Attachment 8b

Materials for Requesting Hospitalization Records

Appendix 8b-1. Cover Letter for Using with HIPAA Authorization

Appendix 8b-2. Return Form

Appendix 8b-3. HIPAA Authorization for Disclosure of Hospital Records

Appendix 8b-4. Questions and Answers about Obtaining Hospital Records

Appendix 8b-5. Cover Letter for Using with HIPAA Waiver

Appendix 8b-6. Documentation Notice for HIPAA Accounting

Attachment 8b. Materials for Requesting Hospitalization Records

Two versions of packages are prepared for requesting hospitalization records, based on how the HIPPA requirements were fulfilled. For living participants we reached in-person during home visits, signed HIPAA authorization will be obtained and included in the package. For living participants who do not allow us to reach them in-person, and deceased participants, a HIPPA waiver has been sought and the wavier related documentations will be included in the package. Below are the lists of materials included in the packages.

For packages with signed HIPAA authorization:

- Cover Letter (Appendix 8b-1)
- Return Form (Appendix 8b-2)¹ For the hospitals to indicate if they have the records for the participant or not, and, if records were retrievable, which records were returned. Each Return Form will be labeled with the name, date of birth, and sex of the participant
- Signed HIPAA Authorization for Disclosure of Hospital Records (Appendix 8b-3)
- Questions and Answers about Obtaining Hospital Records (Appendix 8b-4)
- A large FedEx Tyvek envelope with a pre-printed return airbill For sending records back

For packages with a HIPPA waiver:

- Cover Letter (Appendix 8b-5)
- Return Form (Appendix 8b-2)*
- HIPAA Waiver Documentations
 - Documentation of ERB HIPAA Waiver: To indicate the ERB has granted the HIPAA Waiver
 - Documentation Notice for HIPAA Accounting: To be placed in the medical record by the provider for cases approved for the HIPAA Waiver (Appendix 8b-6)
- Questions and Answers about Obtaining Hospital Records (Appendix 8b-4)
- A large FedEx Tyvek envelope with a pre-printed return airbill For sending records back

¹ These items are identical in both packages.

The National Center for Health Statistics (NCHS), a part of the Centers for Disease Control and Prevention (CDC), conducts the National Health and Nutrition Examination Survey (NHANES) to measure progress towards meeting health and nutrition goals in the United States. The survey collects and reports on a variety of health problems, including diabetes and heart disease. We are now conducting the NHANES Longitudinal Study to follow up on our participants to examine changes in their health outcomes.

Our study participants voluntarily agreed to participate in the study and signed a HIPAA Authorization for disclosure of hospital medical records, which is included in this package. The success of this disease prevention study depends on our ability to follow the health status of our participants over time. Your assistance in expediting the medical records request is greatly appreciated because it will help us learn more about the health status of our participants. You may participate by mailing the Return Form and requested documents in the enclosed FedEx envelope with pre-printed return airbill to our contractor, Westat. Inc.

For this study, we are requesting that you return the following documents for all hospitalizations between {insert data of baseline MEC exam} and {insert date of follow-up interview}:

- {Hospital face sheet}¹
- {Discharge Summary, if not available, then progress note from last day of hospitalization}
- {Emergency room report}
- {Admission notes}
- {Progress notes for every day of hospitalization}
- {Operative reports}
- {Consultations}
- {Pathology report}
- {Radiology reports}
- {EKGs}
- {Lab reports}
- {Cardiac catheterization reports}

This study is authorized under Section 306 of the Public Health Service Act. The information collected in the study is protected by the Section 308 of the Public Health Service Act and the Confidential Information Protection and Statistical Efficiency Act. The information you supply will be treated confidentially, as specified by law. The information will be used for statistical purposes only; no information that could identify the participant will be released without permission. You have received knowledge of the participant's enrollment in the NHANES study, which was done with the participant's consent. You should not use this knowledge to obtain additional information about the participant through the released NHANES data or by using the NHANES data to link to other databases. Any effort to determine the identity of any reported case is prohibited by this law. If you inadvertently discover the identify of a participant in the NHANES data files, please advise the Director of NCHS, of any such

¹ For the feasibility study, most of the requests will only include the first 2 items on the list: hospital face sheet and discharge summary. Only a small percentage of requests will include the full list of items. The system will print proper list for each request.

discovery at 301-458-4500. Although your participation is voluntary, we hope that you will choose to participate.

