#### 09-25-0129

#### SYSTEM NAME:

Clinical Research: Clinical Research Studies Dealing with Hearing, Speech, Language and Chemosensory Disorders, HHS/NIH/NIDCD.

## SECURITY CLASSIFICATION:

None.

## SYSTEM LOCATION:

National Institute on Deafness and Other Communication Disorders (NIDCD); 6120 Executive Boulevard, Rockville, MD 20852

and at hospitals, medical centers, universities and educational settings under contract. Inactive records may be stored at a Federal Records Center. A list of locations is available upon request from the System Manager at the address below.

# CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Patients and normal volunteers participating in clinical research studies dealing with hearing, speech, language and chemosensory disorders.

#### CATEGORIES OF RECORDS IN THE SYSTEM:

Medical findings, clinical research data, medical and educational histories and research data on the hearing, speech, language, cognition and chemosensory systems of subjects being tested.

# AUTHORITY FOR MAINTENANCE OF THE SYSTEM: 42 U.S.C. 241, 289a, 289c.

# PURPOSE(S)

Clinical research on the disorders of speech, language, and hearing to discover factors leading to these disorders and to improve prevention, diagnoses, and treatment.

# 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 its 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:

Name or identifier code.

#### SAFEGUARDS:

- 1. Authorized users: Employees who maintain the system are instructed to grant access only to the principal investigator and staff assigned to a particular project, and to other authorized personnel (project officer, contracting officer).
- 2. Physical safeguards: Records are locked in cabinets when not in actual use and system location is locked during non-working hours.
- 3. Procedural safeguards: Personnel having access to system are trained in Privacy Act requirements. Records are returned to locked file cabinets at end of working day.

## 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–3610, 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:

Director, Division of Human Communication, NIDCD, Executive Plaza South, Room 400B, 6120 Executive Boulevard, Rockville, MD 20852

#### **NOTIFICATION PROCEDURE:**

Write to:

Chief, Administrative Management Branch, NIDCD, Building 31, Room 3C21, 9000 Rockville Pike, Bethesda, MD 20892

and ask if a file exists with your name in studies of the Division of Communication Sciences and Disorders. Please supply the following information:

- 1. Approximate date and place of examination and/or treatment.
- 2. Name of the study, if known. 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 PROCEDURE:

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 PROCEDURE:

Write to system manager and reasonably identify the record, specify the information to be contested, and state the corrective action sought and the reasons for the correction. The right to contest records is limited to information which is incomplete, irrelevant, incorrect, or untimely (obsolete).

#### **RECORD SOURCE CATEGORIES:**

Information provided by patients, patients' families, hospital records, school records, and clinical investigators.

# SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

# 09-25-0140

# SYSTEM NAME:

International Activities: International Scientific Researchers in Intramural Laboratories at the National Institutes of Health, HHS/NIH/FIC.