

## **National Program of Cancer Registries Cancer Surveillance System 308(d) Assurance of Confidentiality Statement**

A surveillance system of population-based cancer incidence data received from cooperative agreement holders for the National Program of Cancer Registries is being conducted by the National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP) of the Centers for Disease Control and Prevention (CDC), an agency of the United States Department of Health and Human Services, and Macro International Inc., a contractor of the CDC. The information to be received by the CDC is a subset of a standard set of data items that the State central cancer registry routinely receives from hospitals, pathology labs, clinics and private physicians on all cancer patients diagnosed in the state. This information includes patient demographics and cancer diagnosis and treatment data. Once a year in January, CDC will request cumulative data from central cancer registries. The variables reported to CDC may vary from year to year. The cancer registries maintain these data permanently in longitudinal databases that are used for public health surveillance, program planning and evaluation, and research. CDC will update its longitudinal database each year with data received from the states. These data are used by CDC scientists for routine cancer surveillance, program planning and evaluation, and to provide data for research. NCCDPHP, recognizing the sensitivity of the data being furnished by the States, has applied for and obtained an Assurance of Confidentiality to provide a greater level of protection for the data while at CDC and at the contractor site.

Information received by CDC or its contractors as part of this surveillance system that could lead to direct or indirect identification of cancer patients is collected and maintained at CDC under Section 306 of the Public Health Service (PHS) Act (42 USC 242k) with an assurance that it will be held in strict confidence in accordance with Section 308(d) of the PHS Act (42 USC 242m). It will be used only for purposes stated in this Assurance and will not otherwise be disclosed or released, even following the death of cancer patients in this surveillance system.

Information collected by the CDC will be used without personal identifiers for publication in statistical and analytic summaries and for release in restricted release datasets for research. Information that could lead to direct or indirect identification of cancer patients will not be made available to any group or individual. In particular, such information will not be disclosed to: insurance companies; any party involved in civil, criminal, or administrative litigation; agencies of Federal, State or local government; or any other member of the public.

Collected information that could lead to direct or indirect identification of cancer patients will be kept confidential and, aside from NCCDPHP employees, their contractors, and qualified researchers, no one will be allowed to see or have access to the information. CDC employees and contractors will be required to handle the information in accordance with principles outlined in the CDC Staff Manual on Confidentiality and to follow the specific procedures documented in the Confidentiality Security Statement for this project. Qualified researchers and organizations (e.g., the North American Association of Central Cancer Registries, the American Cancer Society, the National Cancer Institute) will be required to sign a detailed data release agreement to have access to restricted release data.

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Frequently Asked Questions**

***Background***

The Centers for Disease Control and Prevention (CDC) is responsible for public health surveillance in the United States. CDC collects, compiles, and publishes a large volume of personal, medical, epidemiologic, and statistical data. The success of CDC's operations depends, in part, on the agency's ability to protect the confidentiality of these data. While it is a matter of principle for CDC to guard sensitive information, and federal statutes such as the Privacy Act provide a degree of protection for personally identifiable data, the Public Health Service Act, Section 308(d) enables CDC to provide the highest level of confidentiality protection for sensitive and mission-significant research and surveillance data.

CDC received a formal delegation of authority from the National Center for Health Statistics (then a separate agency) to grant 308(d) confidentiality protection in 1983. Section 308(d) of the Public Health Service Act (42 U.S.C. 242 m(d)) ensures the confidentiality of data collected under Sections 304 and 306 of the Public Health Service Act. These special legislative authorities were the provisions under which NCHS collects and safeguards most of its survey data, along with the mortality data within the National Death Index. CDC was required to establish a stringent application process, and continues to use the authority sparingly. The agency has granted confidentiality assurances to projects deemed significant to CDC's mission, such as surveillance of hospital infections, AIDS and HIV infections, pregnancy related mortality, and congenital defects. Fewer than fifty projects have received 308(d) protection since CDC received this authority, and currently there are only approximately 25 active projects with 308(d) confidentiality assurances. As a testament of the importance of this project to the mission of CDC, the National Program of Cancer Registries (NPCR) has been afforded this special data protection.

**1. What is stated in Public Health Service Act, Section 308(d)?**

The first clause of Section 308(d) states that CDC must explain the purpose for collecting data to persons or agencies supplying information, and it guarantees that CDC will be limited to those specified uses unless an additional consent is obtained. Moreover, the information obtained may be used only by staff of CDC, or its contractors, in the pursuit of such stated 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. What process did NPCR undertake to obtain 308(d) confidentiality protection?**

NPCR staff worked with the CDC Office of General Counsel and the CDC Confidentiality and Privacy Officer to prepare the application for the NPCR Cancer Surveillance System (CSS)

project. The application contained the following four components:

- a. A Justification Statement summarizing the NPCR-CSS project's programmatic purpose, the type of data to be collected, and the uses to be made of the information. This statement also included an assurance that a) the requested data would not be furnished without the guarantee of a confidentiality assurance, b) confidentiality assurance is important to protect the individuals described in the data and to reassure the institutions submitting data, c) the information cannot reliably be obtained from other sources, d) the information is essential to the project's success, e) granting the confidentiality assurance would not prohibit CDC from fulfilling its responsibilities, and f) the advantages of assuring confidentiality outweigh the disadvantages.
- b. An Assurance of Confidentiality Statement delineating anticipated data uses and those with whom identifiable data would be shared, along with general advisements regarding the confidentiality protection.
- c. A Confidentiality Security Statement detailing the stringent safeguarding measures in place to ensure that the promise of confidentiality would not be jeopardized by practices of staff handling the data.
- d. An IRB Review Status Statement verifying NPCR-CSS's exemption from CDC Institutional Review Board (IRB) approval. (The Human Subjects Administrator at the National Center for Chronic Disease Prevention and Health Promotion determined that NPCR-CSS activities are routine surveillance and not research on human subjects. Therefore, protocol review by CDC IRB was deemed not necessary.)

