DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Privacy Act of 1974; New System of Records

AGENCY: National Institutes of Health, HHS.

ACTION: Notification of a new system of records.

SUMMARY: In accordance with the requirements of the Privacy Act, the National Institutes of Health (NIH) is publishing a notice of a new system of records, 09–25–0200, ''Clinical, Epidemiologic and Biometric Studies of the National Institutes of Health (NIH), HHS/NIH/OD.'' This system notice serves as an umbrella system for most NIH clinical, epidemiologic and biometric research studies. Thirty-eight existing NIH system notices were subsumed under this notice (listed in the system notice under System Manager(s)), to reduce the number and avoid future proliferation of like system notices. We are also proposing routine uses for this new system; with two exceptions, these routine uses were already contained in the preceding system notices. The first new routine use will allow disclosure to authorized organizations which provide health services to subject individuals or provide third-party reimbursement or fiscal intermediary functions. The purpose of the disclosure is to plan for or provide such services, bill or collect third-party reimbursements. The second new routine use will allow disclosure for the purpose of reporting child, elder, or spousal abuse or neglect, or any other type of abuse or neglect as required by State or Federal law.

DATES: NIH invites interested parties to submit comments on the proposed internal and routine uses on or before May 7, 1997. NIH has sent a report of a New System to the Congress and to the Office of Management and Budget (OMB) on November 6, 1996. This system of records will be effective 40 days from the date of publication unless NIH receives comments on the routine uses which would result in a contrary determination.

ADDRESS: Please submit comments to: NIH Privacy Act Officer, Building 31, Room 1B05, 31 Center Drive MSC 2075, Bethesda, MD 20892–2075, 301–496–2832.

Comments received will be available for inspection at this same address from 9 a.m. to 3 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: NIH Privacy Act Officer, Building 31, Room 1B05, 31 Center Drive MSC 2075, Bethesda, MD 20892–2075, 301–496–2832.

The numbers listed above are not toll free.

SUPPLEMENTARY INFORMATION: The National Institutes of Health (NIH) proposes to establish a new system of records: 09–25–0200, ''Clinical, Epidemiologic and Biometric Studies of the National Institutes of Health (NIH), HHS/NIH/OD.'' This umbrella system of records will be used by NIH staff to document, track, monitor and evaluate NIH clinical, epidemiologic and biometric research activities. This inclusive system notice will achieve agency administrative efficiencies, avoiding confusion created by the current fragmented pool of Institute, Center and Division (ICD) system notices. Because of its unique organizational structure, NIH has, over the recent decades, experienced a proliferation of almost identical system notices that differ only by disease/disorder under study or ICD interest. This system notice subsumes thirty-eight existing system notices and will offer coverage for research not currently covered by an appropriate system notice. The consolidation of similar research systems of records into one generic-type notice will also serve the public interest. It will alleviate burden on the public associated with multiple attempts at notification, access and correction of record information when individuals are not sure which research system notice applied to their study participation.

The system will comprise records about individuals as relevant to a particular research study. Examples include, but are not limited to: Name, study identification number, address, relevant telephone numbers, Social Security Number (voluntary), driver's license number, date of birth, weight, height, sex, race; medical, psychological and dental information, laboratory and diagnostic testing results; registries; social, economic and demographic data; health services utilization; insurance and hospital cost data, employers, conditions of the work environment, exposure to hazardous substances/compounds; information pertaining to stored biologic specimens (including blood, urine, tissue and genetic materials), characteristics and activities of health care providers and educators and trainers (including curriculum vitae); and associated correspondence. The amount of information recorded on each individual will be only that which is necessary to accomplish the purpose of the system.

The records in this system will be maintained in a secure manner compatible with their content and use. NIH and contractor staff will be required to adhere to the provisions of the Privacy Act and the HHS Privacy Act Regulations. The System Manager will control access to the data. Only authorized users whose official duties require the use of such information will have regular access to the records in this system. Authorized users are HHS employees, and contractors responsible for implementing the research.

Records may be stored on index cards, file folders, computer tapes and disks (including optical disks), photography media, microfiche, microfilm, and audio and video tapes. Manual and computerized records will be maintained in accordance with the standards of Chapter 45–13 of the HHS General Administration Manual, ''Safeguarding Records Contained in Systems of Records,'' supplementary Chapter PHS hf:45–13, the Department's Automated Information System Security Program Handbook, and the National Institute of Standards and Technology Federal Information Processing Standards (FIPS Pub. 41 and FIPS Pub. 31).

