

APPENDIX A

Requirements Relating To Confidentiality and Privacy in Data Collection Contracts

I. Purpose

This appendix provides the wording to be used when the Centers for Disease Control (CDC) contracts with any organization outside CDC for the collection or use of information that identifies individuals and/or establishments when confidentiality has been authorized for a project; it does not relate to contracts involving data for which respondents (individuals or establishments) are advised that all information obtained from them will be made public. Such contracts must contain stipulations to assure confidentiality and physical security of the information and to assure that the contractor's employees abide by the stipulations. One of the three alternative wordings contained in this supplement is to be used in all such contracts, depending upon the laws governing the data collection project.

II. Background

The Privacy Act of 1974 (5 U.S.C. 552a) requires the safeguarding of individuals, and Section 308(d) of the Public Health Service Act (42 U.S.C. 242m) requires the safeguarding of both individuals and establishments against invasion of privacy. As a result of the provisions of these Acts, contractors who collect information identifying individuals and/or establishments must stipulate the appropriate safeguards to be taken regarding such information, depending on the laws governing such data collection projects. Three alternative wordings are provided for use in contracts when such information is collected by contractors outside CDC. Before a contract is signed, one of the alternative wordings covering the contract must be used.

III. Policy

One of the three alternative wordings given in the following sections is to be used in data collection contracts, depending upon the laws governing the particular project for which information is to be collected. If the particular circumstances of a given contract imply the need for different wording from that prescribed as follows, the wording may be changed, provided that the new wording is in keeping with the intentions of this manual and provided that approval for the new wording is obtained from the Director, CDC.

III.A. Alternative One

Alternative One is to be used when both the Privacy Act of 1974 (5 U.S.C. 552a) and Section 308(d) of the Public Health Service Act (42 U.S.C. 242m) apply. The project would involve the collection of information about identified individuals, and it is an activity that is authorized for CDC to perform under Section 304 or 306 of the Public Health Service Act.

Safeguards for Individuals and Establishments Against Invasions of Privacy

In accordance with Subsection (m) of the Privacy Act of 1974 (5 U.S.C. 552a) and Section 308(d) of the Public Health Service Act (42 U.S.C. 242m), the contractor is required to comply with the applicable provisions of the Privacy Act and to undertake other safeguards for individuals and establishments against invasions of privacy.

To provide these safeguards in performance of the contract, the contractor shall:

1. Be bound by the following assurance:

Assurance of Confidentiality

In accordance with Section 308(d) of the Public Health Service Act (42 U.S.C. 242m), the contractor assures all respondents that the confidentiality of their responses to this information request will be maintained by the contractor and CDC and that no information obtained in the course of this activity will be disclosed in a manner in which the individual or establishment is identifiable, unless the individual or establishment has consented to such disclosure, to anyone other than authorized staff of CDC.

2. Maintain the following safeguards to assure that confidentiality is protected by the contractor's employees and to provide for the physical security of the records:

- a. After having read the above assurance of confidentiality, each employee of the contractor participating in this project is to sign the following statement of understanding:

I have carefully read and understand the assurance which pertains to the confidential nature of all records to be handled in regard to this survey. As an employee of the contractor I understand that I am prohibited by law from disclosing any such confidential information which has been obtained under the terms of this contract to anyone other than authorized staff of CDC. I understand that any willful and knowing disclosure in violation of the Privacy Act of 1974 is a misdemeanor and would subject the violator to a fine of up to \$5,000.

(Signature)

(Date)

- b. To preclude observation of confidential information by persons not employed on the project, the contractor shall maintain all confidential records that identify individuals or establishments or from which individuals or establishments could be identified under lock and key.

Specifically, at each site where these items are processed or maintained, all confidential records that will permit identification of individuals or establishments are to be kept in locked containers when not in use by the contractor's employees. The keys or means of access to these containers are to be held by a limited number of the contractor's staff at each site. When confidential records are being used in a room, admittance to the room is to be restricted to employees pledged to confidentiality and employed on this project. If at any time the contractor's employees are absent from the room, it is to be locked.

