system are instructed to grant regular access only to physicians, scientists, and support staff of the National Cancer Institute and Women's Health Initiative, respectively, or their contractors, grantees or collaborators who need such information in order to contribute to the research or administrative purposes of the system. The system managers specifically authorize one-time and special access by others on a need-to-know basis consistent with the purposes and routine uses of the system.

2. Physical safeguards. Records are kept in limited access areas. Offices and records storage locations are locked during off-duty hours. Input data for computer files is coded to avoid individual identification. Where possible, information on individual identities is kept separate from data used for analysis.

3. Procedural safeguards. Access to manual files is granted only to authorized personnel, as described above. Access to computer files is controlled through security codes known only to authorized users. Names and other details necessary to identify individuals are not included in data files used for analysis. These files are indexed by code numbers. Code numbers and complete identifiers are linked only if there is a specific need, such as for data verification.

Contractors, grantees or collaborators who maintain records in this system are instructed to make no further disclosure of the records except as authorized by the system manager and permitted by the Privacy Act. Privacy Act requirements are specifically included in contracts and in agreements with grantees or collaborators participating in research activities supported by this system. HHS project director, contract officers and project officers oversee compliance with these requirements.

The particular safeguards implemented at each site are developed in accordance with Chapter 45–13, "Safeguarding Records Contained in Systems of Records," of the HHS General Administration Manual, supplementary Chapter PHS.hf: 45–13, and Part 6, "ADP Systems Security", of the HHS Information Resources Management Manual and the National Institute of Standards and Technology Federal Information Processing Standards (FIPS Pub. 41 and FIPS Pub. 31).

RETENTION AND DISPOSAL:

Records are retained and disposed of under the authority of the NIH Records Control Schedule contained in NIH Manual Chapter 1743, Appendix 1— "Keeping and Destroying Records" (HHS Records Management Manual, Appendix B–361), item 3000–G–3, which allows records to be kept as long as they are useful in scientific research. Refer to the NIH Manual Chapter for specific disposition instructions.

SYSTEM MANAGER AND ADDRESS:

Associate Director, Surveillance Program, DCPC, National Cancer Institute, Executive Plaza North, Room 343K, 6130 Executive Blvd, MSC 7350, Bethesda, MD 20892–7350

Director, Women's Health Initiative, Office of the Director, National Institutes of Health, Building 1, Room 260, 9000 Rockville Pike, Bethesda, MD 20892

NOTIFICATION PROCEDURE:

To determine if a file exists, write to the appropriate system manager and provide the following information:

- a. System name: "Biomedical Research Records of Subjects: (1) Cancer Studies of the Division of Cancer Prevention and Control, HHS/NIH/NCI; and (2) Women's Health Initiative Studies, HHS/NIH/OD."
- b. Complete name at time of participation;
- c. Facility and home address at the time of participation;
- d. In some cases, where records are retrieved by an identifying number, such as the Social Security Number or Hospital Identification Number, it may be necessary to provide that number. In some cases, to ensure proper identification it may be necessary to provide date(s) of participation (if known), birth date, disease type (if known), and study name and location (if known).

The requester must also verify his or her identity by providing either a notarization of the request or a written certification that the requester is who he or she claims to be and understands that the knowing and willful request for acquisition of a record pertaining to an individual under false pretenses is a criminal offense under the Act, subject to a maximum fine of five thousand dollars.

Individuals seeking notification of or access to medical records should designate a representative (including address) who may be a physician, other health professional, or other responsible individual, who would be willing to review the record and inform the subject individual of its contents, at the representative's discretion.

A parent or guardian who requests notification of, or access to, a child's or incompetent person's medical record shall designate a family physician or other health professional (other than a family member) to whom the record, if any, will be sent. The parent or guardian must verify relationship to the child or incompetent person as well as his or her own identity.

RECORD ACCESS PROCEDURES:

Write to the appropriate system manager and provide the same information as requested under the notification procedure above. Requesters should also reasonably specify the record contents being sought. Individuals may also request listings of accountable disclosures that have been made of their records, if any.

CONTESTING RECORD PROCEDURES:

Write to the appropriate system manager, identify the record, and specify the information contested. State the corrective action sought and your reasons for requesting the correction, and provide supporting information to show that the record is inaccurate, incomplete, irrelevant, untimely, or unnecessary. The right to contest records is limited to information which is incomplete, irrelevant, incorrect, or untimely (obsolete).

RECORD SOURCE CATEGORIES:

HHS agencies, institutions under contract to the U.S. Government, such as universities, medical schools, hospitals, research institutions, commercial institutions, state agencies, other U.S. Government agencies, patients and normal volunteers, physicians, research investigators and other collaborating personnel.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

02-25-0156

SYSTEM NAME:

Records of Participants in Programs and Respondents in Surveys Used to Evaluate Programs of the Public Health Service, HHS/PHS/NIH/OD.

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

This system of records is an umbrella system comprising separate sets of records located either in the organizations responsible for conducting evaluations or at the sites of programs or activities under evaluation. Locations include Public Health (PHS) facilities, or facilities of contractors of the PHS. Write to the appropriate System Manager below for a list of current locations.