SAFEGUARDS:

1. Authorized areas: Only authorized ARC staff (Principal Investigator and his/her research team) are allowed access to these files. The contractor staff has access to the files during the recruitment/screening process.

2. *Physical safeguards:* Files and file rooms are locked after business hours. Building has electronic controlled entry at all times with a 24-hour guard/ television surveillance system. The computer terminals are in a further secured area.

3. *Procedural safeguards:* All users of personal information in connection with the performance of their jobs protect information from unauthorized personnel. Access codes to the research records are available only to the Principal Investigator and his/her research team. Access to the records is strictly limited to those staff members trained in accordance with the Privacy Act. The contractor staff members are required to secure the information in accordance with the Privacy Act. ARC Project Officer and contracting officials will monitor contractor compliance.

4. Implementation guidelines: DHHS Chapter 45–13 and supplementary Chapter PHS.hf: 45–13 of the General Administration Manual; and Chapter 6– 05, "Risk Management," under Part 6 in the Department's ADP Systems Security Manual.

In addition, because much of the data collected in these research projects are sensitive and confidential, special safeguards have been established. Certificates of confidentiality have been issued under Protection of Identity-Research Subjects Regulations (42 CFR part 2a) to those projects initiated since February 1980. This authorization enables persons engaged in research on mental health, including research on the use and effect of psychoactive drugs, to protect the privacy of research subjects by withholding their names or other identifying characteristics from all persons not connected with the conduct of the research. Persons so authorized may not be compelled in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding to identify such individuals. In addition, these records are subject to 42 CFR part 2, the Confidentiality of Alcohol and Drug Abuse Patient Records Regulations (42 CFR 2.56), which state: "Where the content of patient records has been disclosed pursuant to these regulations for the purpose of conducting scientific research * * * information contained therein which would directly or indirectly identify any patient may not be disclosed by the recipient thereof

either voluntarily or in response to any legal process whether Federal or State."

RETENTION AND DISPOSAL:

Records will be disposed of in accordance with the NIH Records Control Schedule, i.e., when the records are 10 years old or no longer required for administrative or research purposes. The records on individuals who do not qualify for a specific research project are kept for one year by the contractor who then destroys them by shredding.

SYSTEM MANAGER(S) AND ADDRESSES:

Medical Records Officer, NIDA, Intramural Research Program, Johns Hopkins Bayview Medical Center— Building C, P.O. Box 5180, Baltimore, Maryland 21224.

NOTIFICATION PROCEDURE:

To determine if a record exists, write to the System Manager at the address above. Provide a notarized signature as proof of identify. This can be waived if the request is made through official federal, state, or local channels. The request should include the patient's register number and/or the number of years of incarceration (for prisoner subjects), full name at time of participation in the research project, date(s) of research participation, and title of research project or name of drug being studied. 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 Addiction Research Center 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 that have been made of his/her records, if any.

CONTESTING RECORD PROCEDURES:

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

RECORD SOURCE CATEGORIES:

The individual; observations and medical recordings (such as blood pressure, dosage of compound administered, etc.) made by the Principal Investigator and his/her research team; system of records number 09–30–0020; drug treatment programs; Bureau of Prisons; case workers; psychiatrists; research laboratories; and pharmacies and hospitals. Many of these records are confidential and privileged communication is guaranteed under section 344(d) of the PHS Act.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

09–25–0205

SYSTEM NAME:

Alcohol, Drug Abuse, and Mental Health Epidemiologic and Biometric Research Data, HHS/NIH/NIAAA, HHS/ NIH/NIDA and HHS/NIH/NIMH.

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

Records are located at the research facilities which collect or provide research data for this system under contract to the agency. Contractors may include, but are not limited to, research centers, clinics, hospitals, universities, research foundations, national associations, and coordinating centers. Records may also be located at the research facilities of the National Institute on Alcohol Abuse and Alcoholism (NIAAA), the National Institute on Drug Abuse (NIDA); and the National Institute of Mental Health (NIMH). A current list of sites is available by writing to the appropriate System Manager at the address below.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individuals who are the subjects of research in epidemiologic, clinical, methodologic, and longitudinal research studies and surveys of mental health and alcohol and drug use/abuse and mental, alcohol, and/or drug abuse disorders. These individuals are selected as representative of the general adult and/or child population or of special groups. Special groups include, but are not limited to, normal individuals serving as controls; clients referred for or receiving medical, mental