If you have any questions or comments about the enclosed material, or the records being requested, please call 1-8XX-XXX-XXXX. If you would like additional information about the NHANES Longitudinal Study, please call Dr. Duong T. Nguyen at 1-800-452-6115. You can also contact him by writing to him at: MS P08, 3311 Toledo Road, Hyattsville, MD 20782. If you have a question about your rights in this research, please call the NCHS Research Ethics Review Board at 1-800-223-8118. Say you are calling about Protocol #XXXX-XX. Your participation in the study is greatly appreciated.

Sincerely yours,

Kathryn S. Porter, MD, MS, FACPM
Captain, U.S. Public Health Service
Director, Division of Health and Nutrition Examination Surveys
National Center for Health Statistics, Centers for Disease Control and Prevention

Enclosures:

Documentation of authorization to disclose health information; Questions and answers about providing medical records; Return Form; FedEx envelope with pre-printed return airbill

Form Approved OMB No. 0920-xxxx Exp. Date xx/xx/20xx

RETURN FORM

NOTICE - CDC estimates the average public reporting burden for this collection of information as 20 minutes per response, including the time for reviewing instructions, searching existing data/information sources, gathering and maintaining the data/information needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC/ATSDR Information Collection Review Office, 1600 Clifton Road, NE, MS D-74, Atlanta, Georgia 30333; ATTN: PRA (0920-xxxxx).

Return this form using the enclosed FedEx envelope with pre-printed return airbill along with the requested documents

Confidential information. If received in error, please call 1-XXX-XXXX.

Please review your records and return the requested documents for the individual identified on the label below.

Place label here with
SP name, Alternative SP Name
Sex
SP date of birth (if provided)
SPID

For this study, we are requesting that you return the following documents for all hospitalizations between {insert data of baseline MEC exam} and {insert date of follow-up interview}:

- {Hospital face sheet}¹
- {Discharge Summary, if not available than progress note from last day of hospitalization}
- {Emergency room report}
- {Admission notes}
- {Progress notes for every day of hospitalization}
- {Operative reports}
- {Consultations}
- {Pathology report}
- {Radiology reports}
- {EKGs}
- {Lab reports}
- {Cardiac catheterization reports}

Please indicate which of the following best describes your hospital records for this individual:

For the feasibility study, most of the requests will only include the first 2 items on the list: hospital face sheet and discharge summary. Only a small percentage of requests will include the full list of items. The system will print proper list for each request.

You have complete hospital records for this individual between {INSERT DATE OF BAESELINE PARTICIPATION} and {INSERT DATE OF FOLLOW-UP EXAM}
You do not have hospital records for this individual between {INSERT DATE OF BAESELINE PARTICIPATION} and {INSERT DATE OF FOLLOW-UP EXAM}. Note: By indicating there are no hospital records for this individual during the indicated time frame, this will help us avoid contacting you again.
You have incomplete hospital records for this individual between {INSERT DATE OF BAESELINE PARTICIPATION} and {INSERT DATE OF FOLLOW-UP EXAM}. Please specify:

If you do not have the FedEx envelope with pre-printed return airbill, please mail this Return Form and requested documents to the following the address:

NHANES Longitudinal Study
National Center for Health Statistics, Centers for Disease Control and Prevention
c/o Westat
1600 Research Blvd. Room RA 1116
Rockville, MD 20850

Thank you for participating in this study.

NHANES Longitudinal Study

HIPAA AUTHORIZATION FOR DISCLOSURE OF HEALTH INFORMATION

If you sign this document, you give permission for hospital personnel at

(Insert hospital name)

to release your health information that identifies you to the National Health and Nutrition Examination Survey (NHANES). NHANES is conducted by the National Center for Health Statistics (NCHS), which is part of the Centers for Disease Control and Prevention (CDC).

Under the Health Insurance Portability and Accountability Act of 1996 (HIPAA), with your permission, hospital personnel can release the following documents to NCHS and/or its contractor: hospital face sheet, with diagnostic codes (ICD-9 and/or ICD-10 CM codes); discharge summaries; progress notes from last day of hospitalization; progress notes for entire hospitalization; emergency room reports; admission notes; operative reports; pathology reports; consultations; radiology reports; EKGs; laboratory reports; and cardiac catheterization reports.

