Director, Division of Stroke and Trauma, NINDS, NIH, Federal Building, Room 8A08, 7550 Wisconsin Avenue, Bethesda, MD 20892

and

Assistant Director, Clinical Neurosciences Program, DIR, NIH, Building 10, Room 5N226, 9000 Rockville Pike, Bethesda, MD 20892

NOTIFICATION PROCEDURE:

To determine if a record exists, write to:

NINDS Privacy Act Coordinator, Federal Building, Room 816, 7550 Wisconsin Avenue, Bethesda, MD 20892

or

NIDCD Privacy Act Coordinator, Building 31, Room 3C02, 9000 Rockville Pike, Bethesda, MD 20892

and provide the following information: 1. System name,

2. Complete name and home address

at the time of the study,

3. Birth date,

4. Facility conducting the study,

5. Disease type (if known),

6. Approximate dates of enrollment in the research study.

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.

Individuals seeking notification of or access to medical records should designate a representative (including address) who may be a physician, other health professional, or other responsible individual, who would be willing to review the record and inform the subject individual of its contents, at the representative's discretion.

A parent or guardian who requests notification of, or access to, a child's or incompetent person's medical record shall designate a family physician or other health professional (other than a family member) of whom the record, if any, will be sent. The parent or guardian must verify relationship to the child or incompetent person as well as his or her own identity.

RECORD ACCESS PROCEDURE:

Same as notifications 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 the system manager and reasonably identify the record, specify the information being 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 in these records is obtained directly from individual participants, and from physicians, research investigators and other collaborating persons, and from medical records and clinical research observations at hospitals, HHS agencies, universities, medical schools, research institutions, commercial institutions, state agencies, and collaborating Federal agencies.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

09-25-0152

SYSTEM NAME:

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

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

Records included in this system are collected by contractors and are located in hospitals and clinics; research centers; educational institutions; commercial; local, State and Federal government agencies; and in National Institute of Dental Research (NIDR) facilities. Inactive records may be stored at Federal Records Centers. A list of locations and contracts is available upon request from the System Manager.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Voluntary participants in epidemiological and biometric studies sponsored by NIDR, including adults and minors, both males and females, with known or suspected diseases or disorders of the teeth and supporting structures, as well as normal or nonsuspect individuals in control or study groups for purposes of comparison.

CATEGORIES OF RECORDS IN THE SYSTEM:

This system consists of medical and dental records and information resulting from personal interviews, questionnaires, or direct observation. The system may also include current addresses of study participants, radiographs, records on biological specimens (e.g., teeth, plaque, etc.), study models, computerized epidemiological data and correspondence.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Sections 301, 401, 405 and 453 of the Public Health Service Act (42 U.S.C. 241, 281, 284, 285h). These sections establish the National Institute of Dental Research and authorize the conduct and support of dental and oral research and related activities.

PURPOSE(S):

This system is used to: (1) Support research on diseases and disorders of the oral cavity (teeth and their supporting structures); their causes and treatment; the incidence and prevalence of these diseases and disorders; and familial, demographic and behavioral factors related to their causes and treatment; (2) provide data for program review, evaluation, planning, and administrative accountability.

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

1. Disclosure may be made to HHS contractors, grantees and collaborating researchers and their staff for the purpose of analyzing data and preparing scientific reports and articles in order to accomplish the research purpose for which the records are collected. The recipients are required to maintain Privacy Act safeguards with regards to such records.

2. Disclosure may be made to organizations deemed qualified by the Secretary to carry out quality assessment, medical audits or utilization review.

3. 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; (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