- c. The contractor and his professional staff will take steps to insure that the intent of the statement of understanding is enforced at all times through appropriate qualifications standards for all personnel working on this project and through adequate training and periodic followup procedures.

3. Print on the questionnaire in a clearly visible location and in clearly visible letters the following notice of the confidential treatment to be accorded the information on the questionnaire by any individual 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 by the contractor and CDC, will be used only for purposes stated in this study, and will not be disclosed or released to anyone other than authorized staff of CDC 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).

4. 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 by CDC and its contractor 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 intended 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 particular individual or establishment supplying the information or described in it is identifiable to anyone other than authorized staff of CDC, unless the individual or establishment has consented to such release.

(The voluntary disclosure by the respondent of requested information after being informed of preceding paragraphs a through d is an acknowledgment of the uses and disclosures contained in paragraph c.)

- 5. Release no information from the data obtained or used under this contract to any person except authorized staff of CDC.
- 6. By a specified date, which may be no later than the date of completion of the contract, return all study data to CDC or destroy all such data, as specified by the contract.

III.B. Alternative Two

Alternative Two is to be used when Section 308(d) of the Public Health Service Act applies to the project but the Privacy Act does not. For example, in the case of a survey of institutions providing health services, the Public Health Service Act provisions relating to "establishments" would apply, but the Privacy Act would not, since it relates only to records on individuals.

Safeguards for Individuals and Establishments Against Invasions of Privacy

In accordance with Section 308(d) of the Public Health Service Act (42 U.S.C. 242m), the contractor is required to give an assurance of confidentiality and to provide for safeguards to assure that confidentiality is maintained.

To provide this assurance and these safeguards in performance of the contract, the contractor shall:

Be bound by the following assurance:

Assurance of Confidentiality

In accordance with Section 308(d) of the Public Health Service Act

(42 U.S.C. 242m), the Director, CDC, assures each respondent that the confidentiality of responses to this information request will be maintained by the contractor and CDC and that no information obtained in the course of this activity may be disclosed in a manner in which the particular establishment or individual supplying the information or described in it is identifiable, unless such establishment or individual has consented to such disclosure, to anyone other than authorized staff of CDC.

- 2. Maintain the following safeguards to assure that this confidentiality is protected by the contractor's employees and to provide for the physical security of the records:

- a. After having read the above assurance of confidentiality, each employee of the contractor participating in this project is to sign the following statement of understanding:

I have carefully read and understand the CDC assurance which pertains to the confidential nature of all records to be handled in regard to this survey. As an employee of the contractor I understand that I am prohibited by law from disclosing any such confidential information which has been obtained under the terms of this contract to anyone other than authorized staff of CDC.

(Signature)

(Date)

- b. To preclude observation of confidential information by persons not employed on the project, the contractor shall maintain all confidential records that identify establishments or individuals or from which establishments or individuals could be identified under lock and key.

Specifically, at each site where these items are processed or maintained, all confidential records that will permit identification of establishments or individuals are to be kept in locked containers when not in use by the contractor's employees. The keys or means of access to these containers are to be held by a limited number of the contractor's staff at each site.

When confidential records are being used in a room, admittance to the room is to be restricted to employees pledged to confidentiality and employed on this project. If at any time the contractor's employees are absent from the room, it is to be locked.

- c. The contractor and his professional staff will take steps to insure that the intent of the statement of understanding is enforced at all times through appropriate qualifications standards for all personnel working on this project and through adequate training and periodic followup procedures.

3. Print on the questionnaire in a clearly visible location and in clearly visible letters the following notice of the confidential treatment to be accorded the information on the questionnaire by any individual 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 by the contractor and CDC, will be used only for purposes stated in this study, and will not be disclosed or released to anyone other than authorized staff of CDC without the consent of the individual or establishment in accordance with Section 308(d) of the Public Health Service Act (42 U.S.C. 242m).