The purpose of collecting hospital medical records is to help better understand risk factors associated with health problems, including diabetes and heart disease. Your hospital medical records will be used to supplement the interview and exam data obtained in NHANES.

Health care facilities are required by law to protect your health information under HIPAA. By signing this document, you authorize hospital personnel to release your hospital medical records for this research. Once your information is released to the study, the information received by the study is no longer covered by HIPAA but is covered by the Public Health Service Act and the Confidential Information Protection and Statistical Efficiency Act (CIPSEA), which prohibits the release of information that would identify you or your hospital(s) outside of NCHS and its contractors without your permission. By contacting the hospital personnel you tell us about, the hospital personnel will know you took part in NHANES. We will tell the hospital personnel that they should not use this knowledge to obtain additional information about you through the released NHANES data or by using the NHANES data to link to other databases. We will inform the hospital personnel that any effort to identify you in the NHANES data is prohibited by the Public Health Service Act and CIPSEA.

Please note that you do not have to sign this Authorization. You will not lose any benefits if you say no. You may change your mind and revoke (take back) this Authorization at any time, except to the extent that the hospital personnel may have already acted based on this Authorization. To revoke this Authorization, you may call: Dr. Duong T. Nguyen at 1-800-452-6115 with the National Center for Health Statistics. Or you may contact him by writing to him at MS P08, 3311 Toledo Road, Hyattsville, MD 20782. If you have a question about your rights in this research, please call the NCHS Research Ethics

Review Board at 1-800-223-8118. Say you are calling about Protocol #XXXX-XX. This authorization expires 36 months from the date of signature.

I authorize and request that hospital personnel release my health information to the National Center for Health Statistics.

Signature of participant	Date
Written name of participant	
Witness (if required)	Date
Relationship of witness to the participant	
Name of staff member present when this form was signed	Date

Assurance of Confidentiality – We take your privacy very seriously. All information that relates to or describes identifiable characteristics of individuals, a practice, or an establishment will be used only for statistical purposes. NCHS staff, contractors and agents will not disclose or release responses in identifiable form without the consent of the individual or establishment in accordance with section 308(d) of the Public Health Service Act (42 USC 242m(d)) and the Confidential Information Protection and Statistical Efficiency Act of 2002 (CIPSEA, Title 5 of Public Law 107-347). In accordance with CIPSEA every NCHS employee, contractor, and agent has taken an oath and is subject to a jail term of up to five years, a fine of up to \$250,000, or both if he or she willfully discloses ANY identifiable information about you. In addition, NCHS complies with the Cybersecurity Enhancement Act of 2015. This law requires the Federal government to protect its information by using computer security programs to identify cybersecurity risks against federal computer networks.

The Cybersecurity Act of 2015 permits monitoring information systems for the purpose of protecting a network from hacking, denial of service attacks and other security vulnerabilities. The software used for monitoring may scan information that is transiting, stored on, or processed by the system. If the information triggers a cyber threat indicator, the information may be intercepted and reviewed for cyber threats. The Cybersecurity Act specifies that the cyber threat indicator or defensive measure taken to remove the threat may be shared with others only after any information not directly related to a cybersecurity threat has been removed, including removal of personal information of a specific individual or information that identifies a specific individual. Monitoring under the Cybersecurity Act may be done by a system owner or another entity the system owner allows to monitor its network and operate defensive measures on its behalf.

[&]quot;Monitor" means "to acquire, identify, or scan, or to possess, information that is stored on, processed by, or transiting an information system"; "information system" means "a discrete set of information resources organized for the collection, processing, maintenance, use, sharing, dissemination or disposition of information"; "cyber threat indicator" means "information that is necessary to describe or identify security vulnerabilities of an information system, enable the exploitation of a security vulnerability, or unauthorized remote access or use of an information system".

Questions and Answers about Obtaining Hospital Records

Q: Why does the NHANES request hospital records?

A: Sources of medical information from hospitals include needed information such as discharge diagnoses, procedures performed, and administrative codes. The quality of the study's results is much improved by combining the information given by participants, or their proxy, with that obtained using hospital records. It is important that we obtain the most reliable information possible so that we can provide the public with reliable information.