The application was submitted to the CDC Confidentiality Officer for review and modification, prepared for presentation to the CDC Confidentiality Review Group (CRG), and in May 2000 NPCR received 308(d) confidentiality protection approval for NPCR-CSS data, including authorization for retroactive confidentiality protection beginning with diagnosis year 1995. NPCR must file for continuation every five years to maintain the assurance. In 2006, NPCR filed and received approval for continuation.

### **3. What makes 308(d) confidentiality assurance the best protection for NPCR-CSS data?**

The 308(d) confidentiality assurance is the only confidentiality protection that covers routine surveillance activities, such as those conducted by NPCR-CSS. The assurance specifies that data protected by 308(d) may be used only for statistical or epidemiological purposes and not released further in identifiable form without consent. Another exclusive advantage of 308(d) is that it also protects indirectly identifiable data. Operationally, this means that NPCR may never release a directly identifiable variable (e.g., social security number) or any combination of variables that could be used to indirectly identify an individual. Finally, 308(d) provides protection for information on both living and deceased individuals.

### **4. Are there any disadvantages to individuals or institutions protected by the 308(d) confidentiality assurances?**

A 308(d) confidentiality assurance does not pose a disadvantage for individuals or institutions

submitting data to CDC. In fact, 308(d) provides an added benefit because it prevents CDC from freely releasing data to researchers and any other persons or entities that could request access to the data. With the confidentiality assurance protecting NPCR-CSS data, NPCR staff members are prohibited from sharing data except for the purposes stated at the time of data collection, unless consent from those provided the assurance is obtained.

**5. Does NPCR's 308(d) confidentiality assurance protect the data from subpoena and Freedom of Information Act (FOIA) requests?**

The 308(d) assurance is the strongest protection against compulsory legal disclosure that CDC can offer. Although CDC receives Freedom of Information Act (FOIA) requests, the FOIA (b)(6) exemption enables CDC to withhold sensitive, individually identified data that would constitute a "clearly unwarranted invasion of personal privacy." It is CDC's firm position that all projects covered by a 308(d) confidentiality assurance, including NPCR-CSS, meet this exemption.

**6. Has a case involving 308(d) been tested in court?**

Yes. CDC's ability to protect data submitted to the agency was upheld in court. The case involved a National Institute for Occupational Safety and Health project collecting death certificate information, which is widely accepted as the least sensitive data protected by 308(d). The court's ruling in favor of the non-release of these data establishes an effective precedent for restricting access to more sensitive data, such as that collected by a cancer registry.

**7. How long are confidential data submitted to NPCR-CSS protected?**

NPCR-CSS data are covered by the 308(d) confidentiality assurance forever. Individual records in the NPCR-CSS surveillance system are protected even following the death of the cancer patients.

**8. Will NPCR release CSS data to persons or agencies outside of CDC?**

An assurance of confidentiality protects NPCR-CSS data held at CDC and by its contractor, Macro International, Inc. Data that are released to external researchers are done so in accordance with the Data Use Agreement (copy attached) prohibiting attempts to identify subjects within the record system. The 308(d) confidentiality protection does not go with the data, and any data released to qualified researchers by CDC are subject to the limits of any coverage afforded by the requesting agency. However, it is important to note that NPCR's confidentiality assurance prohibits the release of any data that are directly or indirectly identifiable. Therefore, CDC would not release highly sensitive NPCR-CSS data. Under the 308(d), NPCR is permitted to release NPCR-CSS data to qualified researchers and organizations, such as the North American Association of Central Cancer Registries (NAACCR), the American Cancer Society (ACS), and the National Cancer Institute (NCI). This is so because these entities were specifically mentioned in the NPCR-CSS confidentiality assurance as anticipated recipients of identifiable data. Prior to the restricted release of NPCR-CSS data, a detailed data use agreement must be

signed by the requesting party. Information that could lead to the identification of cancer patients, through either direct or indirect methods, cannot be made available to any other group or individual. In particular, NPCR cannot disclose information to insurance companies; any party involved in civil, criminal, or administrative litigation; agencies of federal, state or local government; or any other member of the public.

**9. Are there penalties for violating the confidentiality assurance?**

NPCR employees and contractors at Macro International, Inc. working on the NPCR-CSS project may be subject to fine, imprisonment, and termination of employment for unauthorized disclosure of confidential information. To assure that all NPCR employees are aware of their responsibilities to maintain and protect NPCR-CSS records and the penalties for failing to comply, CDC employees must read and sign a data use agreement. Contract employees at Macro International, Inc. with access to NPCR-CSS data are required to sign a Confidentiality Agreement.