Appendix F

Privacy Act System of Records Notice

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

STORAGE:

Records are stored on paper forms in file folders and in electronic databases.

RETRIEVABILITY:

Records are retrieved by name, date of birth, type of medical staff membership, Institute/Center and licensing status.

SAFEGUARDS:

1. *Authorized Users:* Data on the computer network system is accessed by a password known only to authorized users who are NIH employees and contractor staff responsible for implementing the medical staff credentials data system. Access to information is thus limited to those with a need to know.

2. *Physical Safeguards:* Rooms where records are stored are locked when not in use. During regular business hours rooms are unlocked but entry is controlled by on-site personnel.

3. *Procedural and Technical Safeguards:* Access to files is strictly controlled by the system manager. Names and other identifying particulars are deleted when data from original records are encoded for analysis. Data stored in computers is accessed through a network system by use of a password known only to authorized users. All authorized users of personal information in connection with the performance of their jobs (see Authorized Users, above) protect information from public view and from unauthorized personnel entering an unsupervised office.

These practices are in compliance 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, and the HHS Automated Information Systems Security Program Handbook.

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 1B ''Keeping and Destroying Records'' (HHS Records Management Manual, Appendix B–361), item 2300–293–4, ''Medical Staffs' Credential Files,'' which allows inactive records to be transferred to the Federal Records Center at five year intervals and to be destroyed after thirty years. Refer to the NIH Manual Chapter for specific disposition instructions.

SYSTEM MANAGER(S) AND ADDRESS:

Chief, Credentialing Services Office, Clinical Center, Building 10, Room 1N204, 10 Center Drive, Bethesda, MD 20892–1192.

NOTIFICATION PROCEDURE:

To determine if a record exists, write to the System Manager at the above address. The requester must provide tangible proof of identity (*e.g.,* driver's license). If no identification papers are available, the requester must 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.

RECORD ACCESS PROCEDURE:

Write to the System Manager specified above to attain access to records and provide the same information as that required under the Notification Procedures. Requesters should also reasonably specify the record contents being requested. Individuals may also request an accounting of disclosure of their records, if any.

CONTESTING RECORD PROCEDURE:

Contact the System Manager specified above and reasonably identify the record, specify the information to be 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:

Subject individual.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

09–25–0200

SYSTEM NAME:

Clinical, Basic and Population-based Research 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, basic, or population-based 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 curricula 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 and Craniofacial 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 Human Genome Research Institute'' 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, basic, and population-based 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 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; 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 research studies.

7. 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.

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:* These practices are in compliance 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, and the HHS Automated Information Systems Security Program Handbook.

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. 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 and Centers.

NOTIFICATION PROCEDURE:

To determine if a record exists, write to the appropriate IC Privacy Act Coordinator listed below. In cases where the requester 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 requester must verify his or her identity by providing either a notarization of the request or by submitting a written certification that the 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 or Center 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, 6011 Executive Blvd., Room 601L, Rockville, MD 20852.

NIH Privacy Act Coordinators

Associate Director for Disease Prevention, Office of the Director (OD), Building 1, Room 260, 1 Center Drive, Bethesda, MD 20892.

Privacy Act Coordinator, Clinical Center (CC), Building 10, Room 1N208, 10 Center Drive, Bethesda, MD 20892.

Privacy Act Coordinator, National Center for Complementary and Alternative Medicine (NCCAM), Building 31, Room 2B11, 31 Center Drive, Bethesda, MD 20892–2182.

Privacy Act Coordinator, National Cancer Institute (NCI), Building 31, Room 10A34, 31 Center Drive, Bethesda, MD 20892.

Privacy Act Coordinator, National Center on Minority Health and Health Disparities (NCMHD), Democracy Plaza II, Room 800, 6707 Democracy Boulevard, Bethesda, MD 20892–5465.

Privacy Act Coordinator, National Center for Research Resources (NCRR), Rockledge I, Room 5140, 6705 Rockledge Drive, Bethesda, MD 20892.

Privacy Act Coordinator, National Eye Institute (NEI), Building 31, Room 6A32, 31 Center Drive, Bethesda, MD 20892–2510.

Privacy Act Coordinator, National Human Genome Research Institute (NHGRI), Building 10, 3C710, 10 Center Drive, Bethesda, MD 20892.

Privacy Act Coordinator, National Heart, Lung, and Blood Institute (NHLBI), Building 31, Room 5A33, 31 Center Drive, Bethesda, MD 20892.

Privacy Act Coordinator, National Institute on Aging (NIA), Gateway Building 31, Room 2C234, 7201 Wisconsin Avenue, Bethesda, MD 20892.

Privacy Act Coordinator, National Institute on Alcohol Abuse and Alcoholism (NIAAA), Willco Building, Room 400, 6000 Executive Boulevard, Bethesda, MD 20892–7003.

Privacy Act Coordinator, National Institute of Allergy and Infectious Diseases (NIAID), 6700–B Rockledge Drive, Room 2143, Bethesda, MD 20892.

