record exists about himself/herself upon written request, with notarized signature. The request should include, if known, name of the researcher, location of the research site, approximate date of data collection, any alias used, and subject identification number.

An individual who requests notification of 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 legal guardian who requests notification of an adolescent's record shall designate a family physician or other health professional (other than a family member) of the Division of Clinical Research staff to whom the record, if any, will be sent. The parent or legal guardian must verify in writing the relationship to the adolescent as well as his/her own identity.

RECORD ACCESS PROCEDURES:

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.

Persons other than subject individuals, who request individually identifiable data from a record must provide written consent from the subject individual permitting the requested disclosure. The only exception (if not in conflict with confidentiality regulations) would be for disclosure to persons or organizations permitted by the Privacy Act, section 3(b), to obtain personally identifiable data.

CONTESTING RECORD PROCEDURES:

Contact the official at the address specified under Notification Procedures above and reasonably identify the record, specify the information being contested, the corrective action sought, with supporting information to show how the record is inaccurate, incomplete, untimely, or irrelevant.

RECORD SOURCE CATEGORIES:

Research subjects, and staff in participating drug abuse treatment programs, written clinical evaluations, counselors, psychiatrists, psychotherapists, family members, research assistants, hospitals.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

09-25-0209

SYSTEM NAME:

Subject-Participants in Drug Abuse Research Studies on Drug Dependence and in Research Supporting New Drug Applications, HHS/NIH/NIDA.

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

Veterans Administration Hospital, Cooperative Studies Program, Department of Veterans Medical Center, Perry Point, MD 21902.

Dixon and Williams Pharmaceutical, 5775 Hyde Park Circle, Jacksonville, Florida 32210.

Medications Development Division, Room 11A–55, and Division of Clinical Research, Room 10A–38, Parklawn Building, National Institute on Drug Abuse, 5600 Fishers Lane, Rockville, MD 20857.

Veterans Affairs Medical Center, 50 Irving Street, NW., Washington, DC 20422.

Veterans Affairs Medical Center, University and Woodland Avenues, Philadelphia, PA 19104.

Veterans Affairs Medical Center, Brentwood Division, Wilshire and Sawtell Boulevards, Los Angeles, CA 90073.

National Institute on Drug Abuse, Division of Intramural Research Programs, 4940 Eastern Avenue, Baltimore, MD 21224.

Write to the system manager at the address below for the address of any new locations where records from this system may be stored.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Voluntary adult clients of federally funded and other drug abuse treatment programs who have requested to receive investigational new or marketed drugs, such as but not limited to, naltrexone, levo-alpha acetylmethadol (LAAM), or Buprenorphine as part of their treatment. Data collection for the earlier LAAM studies began in 1975 and continued through September 1979; additional LAAM studies began in 1992 and will continue through September 1997, naltrexone studies began in 1977 and continued through June 1984; and studies for other investigational new compounds (buprenorphine, gepirone, etc.) began in 1992 and may continue through September 1997.

CATEGORIES OF RECORDS IN THE SYSTEM:

Demographic data, treatment outcome data, treatment process data, client locator information, and personal identifiers (name and assigned numerical identifier).

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Public Health Service Act, sections 301, 464p, and 405 (42 U.S.C. 241, and 284).

PURPOSE(S):

- 1. To maintain information on the safety and effectiveness of drugs for treatment of drug dependence with or without abuse potential in various treatment environments and modalities and changes in the behavior and characteristics of drug abusers who received these substances as part of their treatment regimen.
- 2. To provide data required by the Food and Drug Administration (FDA) to support research on drug dependence and potential new drug applications for various drugs, and to treat drug dependence with or without abuse potential. A new drug application is a notice to FDA that a pharmaceutical company believes they have enough data to demonstrate the safety and efficacy of a substance to satisfy FDA for marketing the substance. FDA may also use the records in routine inspections that FDA conducts in accordance with its responsibilities to develop standards on the composition, quality, safety and efficacy of drugs administered to humans, and to monitor experimental usage of drugs.
- 3. To conduct research on the pharmacology, toxicology, and behavioral characteristics of drugs of abuse alone or in combination with proposed treatment drugs.

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

NIH contractor(s) use the records in the system in order to accomplish the research and development purposes for which the records were collected. In the event of a followup study or continuation study, the responsible project officer may disclose records in this system to a subsequent NIH contractor(s). Any new contractor(s) is and would be required to maintain Privacy Act safeguards with respect to such records and to comply with the confidentiality restrictions of 42 CFR part 2.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Interview and assessment forms, video tapes, magnetic tapes, disks and microfiche in boxes in closed cabinets in a locked room with limited accessibility.