CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individuals covered by this system are those who provide information or opinions that are useful in evaluating programs or activities of the PHS, other persons who have participated in or benefitted from PHS programs or activities; or other persons included in evaluation studies for purposes of comparison. Such individuals may include (1) participants in research studies; (2) applicants for and recipients of grants, fellowships, traineeships or other awards; (3) employees, experts and consultants; (4) members of advisory committees; (5) other researchers, health care professionals, or individuals who have or are at risk of developing diseases or conditions studied by PHS; (6) persons who provide feedback about the value or usefulness of information they receive about PHS programs, activities or research results; (7) persons who have received Doctorate level degrees from U.S. institutions; (8) persons who have worked or studied at U.S. institutions that receive(d) institutional support from PHS.

CATEGORIES OF RECORDS IN THE SYSTEM:

This umbrella system of records covers a varying number of separate sets of records used in different evaluation studies. The categories of records in each set depend on the type of program being evaluated and the specific purpose of the evaluation. In general, the records contain two types of information: (1) Information identifying subject individuals, and (2) information which enables PHS to evaluate its programs and services.

(1) Identifying information usually consists of a name and address, but it might also include a patient identification number, grant number, Social Security Number, or other identifying number as appropriate to the particular group included in an evaluation study.

(2) Information used for evaluation varies according to the program evaluated. Categories of evaluative information include personal data and medical data on participants in clinical and research programs; personal data, publications, professional achievements and career history of researchers; and opinions and other information received directly from individuals in evaluation surveys and studies of PHS programs.

The system does not include any master list, index or other central means of identifying all individuals whose records are included in the various sets of records covered by the system.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Authority for this system comes from the authorities regarding the establishment of the National Institutes of Health, its general authority to conduct and fund research and to provide training assistance, and its general authority to maintain records in connection with these and its other functions (42 U.S.C. 203, 241, 2891–1 and 44 U.S.C. 3101), and section 301 and 493 of the Public Health Service Act.

PURPOSE(S):

This system supports evaluation of the policies, programs, organization, methods, materials, activities or services used by PHS in fulfilling its legislated mandate for (1) conduct and support of biomedical research into the causes, prevention and cure of diseases; (2) support for training of research investigators; (3) communication of biomedical information.

This system is not used to make any determination affecting the rights, benefits or privileges of any individual.

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 and collaborating researchers, organizations, and State and local officials for the purpose of conducting evaluation studies or collecting, aggregating, processing or analyzing records used in evaluation studies. The recipients are required to protect the confidentiality of 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. 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.

4. The Department may disclose information from this system of records to the Department of Justice, to court or other tribunal, or to another party before such tribunal, when (a) HHS, or any component thereof; or (b) any HHS employee in his or her official capacity; or (c) any HHS employee in his or her individual capacity where the Department of Justice (or HHS, where it is authorized to do so) has agreed to represent the employee; or (d) the United States or any agency thereof where HHS or any of its components, is a party to litigation or has an interest in such litigation, and HHS determines that the use of such records by the

Department of Justice, the tribunal, or the other party is relevant and necessary to the litigation and would help in the effective representation of the governmental party, provided, however, that in each case, HHS determines 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:

Data may be stored in file folders, bound notebooks, or computeraccessible media (e.g., magnetic tapes or discs).

RETRIEVABILITY:

Information is retrieved by name and/ or participant identification number within each evaluation study. There is no central collection of records in this system, and no central means of identifying individuals whose records are included in the separate sets of records that are maintained for particular evaluation studies.

SAFEGUARDS:

A variety of safeguards are implemented for the various sets of records in this system according to the sensitivity of the data each set contains. Information already in the public domain, such as titles and dates of publications, is not restricted. However, sensitive information, such as personal or medical history or individually identified opinions, is protected according to its level of sensitivity. Records derived from other systems of records will be safeguarded at a level at least as stringent as that required in the original systems. Minimal safeguards for the protection of information which is not available to the general public included the following:

1. Authorized users: Regular access to information in a given set of records is limited to PHS or to contractor employees who are conducting, reviewing or contributing to a specific evaluation study. Other access is granted only on a case-by-case basis, consistent with the restrictions required by the Privacy Act (e.g., when disclosure is required by the Freedom of Information Act), as authorized by the system manager or designated responsible official.

2. *Physical safeguards:* Records are stored in closed or locked containers, in areas which are not accessible to unauthorized users, and in facilities which are locked when not in use. Records collected in each evaluation project are maintained separately from