the purpose for which the records were collected.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

#### STORAGE:

Data may be stored in file folders, microfilm, magnetic tapes or disks, punched cards, or bound notebooks.

#### RETRIEVABILITY:

Information is retrieved by name and/ or a participant identification number.

#### SAFEGUARDS:

Measures to prevent unauthorized disclosures are implemented as appropriate for each location and for the particular records maintained in each project. Each site implements personnel, physical and procedural safeguards such as the following:

- 1. Authorized users: Employees who maintain records in this system are instructed to grant regular access only to contractor personnel; consultants to the contractor; the NICHD project officer; and NICHD employees whose duties require the use of such information. One time and special access to the data is controlled by the System Manager, the NICHD Project Officer, and the Contract and/or Project Director.
- 2. Physical safeguards: Records are stored in locked files or secured areas. Computer terminals are in secured areas
- 3. Procedural safeguards: Names and other identifying particulars are deleted when data from original records is encoded for analysis. Encoded data is indexed by code numbers. Tables linking these code numbers with actual identifiers are maintained separately. Code numbers and identifiers are linked only if there is a specific need, such as alerting the volunteer subjects to any findings in the study that night affect their health. Data stored in computers is accessed through the use of passwords/ keywords known only to the principal investigators or authorized personnel. These passwords/keywords are changed frequently.

The particular safeguards implemented in each project will be 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; Part 6, "ADP Systems Security," of the HHS ADP Systems 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 trained 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:

Chief, Contracts Management Branch, NICHD, Executive Building, Room 7A07, 6100 Executive Blvd., North Bethesda, MD 20892–7510

## NOTIFICATION PROCEDURE:

To determine if a record exists, write to:

NICHD Privacy Act Coordinator, Executive Building, Room 4A01B, 6100 Executive Blvd., North Bethesda, MD 20892–7510

and provide the following information in writing:

- 1. Full name and address at time of participation in the study.
- 2. Name or description of the study.3. Location and approximate dates of

participation.

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 five thousand dollar fine.

An individual who requests notification of, or access to, a medical record shall, at the time the request is made, designate in writing a responsible representative who will 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, the medical record of a child or incompetent person 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 his or her relationship to the child or incompetent person as well as his or her own identity.

## RECORD ACCESS PROCEDURES:

Same as 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 official specified under notification procedures above, and reasonably identify the record and specify the information being contested, the corrective action sought, and your reasons for requesting the correction, along with supporting information to show how the record is inaccurate, incomplete, untimely or irrelevant. The right to contest records is limited to information which is incomplete, irrelevant, incorrect, or untimely (obsolete).

### **RECORD SOURCE CATEGORIES:**

Information contained in these records is obtained directly from individual participants, medical and clinical research observations, and other federal agencies.

# SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

### 09-25-0154

#### 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 (WHI) Studies, HHS/NIH/OD.

## SECURITY CLASSIFICATION:

None.

## SYSTEM LOCATION:

National Institutes of Health, Executive Plaza North, Room 343K, 6130 Executive Blvd. MSC 7350, Bethesda, MD 20892–7350

and

National Institutes of Health, Building 12, 9000 Rockville Pike, Bethesda, MD 20892

and

National Institutes of Health, Building 1 Room 260, 9000 Rockville Pike, Bethesda, MD 20892

and at hospitals, medical schools, universities, research institutions, commercial organizations, collaborating State and Federal Government agencies, and Federal Records Centers. Write to system manager at the address below for the address of current locations.

## CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

NCI: Adults and children in the following categories: Patients with cancer; persons for whom cancer risk can potentially be lowered; and persons without signs or symptoms who may be identified through screening and detection methods as having cancer or