

Department to present an effective defense.

4. Disclosure may be made to a congressional office from the record of an individual in response to a verified inquiry from the congressional office made at the written request of that individual.

5. A record may be disclosed for a research purpose, when the Department, independently or through its contractor(s):

(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 a bona fide research/analysis purpose exists;

(c) Has required the recipient to: (1) Establish strict limitations concerning the receipt and use of patient-identified data; (2) establish reasonable administrative, technical, and physical safeguards to protect the confidentiality of the data and to prevent the unauthorized use or disclosure of the record; (3) remove, destroy, or return 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 (4) make no further use or disclosure of the record except as authorized by HRSA or its contractor(s) or when required by law;

(d) has determined that other applicable safeguards or protocols will be followed; and

(e) has secured a written statement attesting to the recipient's understanding of, and willingness to abide by these provisions.

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

**STORAGE:**

Records are maintained in file folders, magnetic tapes, and disc packs.

**SAFEGUARDS:**

1. *Authorized users:* Access is limited to authorized HRSA and contract personnel responsible for administering the program. Authorized personnel include the System Manager and Project Officer, and the HRSA Automated Information System (AIS) Systems Security Officer; and the program managers/program specialists who have responsibilities for implementing the program. Both HRSA and its contractor(s) shall maintain current lists of authorized users.

2. *Physical safeguards:* Magnetic tapes, disc packs, computer equipment, and hard-copy files are stored in areas where fire and life safety codes are strictly enforced. All automated and nonautomated documents are protected on a 24-hour basis in locked storage areas. Security guards perform random checks on the physical security of the records storage area. The OPTN and SRTR contractors are required to maintain off site a complete copy of the system and all necessary files to run the computer organ donor-recipient match and update software.

3. *Procedural safeguards:* A password is required to access the terminal and a data set name controls the release of data to only authorized users. All users of personal information in connection with the performance of their jobs protect information from public view and from unauthorized personnel entering an unsupervised office. All authorized users must sign a nondisclosure statement. Access to records is limited to those staff members trained in accordance with the Privacy Act and Automated Data Processing (ADP) security procedures. The contractor(s) is required to assure that the confidentiality safeguards of these records will be employed and that it complies with all provisions of the Privacy Act. All individuals who have access to these records must have the appropriate ADP security clearances. Privacy Act and ADP system security requirements are included in the contracts. The HRSA Project Officer(s) and the System Manager(s) oversee compliance with these requirements. The HRSA authorized users will make visits to the contractors' facilities to assure security and Privacy Act compliance. The contractor(s) is/are required to adhere to a HRSA approved system security plan.

**RETENTION AND DISPOSAL:**

Each donor, candidate, and recipient record shall be retained for 25 years beyond the known death of the organ recipient.

**SYSTEM MANAGER AND ADDRESS:**

Chief, Operations and Analysis Branch, Division of Transplantation, HRSA, Parklawn Building, Room 16C-17, 5600 Fishers Lane, Rockville, MD 20857.

**NOTIFICATION PROCEDURE:**

*Requests by mail:* To determine if a record about you exists, write to the OPTN contractor (see System Location). The request should contain the name and address of the individual; the Social Security number if the individual

chooses to provide it; the name of his/her transplant center, a notarized written statement that the requester is the person he/she claims to be and that he/she understands that the request or acquisition of records pertaining to another individual under false pretenses is a criminal offense subject to a \$5,000 fine. These procedures are in accordance with the Department's regulations (45 CFR part 5b).

*Requests in person:* The individual must meet all the requirements stated above for a request by mail, providing the information in written form, or provide at least one piece of tangible identification. The individual should recognize that in order to maintain confidentiality, and thus the accuracy of data released through repeated internal verification, securing the information by request in person will be time consuming. These procedures are in accordance with the Department's regulations (45 CFR part 5b).

*Requests by telephone:* Since positive identification of the caller cannot be established, telephone requests are not honored.

**RECORD ACCESS PROCEDURES:**

Same as notification procedures. Requestors should also provide a reasonable description of the record being sought. Requestors also may request an accounting of disclosures that have been made of their records, if any. A parent or guardian who requests notification of, or access to, a minor's/incompetent person's medical record shall designate a family physician or other health professional (other than a family member) to whom the record, if any, will be sent. The parent or guardian must verify relationship to the minor/incompetent person as well as his/her own identity. These procedures are in accordance with the Department's regulations (45 CFR part 5b).

**CONTESTING RECORDS PROCEDURES:**

Contact the official at the address specified under notification procedure above and reasonably identify the record, specify the information being contested, and 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.

**RECORD SOURCE CATEGORIES:**

Organ procurement organizations, histocompatibility laboratories, and organ transplant centers.