Q: Is it necessary to return all of the requested documents?

A: Please send us any of the requested documents you have. If you are missing part of the documentation, your response will still be helpful to the study

Q: Am I required to provide the NHANES with this participant's hospital records?

A: Your participation is voluntary. We hope that you will choose to participate.

Q: What do I do if I have no hospital records for this participant?

A: We included a Return Form in the mailing that we have sent to you. On this form, you can indicate that you have no hospital records for this participant. Send the completed return form in the enclosed prepaid envelope. By telling us you do not have any records for this participant, we will know not to send you reminders.

Q: How do I return the requested hospital records?

A: A FedEx envelope with pre-printed return airbill was included in the packet of materials. If you do not have the envelope, please mail the Return Form and requested documents to the following the address:

NHANES Longitudinal Study
National Center for Health Statistics, Centers for Disease Control and Prevention
c/o Westat
1600 Research Blvd. Room RA 1116
Rockville, MD 20850

Q: I have questions about which forms to return and/or how to return the requested documents. Is there someone I can talk with?

A: If you have any questions about procedures related to returning the hospital records, please call Westat at: 1-8XX-XXX-XXXX. Someone will be available to answer the call from 9 AM to 4:30 PM Eastern Standard Time.

Q: Under what legal authority do you collect this information?

A: This study is authorized under Section 306 of the Public Health Service Act (42 USC Sec.242k). The information collected in the study is protected by the Section 308 of the Public Health Service Act (42 USC Sec. 242m(d)) and the Confidential Information Protection and Statistical Efficiency Act (Public Law No: 107-347). The National Center for Health Statistics and the contractor must treat the information you supply confidentially and can only use the information for statistical purposes, as

specified by the federal laws. Information that could identify the participant will not be released without permission.

Q: What is the HIPAA Privacy Rule?

A: The HIPAA Privacy Rule establishes national standards to protect individuals' protected health information. Additional sources of information about the HIPAA Privacy Rule is available at http://www.hhs.gov/ocr/hipaa/, http://www.cdc.gov/mmwr/preview/mmwrhtml/m2e411a1.htm.

Q: What is protected health information?

A: Protected health information includes all medical records and other individually identifiable information used or disclosed by an entity subject to the HIPAA Privacy Rule. This would include directly identifiable information such as patient names or social security numbers.

Q: What is a covered entity?

A: Covered entities are defined in the HIPAA rules as (1) health plans, (2) health care clearinghouses, and (3) health care providers who electronically transmit any health information in connection with transactions for which HHS has adopted standards. Generally, these transactions concern billing and payment for services or insurance coverage. For example, hospitals, academic medical centers, physicians, and other health care providers who electronically transmit claims transaction information directly or through an intermediary to a health plan are covered entities. Covered entities can be institutions, organizations, or persons.

Two versions of Q/A information sheet will be prepared. For request with signed **HIPAA authorization**, the following two items will be included:

Q: Is my participation in this study permitted by the HIPAA Privacy Rule?

A: The Privacy Rule permits covered entities to use or disclose protected health information for research purposes when a research participant authorizes the use or disclosure of information about him or herself. For this study, we asked participants to sign a written authorization allowing for hospital personnel to use or disclose their hospital records.

Q: What does the HIPAA Privacy Rule require me to do if I participate?

A: Health care facilities must ensure they have a copy of the written authorization signed by each participant. By law (45 CFR 164.508), all authorizations must be in plain language and must contain specific elements, including specific information regarding the information to be disclosed or used; the person(s) or classes of persons disclosing and receiving the information; expiration and right to revoke in writing. Written authorization meeting the requirement was sent to health care providers in the original mailing and the document is entitled "HIPAA Authorization for Disclosure of Health Information."

Two versions of Q/A information sheet will be prepared. For request applicable to **HIPAA waiver**, the following two items will be included:

Q: What do I have to do to participate and comply with the HIPAA Privacy Rule?

