being at increased risk of developing cancer. For certain types of epidemiologic studies, e.g., case-control studies, NCI may also collect, for purposes of comparison, records on other persons. These comparison groups could include normal individuals (e.g., family members or neighborhood controls), or other patient groups (e.g., hospital controls) who do not have cancer or are not at a particularly high risk of developing cancer. Health care and educators who provide services and training for all such persons above. WHI: Women for whom risk of cancer and/or other chronic disease may potentially be lowered. Women without signs or symptoms of chronic disease who may be identified through screening and detection methods as being at risk for serious chronic ailments. WHI may also collect, for purposes of comparison, longitudinal records on other women for whom no added disease risk has been identified.

#### CATEGORIES OF RECORDS IN THE SYSTEM:

Information identifying participants (such as name, address, Social Security Number), medical records, progress reports, correspondence, epidemiologic data, and records on biological specimens (e.g., blood, tumors, urine, etc).

## AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

NCI: Sections 301, Research and Investigation, 405 Appointment and Authority of the Directors of the National Research Institutes, and Title IV, Part C, Subpart 1—National Cancer Institute, of the Public Health Service (PHS) Act (42 U.S.C. 241, 284 and 285–285a–5). WHI: 42 U.S.C. 241 and section 402, Appointment and Authority of Director of NIH, of the PHS (42 U.S.C. 282).

### PURPOSE(S):

Records in this system will be used, (1) to evaluate cancer and other chronic disease control programs, such as prevention, screening, detection, diagnosis, treatment, rehabilitation, and continuing care; (2) to identify characteristics of persons who may be particularly susceptible to environmental or occupational factors for substances which cause or prevent cancer and/or other chronic diseases; (3) to determine risk factors or substances which cause or prevent cancer and/or other chronic diseases, and the ways in which they do so; (4) to evaluate statistical and epidemiological methodologies for risk factor assessment, clinical trials, cancer control studies, and the study of the natural history of cancers and/or other

chronic diseases; (5) to plan for, administer, and review research activities as described in the above purposes; (6) information from this system may be reported to the Food and Drug Administration (FDA) as a condition for approval of clinical investigations of new drugs, or to report adverse effects of drugs so that FDA can make informed decisions on authorizing use of such drugs.

# ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

- 1. Disclosure may be made to HHS contractors, grantees and collaborating researchers and their staff in order to accomplish the research purposes for which the records are collected. The recipients are required to comply with the requirements of the Privacy Act with respect to such records.
- 2. Disclosure may be made to organizations deemed qualified by the Secretary to carry out quality assessments, medical audits or utilization review.
- 3. The Department contemplates that it may contract with a private firm for the purposes of collating, analyzing, aggregating or otherwise refining records in this system. Relevant records will be disclosed to such a contractor. The contractor will be required to comply with the requirements of the Privacy Act with respect to such records.
- 4. A record be disclosed for a research purpose, when the Department: (a) Has determined that the use or disclosure does not violate legal or policy limitations under which the record was provided, collected, or obtained; (B) has determined that the research purpose (1) cannot be reasonably accomplished unless the record is provided in individually identifiable form, and (2) warrants the risk to the privacy of the individual that additional exposure of the record might bring; (C) has required the recipient to (1) establish reasonable administrative, technical, and physical safeguards to prevent unauthorized use or disclosure of the record, (2) remove or destroy the information that identifies the individual at the earliest time at which removal or destruction can be accomplished consistent with the purpose of the research project, unless the recipient has presented adequate justification of a research or health nature for retaining such information, and (3) make no further use or disclosure of the record except (a) in emergency circumstances affecting the health or safety of any individual, (b) for use in another research project, under these same conditions, and with written

authorization of the Department, (c) for disclosure to a properly identified person for the purpose of an audit related to the research project, if information that would enable research subjects to be identified is removed or destroyed at the earliest opportunity consistent with the purpose of the audit, or (d) when required by law; (D) has secured a written statement attesting to the recipient's understanding of, and willingness to abide by these provisions.

5. Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

6. In the event of litigation where the defendant is (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, for example, in defending a claim against the Public Health Service based upon an individual's mental or physical condition and alleged to have arisen because of activities of the Public Health Service in connection with such individual, the Department may disclose such records as it deems desirable or necessary to the Department of Justice to enable that Department to present an effective defense, provided that such disclosure is compatible with the purpose for which the records were collected.

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

### STORAGE:

File folders, microfilm, charts, graphs, computer tapes, disks, and punch cards.

### RETRIEVABILITY:

By name, Social Security Number when supplied voluntarily or contained in existing records used in projects under this system, or other identifying 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. NCI and WHI employees who maintain records in this