

NOTIFICATION PROCEDURE:

An individual may learn if a record exists about himself or herself by contacting the system manager at the address above. Requesters in person must provide driver's license or other positive identification. Individuals who do not appear in person must either (1) submit a notarized request to verify their identity or (2) certify that they are the individuals they claim to be and that they understand that the knowing and willful request for or acquisition of a record pertaining to an individual under false pretenses is a criminal offense under the Privacy Act subject to a \$5,000 fine.

An individual who requests notification of or access to medical records shall, at the time the request is made, designate in writing a responsible representative who is willing to review the record and inform the subject individual of its contents at the representative's discretion.

A parent or guardian who requests notification of, or access to, a child'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 child by means of a birth certificate or court order, as well as verify that he or she is who he or she claims to be.

The following information must be provided when requesting notification: (1) Full name; (2) the approximate date and place of the study, if known; and (3) nature of the questionnaire or study in which the requester participated.

RECORD ACCESS PROCEDURES:

Same as notification procedures. Requesters should also reasonably specify the record contents being sought. An accounting of disclosures that have been made of the record, if any, may be requested.

CONTESTING RECORD PROCEDURES:

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

RECORD SOURCE CATEGORIES:

Individuals, state and local health departments, hospitals, laboratories, clinics, and family members of study participants.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

09-20-0090

SYSTEM NAME:

Studies of Testing for Tuberculosis and other Mycobacterioses. HHS/CDC/CPS.

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

Division of Tuberculosis Control, Center for Prevention Services, Freeway Office Park, Rms 127, 137, 142, Centers for Disease Control, 1600 Clifton Road, Atlanta, GA 30333 and Federal Records Center, 1557 St. Joseph Avenue, East Point, GA 30344.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Study participants include patients, clientele, and employees of local and county health departments, hospitals, and other institutions currently observing and/or treating cases of tuberculosis and other mycobacterial diseases. Participants include adults and children.

CATEGORIES OF RECORDS IN THE SYSTEM:

Medical records.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Public Health Service Act, Section 301, "Research and Investigation" (42 U.S.C. 241).

PURPOSE(S):

To study the diagnostic value of tests used to identify persons infected with M. tuberculosis or sensitized by other mycobacteria. These records may also be used by the Food and Drug Administration in conducting research related to Investigational New Drugs (IND).

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

Test results will be returned to the collaborating physician or responsible hospital official.

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.

In the event of litigation where the defendant is (a) the Department, any component of the Department, or any employee of the Department in 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, for example, in defending a claim against the Public Health Service based upon an individual's mental or physical condition and alleged to have arisen because of activities of the Public Health Service in connection with such individual, disclosure may be made to the Department of Justice to enable that Department to present an effective defense, provided that such disclosure is compatible with the purpose for which the records were collected.

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

Cards, file folders, computer tapes/disks and printouts.

RETRIEVABILITY:

Records are retrieved by name and I.D. number.

SAFEGUARDS:

1. AUTHORIZED USERS: Access is granted to only a limited number of physicians, scientists, statisticians, and designated support staff of the Centers for Disease Control (CDC), as authorized by the system manager to accomplish the stated purposes for which the data in this system have been collected.

2. PHYSICAL SAFEGUARDS: Locked cabinets in locked rooms, 24-hour guard service in buildings, personnel screening of visitors, electronic anti-intrusion devices in operation at the Federal Records Center, fire extinguishers, overhead sprinkler system and card-access control equipment in the computer room, computer terminals and automated records located in secured areas.

3. PROCEDURAL SAFEGUARDS: Protection for computerized records includes programmed verification of valid user identification code, account code and password prior to acceptance of a terminal session or job submission, frequently changed passwords, and Vault Management System. Knowledge of individual tape passwords is required to access tapes, and access to systems is limited to users obtaining prior supervisory approval. When Privacy Act tapes are scratched, a special "certified" process is performed in which tapes are completely written over to avoid inadvertent data disclosure. Additional

safeguards may be built into the program by the system analyst as warranted by the sensitivity of the data.

CDC employees who maintain records are instructed to check with the system manager prior to making disclosures of data. When individually identified data are being used in a room, admittance is restricted to specifically authorized personnel.

4. IMPLEMENTATION GUIDELINES: The safeguards outlined above are developed in accordance with Chapter 45-13, "Safeguarding Records Contained in Systems of Records," of the HHS General Administration Manual, supplementary Chapter PHS.hf: 45-13; Part 6, "Automated Information System Security," of the HHS Information Resources Management Manual; the National Bureau of Standards Federal Information Processing Standards (FIPS Pub. 41 and FIPS Pub. 31). FRC safeguards are in compliance with GSA Federal Property Management Regulations, Subchapter B—Archives and Records.

RETENTION AND DISPOSAL:

Records are maintained in agency for five years. Disposal methods include erasing computer tapes, burning or shredding paper materials or transferring records to the Federal Records Center when no longer needed for evaluation and analysis. Records destroyed by paper recycling process when 20 years old, unless needed for further study.

SYSTEM MANAGER(S) AND ADDRESS:

Director, Division of Tuberculosis Control, Center for Prevention Services, Freeway Office Park, Rm. 111, Centers for Disease Control, 1600 Clifton Road, Atlanta, GA 30333.

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RECORD SOURCE CATEGORIES:

Individuals and hospitals.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

09-20-0096

SYSTEM NAME:

Records of Tuskegee Study Health Benefit Recipients. HHS/CDC/CPS.

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

Center for Prevention Services, Freeway Office Park, Rm. 308, Centers for Disease Control, 1600 Clifton Road, Atlanta, GA 30333 and Federal Records Center, 1557 St. Joseph Avenue, East Point, GA 30344.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Adult participants in the study and their family members.

CATEGORIES OF RECORDS IN THE SYSTEM:

Medical records.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Public Health Service Act, Section 301, "Research and Investigation" (42 U.S.C. 241).

PURPOSE(S):

To determine eligibility and provide medical benefits for participants and qualified family members.

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

A record may be disclosed 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 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;(D) has secured a written statement attesting to the recipient's understanding of, and willingness to abide by these provisions. Records may be disclosed to health departments and other public health or cooperating medical authorities in connection with program activities and related collaborative efforts to deal more effectively with diseases and conditions of public health significance. Disclosure may be made to a congressional office from the record of an individual in response to a verified