous items 4.2 (2)a., 4.2 (2)b., 4.2 (2)c., and 4.2 (2)e. This information will be provided in written form, either in the contract, purchase order, or other written statement.

Whenever data are to be collected *over the telephone* by an employee, agent, or contractor of CDC, primarily to accomplish a CDC function, and

where confidentiality has been authorized, the following rules governing assurances and information are to be met:

1. Before eliciting substantive information from a respondent in any telephone survey, the respondent will be given the following information over the telephone:

   a. The law authorizing collection of the information. The interviewer should say, "The survey is being conducted under authority of the Public Health Service Act." If the respondent requests the citation, the interviewer will say that it is Volume 42 of the U.S. Code, Section 242k.
   b. The purpose or purposes for which the information is to be used, such as "for epidemiological or statistical research on health problems."
   c. That participation in the survey is purely voluntary.
   d. The effects, if any, on the respondent for declining to participate, in whole or in part, in the survey.
   e. Respondent is notified of any possible disclosures of identified data to be made outside the Department. (It is most unlikely that there would be any such disclosures. If there are any possible disclosures to be made, they are listed under "routine uses" in the *Federal Register* notice on the system of records in which these data will be kept.)
   f. Respondent is assured that (except for any such disclosures) the confidentiality of any information supplied will be carefully protected, and no one other than HHS and its contractor(s) will have access to any data which identify the respondents.

   The exact wording proposed for informing respondents in any particular telephone survey is to be submitted for approval in the Project Clearance request for the survey and/or the protocol for Human Subjects review.

2. The telephone interviewer must sign a statement that the information required (as indicated above) was given orally to each respondent. This information shall be given by reading the approved text and answering any of the respondent's questions about it before proceeding with the interview. The statement to be signed by each interviewer may be on the form used to collect the survey data.

4.3 Responsibilities

Formal assurances of confidentiality will be given by the Director, CDC. In view of the increased complexities involved in confidentiality assurances resulting from recent legislation and regulations, Center/Institute/Office Direc-

tors are required to submit the confidentiality assurances relating to each data collection program to OPPE/CDC for approval. This approval should be obtained before the Request for Clearance goes to the CDC Project Clearance Officer or Human Subjects Coordinator.

Each Center/Institute/Office Director in CDC has responsibility for assuring compliance with CDC policies pertaining to the confidentiality of records in cases where an assurance of confidentiality has been or is to be given. OPPE/CDC will be available to assist the Center/Institute/Office Director by:

1. Interpreting Department policies pertaining to confidentiality;
2. Providing information to employees as to how and from whom they may get information clarification or related regulations; and
3. Providing advice regarding appropriate disciplinary action that may be taken when employees violate laws, rules, or regulations relating to confidentiality.

The responsibilities of the supervisor include the following:

1. Each supervisor will inform all employees, and subsequently all new employees, of existing CDC policies and procedures relating to the subject of confidentiality and will discuss with such employees their responsibilities in this area.
2. Supervisory personnel will be responsible for assuring that all employees under their jurisdiction comply with regulations applying to the disclosure of official information that permits the identification of individuals or establishments.
3. Supervisors should recognize unique situations that call for more than usual precautionary measures and should make recommendations for improvement if necessary.

Personnel are expected to observe departmental rules and regulations and CDC policy relating to official information for which confidentiality assurances have been given. When in doubt, employees should obtain advice from the supervisor or OPPE/CDC or consult official sources as to what is permitted and what is prohibited.

4.4 Repository of Assurances

A central repository for the filing of statements of assurances has been established in OPPE/CDC. Each organizational element of CDC which has been given approval to use an assurance of confidentiality will forward copies of all such statements to the repository. This will normally include, but not be limited to, assurances given in contracts, special letters, brochures, survey questionnaires, and forms.

5. TREATMENT OF REQUESTS FOR INFORMATION

Whenever a request is received for a specified record,[1] that request is subject to requirements of the FOIA. All Freedom of Information (FOI) requests received by CDC Center/Institute/Office staff should be sent immediately to the Office of Public Affairs to be logged in and processed. The form, Freedom of Information Request (HHS 632 revised 5/82) will be used for processing requests.

The CDC FOI Officer will log in the request and return it to the action office with an FOI request form. The date on the FOI request form is the official receipt date for the timetable of 10 working days. Time is of the essence. Under the provisions of the Act, the agency must inform the requester of its determination within 10 working days of receipt of the request.

The action office staff will initiate the necessary file search and review for *all* records that come within the scope of the request. A Center/Institute/Office official should review the records and recommend release or withholding of documents. In the latter case, a check should be placed in the box(es) on the FOI request form that indicate concern with disclosure. When recommending denial, the Center/Institute/Office official will provide a memorandum describing the nature of the records, sensitivity of the information, and whether or not confidentiality was assured. The FOI request form will be returned to the CDC FOI Officer within 8 working days (allowing 2 days for action), filled out as appropriate, including time and cost information. Two copies of the requested records will accompany the completed form.

Only the Director, Office of Public Affairs, is authorized to make determinations regarding release or denial of records and determinations regarding fees. The FOI Officer for CDC will be the focal point for all CDC FOI requests and should be contacted if there are questions or need for clarification on any FOI request.

[1] "Record" is defined in the Department's regulations (45 CFR Part 5) as including "books, brochures, punch cards, magnetic tapes, paper tapes, sound recordings, maps, pamphlets, photographs, slides, motion pictures, or other documentary materials, regardless of physical form or characteristics, made or received by the Department in pursuance of Federal law or in connection with the transaction of public business and preserved by the Department as evidence of the organization, functions, policies, decisions, procedures, operations, programs, or other activities." "Record" does not include objects or articles such as tangible exhibits, models, equipment, or processing materials; formulas, designs, drawings, or other items of valuable property; books, magazines, pamphlets, or other reference material in formally organized and officially designated libraries of the Department, which are available under the rules of the particular library concerned.