physicians, nurses, technologists, computer operators, and the department's administrative officer.

1. Authorized users: Access is granted only to authorized employees of the Department of Transfusion Medicine including physicians, nurses technologists, computer operators and the secretary to the Chief.

2. *Physical safeguards:* Record facilities are locked when system personnel are not present.

3. Procedural safeguards: Access to manual files is limited to authorized users. Access to computerized records is controlled by the use of security codes known only to the authorized users.

These practices are in compliance with the standards of Chapter 45–13 of the HHS General Administration Manual, "Safeguarding Records Contained in Systems of Records," supplementary Chapter PHS hf: 45–13, and Part 6, "ADP Systems Security," of the HHS Information Resources Management Manual and the National Institute of Standards and Technology Federal Information Processing Standards (FIPS Pub. 41 and FIPS Pub. 31).

RETENTION AND DISPOSAL:

Records are retained and disposed of under the authority of the HIH Records Control Schedule contained in NIH Manual Chapter 1743, Appendix 1—"Keeping and Destroying Records" (HHS Records Management Manual, Appendix B–361), item 3000–E–50. Refer to the NIH Manual Chapter for specific conditions on disposal.

SYSTEM MANAGER AND ADDRESS:

Chief, Tranfusion Medicine Department, National Institutes of Health, 10 Center Drive MSC 1184, Bethesda, MD 20892–1184.

NOTIFICATION PROCEDURE:

Write to the System Manager to determine if a record exists. The requester must also verify his or her identify by providing either a notarization of the request or a written certification that the requester is who he or she claims to be and understands that the knowing and willful request for acquisition of a record pertaining to an individual under false pretenses is a criminal offense under the Act, subject to a five thousand dollar fine.

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 may be a physician, who will be willing to review the record and inform the subject individual of its contents at the representative's discretion.

RECORD ACCESS PROCEDURE:

To obtain access to a record, contact the system manager at the address specified above. Requestors should provide the same information as is required under the notification procedures above. Individuals may also request listings of accountable disclosures that have been made of their records, if any.

CONTESTING RECORD PROCEDURE:

Write to the official specified under notification procedures above, and reasonably identify the record and specify the information being contested, the corrective action sought, and your reasons for requesting the correction, along with supporting information to show how the record is inaccurate, incomplete, untimely, or irrelevant. The right to contest records is limited to information which is incomplete, irrelevant, incorrect, or untimely (obsolete).

RECORD SOURCE CATEGORIES:

Data are collected from the individual.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

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SYSTEM NAME:

Clinical Research: Candidate Normal Volunteer Records, HHS/NIH/CC.

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

National Institutes of Health, Social Work Department, 10 Center Drive MSC 1160, Bethesda, MD 20892– 1160.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Normally healthy individuals who volunteer to participate in NIH studies.

CATEGORIES OF RECORDS IN THE SYSTEM:

Program application, health questionnaire and record of participation.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM: 42 U.S.C. 241, 263.

PURPOSE(S) OF THE SYSTEM:

(1) To determine suitability for participation in the normal volunteer program, (2) to document remuneration of normal volunteers, (3) to provide a record of participation to be used (a) in writing letters of recommendation/reference for the volunteer, and (b) preparing reports on the normal volunteer program.

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

- 1. Clinical research data are made available to approved or collaborating researchers, including HHS contractors and grantees.
- 2. Certain diseases and conditions, including infectious diseases, may be reported to appropriate representatives of State or Federal Government as required by State or Federal law.
- 3. Information may be used to respond to congressional inquiries for constituents concerning admission to the NIH Clinical Center.
- 4. Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

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

STORAGE:

Program applications and health questionnaires are stored in file folders. Records of participation are stored on index cards.

RETRIEVABILITY:

Records are retrieved by name.

SAFEGUARDS:

Measures to prevent unauthorized disclosures are implemented as appropriate for each location and for the particular records maintained in each project. Each site implements personnel, physical, procedural safeguards such as the following:

- 1. Authorized users: Access is granted only to the Normal Volunteer Program staff and to NIH physicians who have requested the recruitment of volunteers for their clinical research projects.
- 2. Physical safeguards: Access to the files is strictly controlled by the files staff. Records may be removed from the file only at the request of the system manager or other authorized employees. Record facilities are locked when system personnel are not present.
- 3. *Procedural safeguards:* Access to the files is strictly controlled by the files staff. Records may be removed from the file only at the request of the system manager or other authorized employees.

RETENTION AND DISPOSAL:

Records are retained and disposed of under the authority of the NIH Records Control Schedule contained in NIH Manual Chapter 1743, Appendix 1— "Keeping and Destroying Records" (HHS Records Management Manual, Appendix B–361), item 3000–E–61, which allows records to be kept until