Data on computer files is accessed by keyword known only to authorized users. Access to information is thus limited to those with a need to know. Rooms where records are stored are locked when not in use. During regular business hours rooms are unlocked but are controlled by on-site personnel. Researchers authorized to conduct research on biological specimens will typically access to the system through the use of encrypted identifiers sufficient to link individuals with records in such a manner that does not compromise confidentiality of the individual. All authorized users of personal information in connection with the performance of their jobs protect information from public view and from unauthorized personnel entering an unsupervised office. Depending upon the sensitivity of the information in the record, additional safeguard measures are employed.

The routine uses proposed for this system are compatible with the stated purposes of the system. The first routine use permits disclosure of a record for an authorized research purpose under specified conditions. The second routine use permitting disclosure to a congressional office is proposed to allow subject individuals to obtain assistance from their representatives in Congress, should they so desire. Such

disclosure would be made only pursuant to a request of the individual. The third routine use allows disclosure to the Department of Justice for use in litigation. The fourth routine use allows disclosure of records to contractor, grantee, experts, consultants or volunteers who have been engaged by the agency to assist in the performance of a service related to this system of records and who need to have access to the records in order to perform the activity. The fifth routine use allows disclosure to certain relevant third parties (e.g., relatives, prior employees, Motor Vehicle Administration, State vita statistics offices) when necessary to obtain information on morbidity and mortality experiences and to locate individuals for follow-up studies. The sixth routine use allows disclosure to tumor registries for maintenance of health statistics. The seventh routine use allows the PHS to inform the sexual and/or needle-sharing partner(s) of a subject individual who is infected with the human immunodeficiency virus (HIV) of their exposure to HIV, or to disclose such information to State or local public health departments under specified circumstances. The eighth routine use allows disclosure of certain diseases and conditions, including infectious diseases, to appropriate representatives of State or Federal Government as required by State or Federal law. The ninth routine use allows records to be disclosed to authorized organizations which provide health services to subject individuals or provide third-party reimbursement or fiscal intermediary functions, for the purpose of planning for or providing such services, billing or collecting third-party reimbursements. The tenth routine use allows disclosure to organizations deemed qualified by the Secretary, DHHS, to carry out quality assessment, medical audits or utilization reviews. The eleventh routine use allows information to be disclosed for the purpose of reporting child, elder or spousal abuse or neglect, or any other type of abuse or neglect as required by State or Federal law.

The following notice is written in the present, rather than future tense, in order to avoid the unnecessary expenditure of public funds to republish the notice after the system has become effective.

Dated: October 30, 1996.

Anthony L. Itteilag,

Deputy Director for Management, National Institutes of Health.

09–25–0200

SYSTEM NAME:

Clinical, Epidemiologic and Biometric Studies of the National Institutes of Health (NIH), HHS/NIH/OD.

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

Records are located at NIH and Contractor research facilities which collect or provide research data for this system. Contractors may include, but are not limited to: Research centers, clinics, hospitals, universities, medical schools, research institutions/foundations, national associations, commercial organizations, collaborating State and Federal Government agencies, and coordinating centers. A current list of sites, including the address of any Federal Records Center where records from this system may be stored, is available by writing to the appropriate Coordinator listed under Notification Procedure.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Adults and/or children who are the subjects of clinical, epidemiologic, and biometric research studies of the NIH. Individuals with disease. Individuals who are representative of the general population or of special groups including, but not limited to: Normal controls, normal volunteers, family members and relatives; providers of services (e.g., health care and social work); health care professionals and educators, and demographic sub-groups as applicable, such as age, sex, ethnicity, race, occupation, geographic location; and groups exposed to real and/or hypothesized risks (e.g., exposure to biohazardous microbial agents).

