specify in writing the record contents at issue and state the corrective action sought and the reasons for the correction. The right to contest with supporting justification. The record is limited to information which is incomplete, irrelevant, incorrect, or untimely (obsolete).

RECORD SOURCE CATEGORIES:

Information contained in these records is obtained directly from individual participants and from medical and clinical research observations

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

09-25-0128

SYSTEM NAME:

Clinical Research: Neural Prosthesis & Biomedical Engineering Studies, HHS/NIH/NINDS.

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

Federal Building, Room 9C02, 7550 Wisconsin Ave., Bethesda, MD 20892 and: (1) At hospitals and medical centers under contract, and (2) Federal Records Centers. A list of locations is available upon request from the system manager.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Patients and normal volunteers, males and females, participating in clinical studies to determine the feasibility of neural prostheses, and in clinical studies related to the development of instrumentation for diagnosis and treatment of neurological and sensory disorders conducted under contract for the National Institute of Neurological Disorders and Stroke (NINDS).

CATEGORIES OF RECORDS IN THE SYSTEM:

Clinical research data as related to studies which seek to determine the feasibility of neural prostheses and to develop instrumentation for diagnosis and treatment of neurological and sensory disorders.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM: 42 U.S.C. 421, 289a, 289c.

PURPOSE(S):

- (1) Clinical research on the development of neural prosthesis (artificial devices) to enhance function of individuals with various disorders of the central nervous system.
- (2) Research on the development of new instruments to improve diagnosis

and treatment of disorders of the nervous system.

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 purpose for which the records are collected. The recipients are required to protect such records from improper disclosure.
- 2. 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.
- 3. 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 against a claim 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 or other appropriate Federal agency to enable that agency 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:

Records are stored in file folders.

RETRIEVABILITY:

Records are retrieved by name.

SAFEGUARDS:

- 1. Authorized users: Employees who maintain records in this system are instructed to grant access only to HHS scientists and their authorized collaborators.
- 2. *Physical safeguards:* Records are kept in a locked room when not in use.
- 3. *Procedural safeguards:* Personnel having access to this system are informed of Privacy Act requirements.

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. Refer to the NIH Manual Chapter for specific disposition instructions.

SYSTEM MANAGER AND ADDRESS:

Head, Neural Prosthesis Program, NINDS, Federal Building, Room 916, 7550 Wisconsin Ave., Bethesda, MD 20892

NOTIFICATION PROCEDURE:

Write to:

Chief, Administrative Services Branch, NINDS, Building 31, Room 8A49, 9000 Rockville Pike, Bethesda, MD 20892

and ask if a file with your name exists in the Neural Prosthesis or Biomedical Engineering Studies. 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.

An individual who requests notification of or access to a medical record shall, at the time the request is made, designate in writing, a responsible representative, who may be a physician, who will be willing to review the record and inform the subject individual of its contents at the representative's discretion.

RECORD ACCESS PROCEDURES:

Same as notification procedures. Requesters should also reasonably specify the record contents being sought. Individuals may also request listings of accountable disclosures that have been made of their records, if any.

CONTESTING RECORD PROCEDURES:

Write to system manager and reasonably identify the record and specify the information to be contested, and state the corrective action sought and the reasons for the correction.

RECORD SOURCE CATEGORIES:

Patients, patients' families, hospital records and clinical investigators.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.