Privacy Act Coordinator, National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), Natcher Building, Room 5AS49, 45 Center Drive, Bethesda, MD 20892.

Privacy Act Coordinator, National Institute of Biomedical Imaging and Bioengineering (NIBIB), Building 31, Room 1B37, 31 Center Drive, Bethesda, MD 20892–2077.

Privacy Act Coordinator, National Institute of Child Health and Human Development (NICHD), Building 31, Room 2A11, 31 Center Drive, Bethesda, MD 20892.

Privacy Act Coordinator, Office of Extramural Affairs, National Institute on Drug Abuse (NIDA), Neuroscience Center, 6001 Executive Boulevard, Room 3158, Bethesda, MD 20892–9547.

Privacy Act Coordinator, National Institute on Deafness and Other Communication Disorders (NIDCD), Building 31, Room 3C02, 31 Center Drive, Bethesda, MD 20892.

Privacy Act Coordinator, National Institute of Dental and Craniofacial Research (NIDCR), Natcher Building, Room 4AS25, 45 Center Drive, Bethesda, MD 20892–6401.

Privacy Act Coordinator, National Institute of Diabetes and Digestive and Kidney Disease (NIDDK), Building 31, Room 9A47, 31 Center Drive, Bethesda, MD 20892.

Privacy Act Coordinator, National Institute of Environmental Health Sciences (NIEHS), PO Box 12233, Research Triangle Park, NC 27709.

Privacy Act Coordinator, National Institute of General Medical Sciences (NIGMS), Natcher Building, Room 2AN32, 45 Center Drive, Bethesda, MD 20892.

Privacy Act Coordinator, National Institute of Mental Health (NIMH), Neuroscience Center, 6001 Executive Boulevard, Room 8102, Bethesda, MD 20892.

Privacy Act Coordinator, National Institute of Neurological Disorders and Stroke (NINDS), Building 31, Room 8A33, 31 Center Drive, Bethesda, MD 20892.

Privacy Act Coordinator, National Institute of Nursing Research (NINR), Rockledge II, Room 710, 6701 Rockledge Drive, Bethesda, MD 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 Manager(s) and Address(es)

Associate Director for Disease Prevention, Office of the Director (OD), Building 1, Room 260, 1 Center Drive, Bethesda, MD 20892.

Computer Systems Analyst, Division of Cancer Treatment and Diagnosis, National Cancer Institute (NCI), Executive Plaza North, Room 344, 6130 Executive Boulevard, Bethesda, MD 20892.

American Burkitt's Lymphoma Registry, Division of Cancer Etiology, National Cancer Institute (NCI), Executive Plaza North, Suite 434, 6130 Executive Boulevard, Bethesda, MD 20892.

Chief, Genetic Epidemiology Branch, Division of Cancer Epidemiology and Genetics, National Cancer Institute (NCI), Executive Plaza South, Room 7122, 6120 Executive Boulevard, Bethesda, MD 20892–7236.

Program Director, Research Resources, Biological Carcinogenesis Branch, Division of Cancer Etiology, National Cancer Institute (NCI), Executive Plaza North, Room 540, 6130 Executive Boulevard, Bethesda, MD 20892.

Chief, Environmental Epidemiology Branch, Division of Cancer Etiology, National Cancer Institute (NCI), Executive Plaza North, Room 443, 6130 Executive Boulevard, Bethesda, MD 20892.

Associate Director, Surveillance Program, Division of Cancer Prevention, National Cancer Institute (NCI), Executive Plaza North, Room 343K, 6130 Executive Boulevard, Bethesda, MD 20892.

Head, Biostatistics and Data Management Section, Center for Cancer Research, National Cancer Institute (NCI), Building 6116, Room 702, 6116 Executive Boulevard, Bethesda, MD 20892.

Chief, Clinical Research Branch, Center for Cancer Research, Frederick Cancer Research and Development Center, National Cancer Institute (NCI), 501 W. 7th Street, Room 3, Frederick, MD 21702.

Deputy Branch Chief, Navy Hospital, NCI-Naval Medical Oncology Branch, Center for Cancer Research, National Cancer Institute (NCI), Building 8, Room 5101, Bethesda, MD 20814.

Chief, Pharmaceutical Management Branch, Cancer Therapy Evaluation Program, Division of Cancer Treatment and Diagnosis, National Cancer Institute (NCI), Executive Plaza North, Room 804, 6130 Executive Boulevard, Bethesda, MD 20892.

Director, Extramural Clinical Studies, Frederick Cancer Research and Development Center, National Cancer Institute (NCI), Fort Detrick, Frederick, MD 21702.

Clinical Operations Manager, National Eye Institute (NEI), Building 10, Room 10S224, 10 Center Drive, Bethesda, MD 20892.

Director, Division of Biometry and Epidemiology, National Eye Institute (NEI), Building 31, Room 6A52, 31 Center Drive, Bethesda, MD 20892.