CATEGORIES OF RECORDS IN THE SYSTEM:

The system contains data about individuals as relevant to a particular research study. Examples include, but are not limited to: Name, study identification number, address, relevant telephone numbers, Social Security Number (voluntary), driver's license number, date of birth, weight, height, sex, race; medical, psychological and dental information, laboratory and diagnostic testing results; registries; social, economic and demographic data; health services utilization; insurance and hospital cost data, employers, conditions of the work environment, exposure to hazardous substances/compounds; information pertaining to stored biologic specimens (including blood, urine, tissue and genetic materials), characteristics and activities of health care providers and educators and trainers (including curriculum vitae); and associated correspondence.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

''Research and Investigation,'' ''Appointment and Authority of the Directors of the National Research Institutes,'' ''National Cancer Institute,'' ''National Eye Institute,'' ''National Heart, Lung and Blood Institute,'' ''National Institute on Aging,'' ''National Institute on Alcohol Abuse and Alcoholism,'' ''National Institute on Allergy and Infectious Diseases,'' ''National Institute of Arthritis and Musculoskeletal and Skin Diseases,'' ''National Institute of Child Health and Human Development,'' ''National Institute on Deafness and Other Communication Disorders,'' ''National Institute of Dental Research,'' ''National Institute of Diabetes, and Digestive and Kidney Diseases,'' ''National Institute of Drug Abuse,'' ''National Institute of Environmental Health Sciences,'' ''National Institute of Mental Health,'' ''National Institute of Neurological Disorders and Stroke,'' and the ''National Center for Human Genome Research,'' of the Public Health Service Act. (42 U.S.C. 241, 242, 248, 281, 282, 284, 285a, 285b, 285c, 285d, 285e, 285f, 285g, 285h, 285i, 285j, 285l, 285m, 285n, 285o, 285p, 285q, 287, 287b, 287c, 289a, 289c, and 44 U.S.C. 3101.)

PURPOSE(S)

To document, track, monitor and evaluate NIH clinical, epidemiologic and biometric research activities.

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

1. A record may 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; e.g., disclosure of alcohol or drug abuse patient records will be made only in accordance with the restrictions of confidentiality statutes and regulations 42 U.S.C. 241, 42 U.S.C. 290dd–2, 42 CFR part 2, and where applicable, no disclosures will be made inconsistent with an authorization of confidentiality under 42 U.S.C. 241 and 42 CFR part 2a; (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 property 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; and (D) has secured a written statement attesting to the recipient's understanding of, and willingness to abide by, these provisions.

2. Disclosure may be made to a Member of Congress or to a Congressional staff member in response to an inquiry of the Congressional office made at the written request of the constituent about whom the record is maintained.

3. The Department of Health and Human Services (HHS) may disclose information from this system of records to the Department of Justice when: (a) The agency or any component thereof; or (b) any employee of the agency in his or her official capacity where the Department of Justice has agreed to represent the employee; or (c) the United States Government, is a party to litigation or has an interest in such litigation, and by careful review, the agency determines that the records are both relevant and necessary to the litigation and the use of such records by the Department of Justice is therefore deemed by the agency to be for a purpose that is compatible with the purpose for which the agency collected the records.

4. Disclosure may be made to agency contractors, grantees, experts, consultants, collaborating researchers, or volunteers who have been engaged by the agency to assist in the performance of a service related to this system of records and who need to have access to the records in order to perform the activity. Recipients shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. Information from this system may be disclosed to Federal agencies, State agencies (including the Motor Vehicle Administration and State vital statistics offices, private agencies, and other third parties (such as current or prior employers, acquaintances, relatives), when necessary to obtain information on morbidity and mortality experiences and to locate individuals for follow-up studies. Social Security numbers, date of birth and other identifiers may be disclosed: (1) To the National Center for Health Statistics to ascertain vital status through the National Death Index; (2) to the Health Care Financing Agency to ascertain morbidities; and (3) to the Social Security Administration to ascertain disabilities and/or location of participants. Social Security numbers may also be given to other Federal agencies, and State and local agencies when necessary to locating individuals for participation in follow-up studies.

6. Medical information may be disclosed in identifiable form to tumor registries for maintenance of health statistics, e.g., for use in epidemiologic studies.

7. (a). PHS may inform the sexual and/or needle-sharing partner(s) of a subject individual who is infected with the human immunodeficiency virus (HIV) of their exposure to HIV, under the following circumstances: (1) The information has been obtained in the course of clinical activities at PHS facilities carried out by PHS personnel or contractors; (2) The PHS employee or contractor has made reasonable efforts to counsel and encourage the subject individual to provide the information to the individual's sexual or needle-sharing partner(s); (3) The PHS employee or contractor determines that the subject individual is unlikely to provide the information to the sexual or needle-sharing partner(s) or that the provision of such information cannot reasonably be verified; and (4) The notification of the partner(s) is made, whenever possible, by the subject individual's physician or by a professional counselor and shall follow standard counseling practices.

