

Agricultural Research Service

USDA/ARS-1

SYSTEM NAME:

Agricultural Research Service—1 Research Medical Records System on Patients and Human Volunteers Participating in Research

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

Records are located at the Agricultural Research Service (ARS) research centers and locations. A current list of centers and locations is available by writing to the National Program Leader, Human Nutrition, National Program Staff, ARS, U.S. Department of Agriculture (USDA), 5601 Sunnyside Avenue, Beltsville, MD 20705.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individuals participating in human research carried out by staff at ARS research centers and locations.

CATEGORIES OF RECORDS IN THE SYSTEM:

Medical and nutritional histories, medical and nutritional examinations, diagnostic and treatment data, social and economic data, clinical laboratory data, statistical summaries, and correspondence.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

7 U.S.C. 2201, 7 U.S.C. 427, and 7 U.S.C. 3101 *et seq.*

PURPOSE(S):

The purpose of this Privacy Act system of records is to conduct research related to human dietary requirements at all stages of life. The results of this research are published in the scientific literature. Typically, research results are pooled from many individuals and individual information is not released or published.

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

Records in this system may be disclosed to:

1. The Department of Justice when (a) the agency or any component thereof; or (b) any employee of the agency in his or her official capacity where the Department of Justice has agreed to represent the employee; or (c) any employee of the agency in his or her individual capacity where the agency has agreed to represent the employee; or (d) the United States Government is a party to litigation or has an interest in such litigation and, by careful review, the agency determines that the records are both relevant and necessary to the litigation and the use of such records by the Department of Justice is therefore deemed by the agency to be for a purpose that is compatible with the purpose for which the agency collected the records.
2. A court or adjudicative body in a proceeding when (a) the agency or any component thereof; or (b) any employee of the agency in his or her official capacity; or (c) any employee of the agency in his or her individual capacity where the agency has agreed to represent the employee; or (d) the United States Government is a party to litigation or has an interest in such litigation and, by careful review, the agency determines that the records are both relevant and necessary to the litigation and the use of such records is therefore deemed by the agency to be for a purpose that is compatible with the purpose for which the agency collected the records.
3. When a record on its face, or in conjunction with other records, indicates a violation or potential violation of law, whether civil, criminal, or regulatory in nature, and whether arising by general statute or particular program statute, or by regulation, rule, or order issued pursuant thereto, disclosure may be made to the appropriate agency, whether Federal, foreign, State, local, or tribal, or other public authority responsible for enforcing, investigating, or prosecuting such violation or charged with enforcing or implementing the statute, rule, regulation, or order issued pursuant thereto, if the information disclosed is relevant to any enforcement, regulatory, investigative, or prosecutive responsibility of the receiving entity.
4. Appropriate agencies, entities, and persons when (a) ARS suspects or has confirmed that the security or confidentiality of information in the system of records has been compromised, (b) the USDA has determined that as a result of the suspected or confirmed compromise there is a risk of harm to economic or property interests, identity theft or fraud, or harm to the security or integrity of this system or other systems or programs (whether maintained by USDA or another agency or entity) that rely upon the compromised information, and (c) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with USDA's efforts to respond to the suspected or confirmed compromise and prevent, minimize, or remedy such harm.

5. Records from this system of records may be disclosed to the National Archives and Records Administration or to the General Services Administration for records management inspections conducted under 44 U.S.C. 2904 and 2906.

6. To agency contractors, grantees, experts, consultants, or volunteers who have been engaged by the agency to assist in the performance of a service related to this system of records and who need to have access to the records in order to perform the activity. Recipients shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

7. To a Member of Congress or to a Congressional staff member in response to an inquiry of the Congressional staff office made at the written request of the constituent about whom the record is maintained.

DISCLOSURE TO CONSUMER REPORTING AGENCIES:

None.

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

STORAGE:

Records are kept in file folders or maintained electronically.

RETRIEVABILITY:

Records are retrievable by the name of the volunteer and a number assigned to the volunteer.

SAFEGUARDS:

Paper records are stored in locked rooms or locked file cabinets and electronic records are stored in secured databases. Access is restricted to authorized personnel only. The identity of the participant is kept in a separate file from the information and the information is associated with a blinded coded number.

RETENTION AND DISPOSAL:

Clinical and scientific records are retained and disposed of in conformance with the ARS Records Schedule, NCI-310-80-2, Item 200, as appropriate.

SYSTEM MANAGER(S) AND ADDRESS:

National Program Leader, Human Nutrition, National Program Staff, ARS, USDA, 5601 Sunnyside Avenue, Beltsville, MD 20705.

NOTIFICATION PROCEDURE:

Individuals seeking notification of and access to any record contained in this system of records, or seeking to contest its content, may submit a request in writing to the Headquarters or component's Freedom of Information Act (FOIA) Officer, whose contact information can be found at <http://www.da.usda.gov/foia.htm> under "contacts." If an individual believes more than one component maintains Privacy Act records concerning him or her, the individual may submit the request to the Chief FOIA Officer, Department of Agriculture, 1400 Independence Avenue, SW., Washington, DC 20250.

When seeking records about yourself from this system of records or any other Departmental system of records your request must conform with the Privacy Act regulations set forth in 6 CFR part 5. You must first verify your identity, meaning that you must provide your full name, current address and date and place of birth. You must sign your request, and your signature must either be notarized or submitted under 28 U.S.C. 1746, a law that permits statements to be made under penalty of perjury as a substitute for notarization. While no specific form is required, you may obtain forms for this purpose from the Chief FOIA Officer, Department of Agriculture, 1400 Independence Avenue, SW., Washington, DC 20250. In addition you should provide the following:

- An explanation of why you believe the Department would have information on you;
- Identify the component(s) of the Department you believe may have the information about you;
- Specify when you believe the records would have been created;
- Any additional information that will help the FOIA staff determine which USDA component agency may have responsive records;
- If your request is seeking records pertaining to another living individual, you must include a statement from that individual certifying his/her agreement for you to access his/her records.

Without this bulleted information the component(s) may not be able to conduct an effective search, and your request may be denied due to lack of specificity or lack of compliance with applicable regulations.

RECORD ACCESS PROCEDURES:

See "Notification procedure" above.

CONTESTING RECORD PROCEDURES:

See "Notification procedure" above.

RECORD SOURCE CATEGORIES:

Records in this system come primarily from the volunteers, health care personnel, other hospitals and physicians, employers, and social agencies.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.