A: There are several things you must do to ensure you comply with the Rule when participating in the survey. First, the privacy notice that you provide to your patients must indicate that patient information may be disclosed for research or public health purposes. Many of the model notices that have been developed and made available by professional associations include this information. Also,

the National Center for Health Statistics (NCHS) has provided and made available on our website the material that you may need to verify, under the requirements of the Privacy Rule, that you are allowed to disclose to NCHS the information requested as part of this survey. This includes the authority under which NCHS is collecting this information and that the information being collected is the minimum necessary. Please see Documentation Notice for HIPAA Accounting and the following website: http://www.cdc.gov/vaccines/imzmanagers/laws/HIPAA/overview.html. Finally, you will need to keep track of disclosures made for this survey. We will give you a document that contains the information that you need to keep track of the disclosures.

Q: Why do I have to account for these disclosures?

A: Under the HIPAA Privacy Rule, patients have a right to an accounting of disclosures that have been made of their identifiable information for various purposes, including disclosures for public health and research purposes. We have provided you with a form to account for the disclosures made as part of this survey.

Q: Are there additional participant (patient) confidentiality considerations?

A: When asking permission from NHANES participants to contact hospitals, the participants were told that this would inform hospital personnel that they had participated in NHANES. Some of the personnel contacted to provide hospital records for this study may also be users of the NHANES data files. Users of the NHANES data files, including hospital personnel asked to provide hospital records, are instructed to: 1) Use the data in these data files for statistical reporting and analysis only; 2) Not link these data files with individually identifiable data from other NCHS or non-NCHS data files; and 3) Make no use of the identity of any person or establishment discovered inadvertently and advise the Director of NCHS, of any such discovery at 301-458-4500. Any effort to determine the identity of any reported case in the NHANES study is prohibited by the Public Health Service Act (Section 308 (d)) and the Confidential Information Protection and Statistical Efficiency Act (Public Law No: 107-347).

Q: Do I have to have an Institutional Review Board (IRB) review this research project?

A: No. For research projects, only one IRB must review the project. The NCHS IRB, the Research Ethics Review Board, has the authority to review such projects under the Regulations for the Protection of Human Subjects and has done so. Your IRB may review the project as well and may also verify that the documentation we have provided adheres to the requirements of the Regulations for the Protection of Human Subjects and the HIPAA Privacy Rule. Please feel free to call the NCHS Research Ethics Review Board at the toll-free number 1-800-223-8118 if you have any questions.

Q: Where do I get more information?

A: If you have any questions or comments about the enclosed material, or the records being requested, please call 1-8XX-XXX-XXXX. If you would like additional information about the NHANES Longitudinal Study, please call Dr. Duong T. Nguyen at 1-800-452-6115. You can also contact him by writing to him at MS P08, 3311 Toledo Road, Hyattsville, MD 20782. If you have a question about your rights in this research, please call the NCHS Research Ethics Review Board at 1-800-223-8118. Say you are calling about Protocol #XXXX-XX.

The National Center for Health Statistics (NCHS), a part of the Centers for Disease Control and Prevention (CDC), conducts the National Health and Nutrition Examination Survey (NHANES) to measure progress towards meeting health and nutrition goals in the United States. The survey collects and reports on a variety of health problems, including diabetes and heart disease. We are now conducting the NHANES Longitudinal Study to follow up on our participants to examine changes in their health outcomes.

To supplement the reported responses about various health conditions, we are requesting hospital records. The data from hospital records will be used in conjunction with other data collected in the study to learn about risk factors for developing selected health problems, including diabetes and heart disease. The protected health information requested is the minimum necessary to accomplish the objectives of the study.

The participant's designated proxy, has agreed to participate in this study and has provided us with a list of previous hospitalizations that occurred during the period of interest. The success of this disease prevention study depends on our ability to follow the health status of our participants over time. Your assistance in expediting the medical records request is greatly appreciated because it will help us learn more about the health status of our participants. You may participate by mailing the Return Form and requested documents in the enclosed in the enclosed FedEx envelope with pre-printed return airbill to our contractor, Westat. Inc.