(b). PHS may disclose information to State or local public health departments, to assist in the notification of the subject individual's sexual and/or needle-sharing partner(s), or in the verification that the subject individual has notified such sexual or needle-sharing partner(s).

8. Certain diseases and conditions, including infectious diseases, may be reported to appropriate representatives of State or Federal Government as required by State or Federal law.

9. Disclosure may be made to authorized organizations which provide health services to subject individuals or provide third-party reimbursement or fiscal intermediary functions, for the purpose of planning for or providing such services, billing or collecting third-party reimbursements.

10. The Secretary may disclose information to organizations deemed qualified to carry out quality assessment, medical audits or utilization reviews.

11. Disclosure may be made for the purpose of reporting child, elder or spousal abuse or neglect or any other type of abuse or neglect as required by State or Federal law.

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

STORAGE:

Records may be stored on index cards, file folders, computer tapes and disks (including optical disks), photography media, microfiche, microfilm, and audio and video tapes. For certain studies, factual data with study code numbers are stored on computer tape or disk, while the key to personal identifiers is stored separately, without factual data, in paper/computer files.

RETRIEVABILITY:

During data collection stages and follow-up, retrieval is by personal identifier (e.g., name, Social Security Number, medical record or study identification number, etc.). During the data analysis stage, data are normally retrieved by the variables of interest (e.g., diagnosis, age, occupation).

SAFEGUARDS:

1. *Authorized Users:* Access to identifiers and to link files is strictly limited to the authorized personnel whose duties require such access. Procedures for determining authorized access to identified data are established as appropriate for each location. Personnel, including contractor personnel, who may be so authorized include those directly involved in data collection and in the design of research studies, e.g., interviewers and interviewer supervisors; project managers; and statisticians involved in designing sampling plans. Other one-time and special access by other employees is granted on a need-to-know basis as specifically authorized by the system manager.

Researchers authorized to conduct research on biologic specimens will typically access the system through the use of encrypted identifiers sufficient to link individuals with records in such a manner that does not compromise confidentiality of the individual.

2. *Physical Safeguards:* Records are either stored in locked rooms during off-duty hours, locked file cabinets, and/or secured computer facilities. For certain studies, personal identifiers and link files are separated and stored in locked files. Computer data access is limited through the use of key words known only to authorized personnel.

3. *Procedural Safeguards:* Collection and maintenance of data is consistent with legislation and regulations in the protection of human subjects, informed consent, confidentiality, and confidentiality specific to drug and alcohol abuse patients where these apply. When anonymous data is provided to research scientists for analysis, study numbers which can be matched to personal identifiers will be eliminated, scrambled, or replaced by the agency or contractor with random numbers which cannot be matched. Contractors who maintain records in this system are instructed to make no further disclosure of the records. Privacy Act requirements are specifically included in contracts for survey and research activities related to this system. The OHS project directors, contract officers, and project officers oversee compliance with these requirements. Personnel having access are trained in Privacy Act requirements. Depending upon the sensitivity of the information in the record, additional safeguard measures may be employed.

4. *Implementation Guidelines:* DHHS Chapter 45–13 and supplementary Chapter PHS.hf: 45–13 of the HHS General Administration Manual and Part 6, ''ADP System Security'' of the HHS ADP Systems Security Manual.

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. Collaborative Perinatal Project records are retained in accordance with item 3000–G–4, which does not allow records to be destroyed. William A. White Clinical Research Program medical records (Saint Elizabeths Hospital, NIMH) are retained for 5 years after last discharge or upon death of a patient and then transferred to the Washington National Records Center, where they are retained until 30 years after discharge or death. Refer to the NIH Manual Chapter for specific conditions on disposal or retention instructions.

SYSTEM MANAGER(S) AND ADDRESS:

See Appendix I for a listing of current system managers. This system is for use by all NIH Institutes, Centers, and Divisions. The following system notices have been subsumed under this umbrella system notice.