4. 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:
- That the collection of the information by CDC and its contractor is authorized by Section 308 of the Public Health Service Act (42 U.S.C. 242k);
 - Of the purpose or purposes for which the information is intended to be used, any plans for disclosures of information in a form that would permit the identification of an establishment or individual, and a statement that the data will be used solely for epidemiological or statistical research and reporting purposes;
 - That participation is voluntary and there are no penalties for declining to participate in whole or in part; and
 - That no information collected under the authority of Section 308 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 to anyone other than authorized staff of CDC if the particular establishment or individual supplying the information or described in it is identifiable unless such establishment or individual has consented to such release.
- (The voluntary disclosure by the respondent of requested information after being informed of preceding paragraphs a through c is an acknowledgment of the uses and disclosures contained in paragraph b.)
5. Release no information from the data obtained or used under this contract to any person except authorized staff of CDC.
6. By a specified date, which may be no later than the date of completion of the contract, return all study data to CDC or destroy all such data, as specified by the contract.

III.C. Alternative Three

Alternative Three is to be used when the Privacy Act of 1974 applies to a given data collection project but Section 308(d) of the Public Health Service Act does not. This situation occurs when information is to be collected about identified individuals under an appropriation authorized by a law other than Section 304 or 306 of the Public Health Service Act.

**Safeguards for Individuals Against
Invasions of Personal Privacy**

In accordance with Subsection (m) of the Privacy Act of 1974 (5 U.S.C. 552a), the contractor is required to provide certain safeguards for individuals against invasion of personal privacy.

To provide these safeguards in performance of the contract, the contractor shall:

- Initiate the following safeguards to protect against unauthorized disclosure of information which would permit identification of any individual supplying the information or described in it:

- Each employee of the contractor participating in this project is to sign the following statement of understanding after having read Subsections (m) and (i)(1) of the Privacy Act of 1974 (5 U.S.C. 552a):

I have carefully read and understand Subsections (m) and (i)(1) of the Privacy Act of 1974. As an employee of the contractor I understand that I am prohibited by law from disclosing any such protected information which has been obtained under the terms of this contract to anyone other than authorized staff of CDC. I understand that any willful and knowing disclosure in violation of the Privacy Act of 1974 is a misdemeanor and would subject the violator to a fine of up to \$5,000.

(Signature)

(Date)

- To preclude observation of protected information by persons not employed on the project, the contractor shall maintain all confidential records that identify individuals or from which they could be identified under lock and key.

Specifically, at each site where these items are processed or maintained, all confidential records that will permit identification of individuals are to be kept in locked containers when not in use by the contractor's employees. The keys or means of access to these containers are to be held by a limited number of the contractor's staff at each site. When confidential records are being

used in a room, admittance to the room is to be restricted to employees pledged to nondisclosure and employed on this project. If at any time the contractor's employees are absent from the room, it is to be locked.

- c. The contractor and his professional staff will take steps to insure that the intent of the statement of understanding is enforced at all times through appropriate qualifications standards for all personnel working on this project and through adequate training and periodic followup procedures.
2. Print on the questionnaire in a clearly visible location and in clearly visible letters the following notice of the confidential treatment to be accorded the information on the questionnaire by any individual who may see it:

Protected Information

Information contained on this form which would permit identification of any individual has been collected with an assurance that it will not be voluntarily disclosed to anyone other than staff of CDC except as consented to by the individual or required by Federal law.

3. On a letter or other form that can be retained by the individual, or on the questionnaire form itself if it is a self-administered questionnaire, inform in clear and simple terms each individual asked to supply information:
- a. Of the statutory authority that authorized the solicitation of the information;
 - b. Of the purpose or purposes for which the information is intended 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 by the contractor and the U. S. Department of Health and Human Services, 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 furnished will be disclosed in a manner that identifies the individual and that the Department will not voluntarily disclose such information in a manner that permits identification of an individual except as consented to by the individual in writing or as required by Federal law, or for routine use as provided for in preceding paragraph c.
4. Release no information from the data obtained or used under this contract to any person except authorized staff of CDC.

5. By a specified date, which may be no later than the date of completion of the contract, return all study data to CDC or destroy all such data, as specified by the contract.

IV. Dissemination

All contracts involving the collection of information on individuals and/or establishments, in which the individuals or establishments are identified, must stipulate one of the above wordings except when respondents are advised that all of the data received from them are to be made public. Center/Institute/Office Directors should make sure that employees of CDC are familiar with contract requirements.