develop standards on the composition, quality, safety, and efficacy of drugs administered to humans, and to monitor experimental usage of drugs.

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

1. We may disclose to a congressional office the record of an individual in response to a verified inquiry from the congressional office made at the written request of the individual.

2. NIH contractors, use the records in this system to accomplish the research purpose for which the records are collected. The contractors are required to maintain Privacy Act safeguards with respect to such records.

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

#### STORAGE:

The contractor maintains the records on paper in file folders.

#### RETRIEVABILITY:

The contractor indexes and retrieves the records by the subject-participant's name.

# SAFEGUARDS:

- 1. Authorized users: Only the contract Project Director and his/her research team and the Federal Project Officer and his/her support staff have access to these records.
- 2. Physical safeguards: The contractor keeps all records in a locked metal file cabinet in premises with limited accessibility. Only the clinical investigator (Project Director) has the key to the locked files.
- 3. Procedural safeguards: Only the contract staff have access to the files. Persons other than subject participants who request individually identifiable data from a record, must provide written consent from the subject participant permitting the requested disclosure. The only exception would be for disclosure to persons or organizations permitted by the Privacy Act, Section 3(B) to obtain personally identifiable data.
- 4. Implementation guidelines: DHHS Chapter 45–13 and supplementary Chapter PHS.hf: 45–13 of the General Administration Manual. In addition, the contract staff complies with contractor's (University of California, San Francisco) standard procedures for safeguarding

# RETENTION AND DISPOSAL:

The records will be kept no later than June 2002 (5 years after the anticipated completion of the studies). At that time, the NIDA project officer will authorize in writing the clinical investigators to

destroy the records by shredding or burning.

# SYSTEM MANAGER(S) AND ADDRESS:

Project Officer, Pharmacokinetic Studies on Drugs of Abuse, Medications Development Division, National Institute on Drug Abuse, National Institutes of Health, Room 11A55, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857.

# NOTIFICATION PROCEDURE:

To determine if a record exists, write to the system manager listed above.

Provide the following information: Subject-participant's full name and a letter of request (or permission, if the requester is not the subject-participant) with notarized signature of the individual who is the subject of the record, approximate date(s) of experiment(s) in which the individual participated, and drug name (if known). In addition, 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 content at the representative's discretion.

# **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.

# CONTESTING RECORD PROCEDURES:

Contact the System Manager at the address above and reasonably identify the record, specify the information to be contested, the corrective action sought, with supporting information to show how the record is inaccurate, incomplete, untimely, or irrelevant.

# RECORD SOURCE CATEGORIES:

The subject-participants and the contractor personnel conducting the research studies.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

# 09-25-0208

# SYSTEM NAME:

Drug Abuse Treatment Outcome Study (DATOS), HHS/NIH/NIDA.

# SECURITY CLASSIFICATION:

None.

# SYSTEM LOCATION:

Research Triangle Institute, Center for Social Research and Policy Analysis,

Research Triangle Park, North Carolina 27709.

# CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Voluntary adult clients of federally funded treatment programs, including Treatment Alternative Street Crime (TASC) Programs of the Department of Justice, who requested to be included in TOPS from 1979 through 1986. New data collected from voluntary adults/adolescent clients of public and private funded-treatment programs beginning in 1991 and will continue through 1995.

# CATEGORIES OF RECORDS IN THE SYSTEM:

The categories are: 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 and 405 (42 U.S.C. 241 and 284.

# PURPOSE(S):

The purpose of the system is to compile information on drug abusers in drug abuse treatment programs in order to derive information on the treatment environments and abusers' behaviors and characteristics subsequent to treatment. Researchers and drug abuse service providers may use the aggregate data to address issues and generate hypotheses to understand better the interactions among the client and community.

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

1. Within the restrictions set forth in HHS regulations concerning the confidentiality of drug abuse patient records (42 CFR 2.56), we may disclose a record 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 purpose of the research project, unless