09–25–0001 Clinical Research: Patient Records, HHS/NIH/NHLBI

09–25–0010 Research Resources: Registry of Individuals Potentially Exposed to Microbial Agents, HHS/NIH/NCI

09–25–0015 Clinical Research: Collaborative Clinical Epilepsy Research, HHS/NIH/NINDS

09–25–0016 Clinical Research: Collaborative Perinatal Project, HHS/NIH/NINDS

09–25–0026 Clinical Research: Nervous System Studies, HHS/NIH/NINDS

09–25–0028 Clinical Research: Patient Medical Histories, HHS/NIH/NINDS and HHS/NIH/NIDCD

09–25–0031 Clinical Research: Serological and Virus Data in Studies Related to the Central Nervous System, HHS/NIH/NINDS

09–25–0037 Clinical Research: The Baltimore Longitudinal Study of Aging, HHS/NIH/NIA

09–25–0038 Clinical Research: Patient Data, HHS/NIH/NIDDK

09–25–0039 Clinical Research: Diabetes Mellitus Research Study of Southwestern American Indians, HHS/NIH/NIDDK

09–25–0040 Clinical Research: Southwestern American Indian Patient Data, HHS/NIH/NIDDK

09–25–0042 Clinical Research: National Institute of Dental Research Patient Records, HHS/NIH/NIDR

09–25–0044 Clinical Research: Sensory Testing Research Program, HHS/NIH/NIDR

09–25–0046 Clinical Research: Catalog of Clinical Specimens from Patients, Volunteers and Laboratory Personnel, HHS/NIH/NIAID

09–25–0053 Clinical Research: Vision Studies, HHS/NIH/NEI

09–25–0057 Clinical Research: Burkitt's Lymphonma Registry, HHS/NIH/NCI

09–25–0060 Clinical Research: Division of Cancer Treatment Clinical Investigations, HHS/NIH/NCI

09–25–0067 Clinical Research: National Cancer Incidence Surveys, HHS/NIH/NCI

09–25–0069 NIH Clinical Center Admissions of the National Cancer Institute, HHS/NIH/NCI

09–25–0074 Clinical Research: Division of Cancer Biology and Diagnosis Patient Trials, HHS/NIH/NCI

09–25–0077 Biological Carcinogenesis Branch Human Specimen Program, HHS/NIH/NCI

09–25–0126 Clinical Research: National Heart, Lung, and Blood Institute Epidemiological and Biometric Studies, HHS/NIH/NHLBI

09–25–0128 Clinical Research: Neural Prosthesis and Biomedical Engineering Studies, HHS/NIH/NINDS

09–25–0129 Clinical Research: Clinical Research Studies Dealing with Hearing, Speech, Language and Chemosensory Disorders, HHS/NIH/NIDCD

09–25–0130 Clinical Research: Studies in the Division of Cancer Cause and Prevention, HHS/NIH/NCI

09–25–0134 Clinical Research: Epidemiology Studies, National Institute of Environmental Health Sciences, HHS/NIH/NIEHS

09–25–0142 Clinical Research: Records of Subjects in Intramural Research, Epidemiology, Demography and Biometry Studies on Aging, HHS/NIH/NIA

09–25–0143 Biomedical Research: Records of Subjects in Clinical, Epidemiologic and Biometric Studies of the National Institute of Allergy and Infectious Diseases, HHS/NIH/NIAID

09–25–0145 Clinical Trials and Epidemiological Studies Dealing with Visual Disease and Disorders in the National Eye Institute, HHS/NIH/NEI

09–25–0148 Contracted and Contract-Related Research: Records of Subjects in Clinical, Epidemiological and Biomedical Studies of the National Institute of Neurological Disorders and Stroke and the National Institute on Deafness and Other Communication Disorders, HHS/NIH/NINDS and HHS/NIH/NIDCD

09–25–0152 Biomedical Research: Records of Subjects in National Institute of Dental Research Contracted Epidemiological and Biometric Studies, HHS/NIH/NIDR

09–25–0153 Biomedical Research: Records of Subjects in Biomedical and Behavioral Studies of Child Health and Human Development, HHS/NIH/NICHD

09–25–0154 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

09–25–0170 Diabetes Control and Complications Trial (DCCT) Data System, HHS/NIH/NIDDK

