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 an Institute Division or a contractor provides anonymous data 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 HHS project directors, contract officers, and project officers oversee compliance with these requirements.

4. Implementation guidelines: DHHS Chapter 45– and supplementary Chapter PHS.hf: 45–13 of the General Administration Manual and Part 6, "ADP System Security" of the HHS ADP Systems Security Manual.

RETENTION AND DISPOSAL:

Personal identifiers are retained only as long as they are needed for the purposes of the current research project, and for followup studies generated by the present study. Removal or disposal of identifiers is done according to the storage medium (e.g., erase computer tape, shred or burn index cards, etc.). A staff person designated by the System Manager will oversee and will describe and confirm the disposal in writing.

SYSTEM MANAGER(S) AND ADDRESS:

Privacy Act Coordinator, National Institute of Mental Health, Room 7C–22, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857.

Deputy Director, Division of Biometry and Epidemiology, National Institute on Alcohol Abuse and Alcoholism, Willco Building, Suite 514, 6000 Executive Blvd. MSC 7003, Bethesda, MD 20892–7003.

Deputy Director, Division of Clinical and Prevention Research, National Institute on Alcohol Abuse and Alcoholism, Willco Building, Suite 505, 6000 Executive Blvd. MSC 7003, Bethesda, MD 20892–7003.

Privacy Act Coordinator, National Institute on Drug Abuse, Room 10A–42, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857.

NOTIFICATION PROCEDURE:

To determine if a record exists, write to the appropriate System Manager at the address above. Provide 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 a notarized statement by two witnesses attesting to the individual's identity.

RECORD ACCESS PROCEDURE:

Same as notification procedures. Requesters should also reasonably specify the record contents being sought. An individual may also request an accounting of disclosures of his/her record, if any.

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 will 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) to 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.

CONTESTING RECORD PROCEDURE:

Contact the appropriate official at the address specified under System Manager(s) above 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), by 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, such as health, mental health, alcohol, and/or drug abuse care providers; relatives; guardians; and clinical medical research records.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

09-25-0207

SYSTEM NAME:

Subject-Participants in Pharmacokinetic Studies on Drugs of Abuse and on Treatment Medications, HHS/NIH/NIDA.

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

University of California, San Francisco, Langley Porter Psychiatric Institute, San Francisco, California 94143.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Normal, healthy adults who voluntarily participate in studies on the pharmacokinetics and pharmacodynamics of psychoactive drugs at Langley Porter Psychiatric Institute, during the period September 1987 through June, 1997.

CATEGORIES OF RECORDS IN THE SYSTEM:

Research records on each subjectparticipant contain the following information: Name; clinician's records including medical history, laboratory test results, physical examinations, psychological profile, and drug use profile; drug study data including records of drugs administered, exposures to radioactivity, and drug reactions; and date of study in which the subject participated.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Public Health Service Act, sections 301(a), 503 and 405 (42 U.S.C. 241 and 284).

PURPOSE(S):

The primary purpose of this system is to support research on the pharmacokinetics and pharmacodynamics of drugs of abuse as well as treatment drugs. The term "pharmacokinetics" refers to the manner in which the human body processes a drug. "Pharmacodynamics" refers to the manner in which the drug affects the human body.

The clinical investigator used data of a medical nature that is contained in the system to make determinations regarding drug dosages and/or radiochemical exposures appropriate to the individual human subject-participants, in order to preserve and protect the health of each. The system also provides baseline data for studying the drug effects.

The Food and Drug Administration (FDA) also may use the records in routine inspections FDA conducts in accordance with its responsibilities to