file cabinets in file folders. During normal business hours, OTT Patent Branch and Licensing Branch on-site personnel regulate availability of the files. During evening and weekend hours the offices are locked and the building is closed.

3. Procedural and technical safeguards: Data stored in computers will be accessed through the use of keywords known only to the authorized users. A password is required to access the data base. All users of personal information in connection with the performance of their jobs (see Authorized Users, above) protect information, including confidential business information submitted by potential licensees, 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, 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).

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 1100–L, which allows records to be kept for a maximum of twenty (20) years. Refer to the NIH Manual Chapter for specific disposition instructions.

SYSTEM MANAGER AND ADDRESS:

Chief, Technology Management Branch, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Third Floor, Rockville, Maryland 20852.

Division of Extramural Reports, Office of Extramural Research, National Institutes of Health, Building 31, Room 5B41, 31 Center Drive, Bethesda, MD 20892–2184.

NOTIFICATION PROCEDURES:

To determine if a record exists, write to the System Manager listed above. 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. The request should include: (a) Full name, and (b) appropriate identifying information on the nature of the invention.

RECORD ACCESS PROCEDURES:

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

CONTESTING RECORD PROCEDURES:

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:

Inventors and other collaborating persons, grantees, fellowship recipients and contractors; other Federal agencies; scientific experts from non-Government organizations; contract patent counsel and their employees and foreign contract personnel; Unites States and foreign patent offices; prospective licensees; and third parties whom PHS contacts to determine individual invention ownership or Government ownership.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

09-25-0170

SYSTEM NAME:

Diabetes Data System, HHS/NIH/ NIDDK.

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

A list of all contractor/subcontractor locations is available upon request for the System Manager (see address below).

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individuals who participated in the Diabetes Prevention Trial—Type 1 Diabetes (DPT-1); the Diabetes Prevention Trial—Type 2 Diabetes (DPT-2); the Epidemiology of Diabetes Interventions and Complications Study (EDIC); the International Pancreas and Islet Transplant Registry (IPITR), and family members of these participants.

CATEGORIES OF RECORDS IN THE SYSTEM:

Participant names, addresses, phone numbers; Social Security numbers (voluntary), phone numbers, driver's license numbers, employer information, spouse names, study identification numbers, educational background, occupational history, names of medical provider, medical record identification numbers, health and medical record data collected during these trials and follow-up studies; the names, addresses and phone numbers of acquaintances and relatives to assist in follow-up; a family tree (or pedigree) and information pertaining to DCCT stored biologic specimens (including blood, urine and genetic materials).

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Section 301(a) of the Public Health Service (PHS) Act (42 U.S.C. 241(a)), describing the general powers and duties of the Public Health Service relating to research and investigation, and section 426 of the PHS Act (42 U.S.C. 285c) describing the purpose of the National Institute of Diabetes and Digestive and Kidney Diseases to conduct research with respect to, among other areas, diabetes mellitus.

PURPOSE(S):

These records are used to: (1) Conduct research on diabetes mellitus in order to understand the disease and find better treatments and/or an eventual cure; (2) conduct follow-up studies (projected follow-up of 7–10 years) on the morbidity and mortality experiences of study participants; and (3) provide relevant demographic, health and medical record data on participants to biomedical researchers authorized to use information and stored biologic materials.

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

1. 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.

2. 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