09–25–0172 Clinical Research: National Center for Human Genome Research, HHS/NIH/NCHGR

09–25–0201 Clinical Research: National Institute of Mental Health Patient Records, HHS/NIH/NIMH

09–25–0205 Alcohol, Drug Abuse, and Mental Health Epidemiologic and Biometric Research Data, HHS/NIH/NIAAA, HHS/NIH/NIDA and HHS/NIH/NIMH

09–25–0212 Clinical Research: Neuroscience Research Center Patient Medical Records, HHS/NIH/NIMH

NOTIFICATION PROCEDURE:

To determine if a record exists, write to the appropriate ICD Privacy Act Coordinator listed below. In cases where the requestor knows specifically which System Manager to contact, he or she may contact the System Manager directly (See Appendix I). Notification requests should include: Individual's name; current address; date of birth; date, place and nature of participation in specific research study; name of individual or organization administering the research study (if known); name or description of the research study (if known); address at the time of participation; and in specific cases, a notarized statement (some highly sensitive systems require two witnesses attesting to the individual's identity). A requestor must verify his or her identity by providing either a notarization of the request or by submitting a written certification that the requestor 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.

Individuals will be granted direct access to their medical records unless the System Manager determines that such access is likely to have an adverse effect (i.e., could cause harm) on the individual. In such cases when the System Manager has determined that the nature of the record information requires medical interpretation, the subject of the record shall be requested to 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. The representative may be a physician, other health professional, or other responsible individual. In this case, the medical/dental record will be sent to the designated representative. Individuals will be informed in writing if the record is sent to the representative. This same procedure will apply in cases where a parent or guardian requests notification of, or access to, a child's or incompetent person's medical record. The parent or guardian must also verify (provide adequate documentation) their relationship to the child or incompetent person as well as his or her own identity to prove their relationship.

If the requester does not know which Institute, Center or Division Privacy Act Coordinator to contact for notification purposes, he or she may contact directly the NIH Privacy Act Officer at the following address: NIH Privacy Act Officer, Office of Management Assessment, Building 31, Room 1B05, 31 Center Drive MSC 2075, Bethesda, MD 20892–2075.

NIH Privacy Act Coordinators

Office of the Director, (OD), NIH
Associate Director for Disease Prevention, OD, NIH
Building 1, Room 260
1 Center Drive
Bethesda, MD 20892
National Cancer Institute (NCI)
Privacy Act Coordinator, NCI, NIH
Building 31, Room 10A34
31 Center Drive
Bethesda, MD 20892
National Eye Institute (NEI)
Privacy Act Coordinator, NEI, NIH
Building 31, Room 6A–19
31 Center Drive
Bethesda, MD 20892
National Heart, Lung and Blood Institute (NHLBI)
Privacy Act Coordinator, NHLBI, NIH
Building 31, Room 5A08
31 Center Drive
Bethesda, MD 20892
National Institute on Aging (NIA)
Privacy Act Coordinator, NIA, NIH
Building 31, Room 2C12
31 Center Drive
Bethesda, MD 20892
National Institute on Alcohol Abuse and Alcoholism (NIAAA)
Privacy Act Coordinator, NIAAA, NIH
Wilco Building, Suite
6000 Executive Blvd., MSC 7003
Bethesda, MD 20892–7003
National Institute of Allergy and Infectious Diseases (NIAID)
Privacy Act Coordinator, NIAID, NIH
Solar Building, Room 3C–23
6003 Executive Blvd.
Bethesda, MD 20892
National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)
Privacy Act Coordinator, NIAMS, NIH
Natcher Building, Room 5QS49
45 Center Drive
Bethesda, MD 20892
National Institute of Child Health and Human Development (NICHD)
Privacy Act Coordinator, NICHD, NIH
6100 Executive Blvd., Room 5D01
North Bethesda, MD 20892
National Institute on Deafness and Other Communication Disorders (NIDCD)
Privacy Act Coordinator, NIDCD, NIH
Building 31, Room 3C02
9000 Rockville Pike
Bethesda, MD 20892
National Institute of Dental Research (NIDR)
Privacy Act Coordinator, NIDR, NIH
Building 31, Room 2C–35
31 Center Drive, MSC 2290
Bethesda, MD 20892–2290
National Institute of Diabetes and Digestive and Kidney Disease (NIDDK)
Privacy Act Coordinator, NIDDK, NIH
Building 31, Room 9A47
31 Center Drive
Bethesda, MD 20892
National Institute on Drug Abuse (NIDA)
Privacy Act Coordinator, NIDA, NIH
Parklawn Building, Room 10A–42
5600 Fishers Lane
Rockville, Maryland 20857
National Institute of Environmental Health Sciences (NIEHS)
Chief, Epidemiology Branch, NIEHS, NIH
P.O. Box 12233
Research Triangle Park
North Carolina 27709
National Institute of Mental Health (NIMH)
Privacy Act Coordinator, NIMH, NIH
Parklawn Building, Room 7C–22
5600 Fishers Lane
Rockville, Maryland 20857
National Institute of Neurological Disorders and Stroke (NINDS)
Privacy Act Coordinator, NINDS, NIH
Federal Building, Room 816
7550 Wisconsin Avenue
Bethesda, MD 20892
National Center for Human Genome Research (NCHGR)
Chief, Office of Human Genome Communications, NGHGR, NIH
Building 38A, Room 617
9000 Rockville Pike
Bethesda, Maryland 20892