For this study, we are requesting that you return the following documents for all hospitalizations between {insert data of baseline MEC exam} and {insert date of follow-up interview}:

- {Hospital face sheet}¹
- {Discharge Summary, if not available than progress note from last day of hospitalization}
- {Emergency room report}
- {Admission notes}
- {Progress notes for every day of hospitalization}
- {Operative reports}
- {Consultations}
- {Pathology report}
- {Radiology reports}
- {EKGs}
- {Lab reports}
- {Cardiac catheterization reports}

Please be assured that there are several ways that the Privacy Rule (as mandated by the Health Insurance Portability and Accountability Act (HIPAA)) allows you to participate in this study. Disclosures of patient data are permitted for public health surveillance purposes and for research for which a waiver of authorization has been approved by a Research Ethics Review Board – both of these apply to this

For the feasibility study, most of the requests will only include the first 2 items on the list: hospital face sheet and discharge summary. Only a small percentage of requests will include the full list of items. The system will print proper list for each request.

survey. We invite you to visit our website: http://www.cdc.gov/nchs/nhanes-ls for information regarding the survey. Additional information regarding HIPAA is available at the following website: http://www.cdc.gov/mmwr/preview/mmwrhtml/m2e411a1.htm. To assist you with HIPAA recordkeeping, we have provided you with a Documentation Notice for HIPAA Accounting. This document should be placed in each participant's record.

This study is authorized under Section 306 of the Public Health Service Act. The information collected in the study is protected by the Section 308 of the Public Health Service Act and the Confidential Information Protection and Statistical Efficiency Act. The information you supply will be treated confidentially, as specified by law. The information will be used for statistical purposes only; no information that could identify the participant will be released without permission. You have received knowledge of the participant's enrollment in the NHANES study, which was done with the participant's consent. You should not use this knowledge to obtain additional information about the participant through the released NHANES data or by using the NHANES data to link to other databases. Any effort to determine the identity of any reported case is prohibited by this law. If you inadvertently discover the identify of a participant in the NHANES data files, please advise the Director of NCHS, of any such discovery at 301-458-4500. Although your participation is voluntary, we hope that you will choose to participate.

If you have any questions or comments about the enclosed material, or the records being requested, please call 1-8XX-XXX-XXXX. If you would like additional information about the NHANES Longitudinal Study, please call Dr. Duong T. Nguyen at 1-800-452-6115. You can also contact him by writing to him at MS P08, 3311 Toledo Road, Hyattsville, MD 20782. If you have a question about your rights in this research, please call the NCHS Research Ethics Review Board at 1-800-223-8118. Say you are calling about Protocol #XXXX-XX. Your participation in the study is greatly appreciated.

Sincerely yours,

Kathryn S. Porter, MD, MS, FACPM Captain, U.S. Public Health Service Director, Division of Health and Nutrition Examination Surveys National Center for Health Statistics, Centers for Disease Control and Prevention

Enclosures:

Documentation Notice for HIPAA Accounting; Documentation of ERB Waiver; Questions and answers about providing medical records; Return Form; FedEx envelope with pre-printed return airbill

{SP name} {SP alternative names} {SP sex} {SP Date of Birth}

NHANES Longitudinal Study

DOCUMENTATION NOTICE FOR HIPAA ACCOUNTING

(To be placed in the medical record.)

Information contained in this document can be used to comply with the Privacy Rule requirements as mandated by the Health Insurance Portability and Accountability Act (HIPAA) to account for disclosures of protected health information.

Disclosure date:	
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Name and address of recipient:

NHANES Longitudinal Study National Center for Health Statistics, Centers for Disease Control and Prevention c/o Westat 1600 Research Blvd. Room RA 1116 Rockville, MD 20850

Purpose:

The National Center for Health Statistics, part of Centers for Disease Control and Prevention (CDC) is conducting the NHANES Longitudinal Study. Hospital records will be used supplement the self- and/or proxy-reported responses to learn about risk factors for developing selected health problems, including diabetes and heart disease.

Description:

This document has been placed in the medical file as an indicator that information from this hospital was used for the NHANES Longitudinal Study. Information reported may have included: hospital face sheet, with diagnostic codes (ICD-9 and/or ICD-10 CM codes); discharge summaries; progress notes from last day of hospitalization; progress notes for entire hospitalization; emergency room reports; admission notes; operative reports; pathology reports; consultations; radiology reports; EKGs; laboratory reports; and cardiac catheterization reports.

All information collected is held confidential and will be used only to generate statistical summaries. The Public Health Service Act authorizes data collection for the NHANES Longitudinal Study. The information you provide is treated confidentially as specified by law in the Public Health Service Act and the Confidential Information Protection and Statistical Efficiency Act.