health, and alcohol and/or drug abuse related treatment and prevention services; providers of services; demographic sub-groups as applicable, such as age, sex, ethnicity, race, occupation, geographic location; and groups exposed to hypothesized risks, such as relatives of individuals who have experienced mental health and/or alcohol, and/or drug abuse disorders, life stresses, or have previous history of mental, alcohol, and/or drug abuse related illness.

### CATEGORIES OF RECORDS IN THE SYSTEM:

The system contains data about the individual as relevant to a particular research study. Examples include, but are not limited to, items about the health/mental health and/or alcohol or drug consumption patterns of the individual; demographic data; social security numbers (voluntary); past and present life experiences; personality characteristics; social functioning; utilization of health/mental health, alcohol, and/or drug abuse services; family history; physiological measures; and characteristics and activities of health/mental health; alcohol abuse, and/or drug abuse care providers.

### AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Public Health Service Act, sections 301 and 405 (42 U.S.C. 241, and 284, General Research and Investigation Authorities); Public Health Service Act, sections 301, 302, 303 and Title V, Parts A and B (42 US.C. 241, 242, 242(a).

## PURPOSE(S):

The purpose of the system of records is to collect and maintain databases for research activities. Analyses of these data involve groups of individuals with given characteristics and do not refer to special individuals. The generation of information and statistical analyses will ultimately lead to a better description and understanding of mental, alcohol, and/or drug abuse disorders, their diagnosis, treatment and prevention, and the promotion of good physical and mental health.

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

1. A record may be disclosed for a research purpose, when the Department: (a) As determined that the use or disclosure does not violate legal or policy limitations under which the record was provided, collected, or obtained; e.g., disclosure of alcohol or drug abuse patient records will be made only in accordance with the restrictions of confidentiality statutes and regulations 42 U.S.C. 290 (dd-3), 42 U.S.C. 241 and 405, 42 CFR part 2, and

where applicable, no disclosures will be made inconsistent with an authorization of confidentiality under 42 U.S.C. 242a and 42 CFR part 2a; (b) as 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, and (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 the recipient has presented adequate justification of a research or health nature for retaining such information, and (3) make no further use or disclosure of the record except—(A) in emergency circumstances affecting the health or safety of any individual, (B) for use in another research project, under these same conditions, and with written authorization of the Department, (C) for disclosure to a properly identified person for the purpose of an audit related to the research project, if information that would enable research subjects to be identified is removed or destroyed at the earliest opportunity consistent with the purpose of the audit, or (D) when required by law; and (d) has secured a written statement attesting to the recipient's understanding of, and willingness to abide by, these provisions.

- 2. Disclosure may be made to a congressional office from the record of an individual in response to a verified inquiry from a congressional office made at the written 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 is 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; the Department may disclose such records as it deems desirable or necessary to the Department of Justice to enable that Department to present an effective defense, provided such disclosure is compatible with the purpose for which the records were collected (e.g., disclosure may be made to the

Department of Justice or other appropriate Federal agencies in defending claims against the United States when the claim is based upon an individual's mental or physical condition and is alleged to have arisen because of the individual's participation in activities of a Federal Government supported research project).

4. The Department contemplates that it will contract with a private firm for the purpose of collecting, analyzing, aggregating, or otherwise refining records in this system. Relevant records will be disclosed to such contractor. The contractor shall be 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:

Records may be stored on index cards, file folders, computer tapes and disks, microfiche, microfilm, and audio and video tapes. Normally, the factual data, with study code numbers, are stored on computer tape or disk, while the key to personal identifiers is stored separately, without factual data, in paper files.

### RETRIEVABILITY:

During data collection stages and followup, if any, retrieval by personal identifier (e.g., name, social security number) (in some studies), or medical record number), is necessary. During the data analysis stage, data are normally retrieved by the variables of interest (e.g., diagnosis, age, occupation).

## SAFEGUARDS:

- 1. Authorized users: Access to identifiers and to link files is strictly limited to the authorized personnel whose duties require such access. Procedures for determining authorized access to identified data are established as appropriate for each location. Personnel, including contractor personnel, who may be so authorized include those directly involved in data collection and in the design of research studies, e.g., interviewers and interviewer supervisors; project managers; statisticians involved in designing sampling plans.
- 2. Physical safeguards: Records are stored in locked rooms, locked file cabinets, and/or secured computer facilities. Personal identifiers and link files are separated as much as possible and stored in locked files. Computer data access is limited through the use of key words known only to authorized personnel.
- 3. *Procedural safeguards:* Collection and maintenance of data is consistent