RECORD ACCESS PROCEDURE:

Same as notification procedures. Requesters should reasonably specify the record contents being sought. An individual may also request an accounting of disclosures of his/her record, if any.

CONTESTING RECORD PROCEDURE:

Contact the appropriate official at the address specified under Notification Procedure, and reasonably identify the record, specify the information being contested, and state corrective action sought, with supporting information to show how the record is inaccurate, incomplete, untimely, or irrelevant.

RECORD SOURCE CATEGORIES:

The system contains information obtained directly from the subject individual by interview (face-to-face or telephone), written questionnaire, or by other tests, recording devices or observations, consistent with legislation and regulation regarding informed consent and protection of human subjects. Information is also obtained from other sources, including but not limited to: Referring medical physicians, mental health/alcohol/drug abuse or other health care providers; hospitals; organizations providing biological specimens; relatives; guardians; schools; and clinical medical research records.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

Appendix I: System Managers and Addresses

Office of the Director, NIH

Associate Director for Disease Prevention, OD, NIH
Building 1, Room 260
1 Center Drive
Bethesda, MD 20892

National Cancer Institute
Computer Systems Analyst, DCBD, NCI, NIH
Executive Plaza North, Room 344
Bethesda, MD 20892

American Burkitt's Lymphoma Registry
Division of Cancer Etiology, NCI, NIH
Executive Plaza North, Suite 434
6130 Executive Blvd.
Bethesda, MD 20892

Chief, Genetic Epidemiology Branch, EBP, DCE, NCI, NIH
Executive Plaza North, Suite 439
6130 Executive Blvd.
Bethesda, MD 20892

Chief, Clinical Genetics Section
Clinical Epidemiology Branch, DCE, NCI, NIH
Executive Plaza North, Suite 400
6130 Executive Blvd.
Bethesda, MD 20892

Program Director, Research Resources
Biological Carcinogenesis Branch, DCE, NCI, NIH
Executive Plaza North, Room 540
6130 Executive Blvd.
Bethesda, MD 20892

Chief, Environmental Epidemiology Branch, DCE, NCI, NIH
Executive Plaza North, Room 443
6130 Executive Blvd.
Bethesda, MD 20892

Associate Director, Surveillance Program, DCPC, NCI, NIH
Executive Plaza North, Room 343K
6130 Executive Blvd.
Bethesda, MD 20892

Head, Biostatistics and Data Management Section, DCT, NCI, NIH
8601 Old Georgetown Road
Bethesda, MD 20892

Chief, Clinical Research Branch
Biological Response Modifiers Program
Frederick Cancer Research and Development Center, DCT, NCI, NIH
501 W. 7th Street, Suite #3
Frederick, MD 21701

Deputy Branch Chief, Navy Hospital NCI—Naval Medical Oncology Branch, DCT, NCI, NIH
Building 8, Room 5101
Bethesda, MD 20814

Chief, Pharmaceutical Management Branch
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BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Fiscal Year (FY) 1997 Funding Opportunities for Knowledge Development and Application Cooperative Agreements

AGENCY: Substance Abuse and Mental Health Services Administration (SAMHSA), HHS.

ACTION: Clarification of Notice of Funding Availability (NOFA).

This notice is to clarify questions/issues that have been raised subsequent to the publication of the NOFA for SAMHSA's ''Cooperative Agreements for Integrating Mental Health and Substance Abuse Prevention and Treatment Services with Primary Health Care Service Settings or with Early Childhood Service Settings, for Children ages Birth to 7 and their Families/Caregivers'' (Short Title: Starting Early Starting Smart—SESS). The NOFA was published in the **Federal Register** (Vol. 62, No. 31), Friday February 14, 1997, on pages 6974–6977. The receipt date for applications is April 17, 1997.

Award Amounts: On page 6976 under the Cooperative Agreements/Amounts section, the notice states that approximately $5.9 million will be available to support approximately 10 SESS site awards and $500,000 to support one data coordinating center award. To clarify, it is anticipated that funds available to support the data coordinating center may increase commensurate with the increased center tasks and responsibilities in years 2–4. In addition, proposed budgets must be for total costs (direct + indirect).

Evaluation Costs: The percentage of the total proposed budget for evaluation costs is determined by the proposed study design and the costs associated with the steering committee and the data coordinating center. The budget must be consonant with the cost of doing the evaluation required by the study design. The proposed study design, evaluation associated costs, and overall budget will be evaluated by a peer review group as part of their overall assessment of the application.

Eligible Applicants: On page 6976 under the Eligible Applicants section, the notice states that applications ''* * * may be submitted by units of State or local governments and by domestic private nonprofit and for-profit organizations * * *,'' and that each SESS site proposal must include documentation regarding the existence of an infrastructure and two years of experience providing behavioral health and other relevant services to the target population. SAMHSA has determined that ''home-based'' early childhood service settings are eligible applicants if they meet other eligibility requirements as specified in the announcement.

FOR FURTHER INFORMATION CONTACT: Rose C. Kittrell, MSW, SAMHSA, Rockwall II, Room 1075, 5600 Fishers Lane, Rockville, MD 20857; (301) 443–0354 or 443–0365.

Dated: April 1, 1997.

Richard Kopanda,

Executive Officer, SAMHSA.

[FR Doc. 97–8705 Filed 4–4–97; 8:45 am]

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DEPARTMENT OF THE INTERIOR

Central Utah Project Completion Act; Notice of Availability of the Record of Decision on the Wasatch County Water Efficiency Project and Daniel Replacement Project Final Environmental Impact Statement Documenting the Department of the Interior's Approval for the Central Utah Water Conservancy District To Proceed With the Construction of the Proposed Action Alternative

AGENCY: Office of the Assistant Secretary—Water and Science, Department of the Interior.

ACTION: Notice of availability of the Wasatch County Water Efficiency Project and Daniel Replacement Project Record of Decision.

SUMMARY: On March 21, 1997, Patricia J. Beneke, Assistant Secretary—Water and Science, Department of the Interior, signed the Record of Decision (ROD) which documents the selection of the Proposed Action Alternative as presented in the Wasatch County Water Efficiency Project and Daniel Replacement Project (WCWEP and DRP) Final Environmental Impact Statement (FEIS), INT FES 96–58, filed November 22, 1996, and as described in the WCWEP Feasibility Study dated January 1997. The ROD also approves the Central Utah Water Conservancy District (CUWCD) proceeding with construction of WCWEP and DRP, in accordance with statutory and contractual obligations. Construction of WCWEP will provide a replacement water supply out of water conserved in Wasatch County, for the water presently being diverted from the Strawberry River basin. The replacement supply will be delivered by means of the DRP.

The FEIS for WCWEP and DRP, considered three alternatives to restore flows in the upper Strawberry River and to provide water and water conveyance facilities from Jordanelle Reservoir to the existing Daniel Irrigation Company (DIC) water storage facilities as mandated in section 303 of the Central Utah Project Completion Act (CUPCA) and a No Action Alternative. The Department of the Interior (Interior), the Utah Reclamation Mitigation and Conservation Commission (Mitigation Commission), and the CUWCD served as the Joint Lead Agencies in the preparation of the NEPA compliance documents.

In addition to satisfying the requirements and authorizations of CUPCA, the construction of the WCWEP and DRP will satisfy Interior's environmental commitment made in the