Request for Records Disposition Authority

Records Schedule Number	DAA-AU-2018-0001
Schedule Status	Returned Without Action
Agency or Establishment	Department of the Army
Record Group / Scheduling Group	Army Undifferentiated
Records Schedule applies to	Agency-wide
Schedule Subject	Research Involving Human Subjects IAW the Food and Drug Administration (FDA) Regulations (Records governed from 0-6 years as defined by the signed copy of the Protocol / Consent Form)
Internal agency concurrences will be provided	No
Background Information	The functional category for records in this request is governed by AR 70-25, Use of Volunteers as Subjects of Research. The U.S. Army Medical Research and Material Command (USAMRMC) reflects the present legal requirements pertaining to the use of humans as research subjects funded by research, development, test and evaluation appropriations. Only persons who are fully informed and volunteer in advance to take part may be used as subjects in research; except when the measures used are intended to be beneficial to the subject and informed consent is obtained in advance from a legal representative on the subject's behalf.

Item Count

Number of Total Disposition Items	Number of Permanent Disposition Items	Number of Temporary Disposition Items	Number of Withdrawn Disposition Items
0	0	0	1

GAO Approval

Outline of Records Schedule Items for DAA-AU-2018-0001

Sequence Number	
1	Use of Volunteers as Subjects of Research
1.1	Research Involving Human Subjects IAW the Food and Drug Administration (FDA) Regulations (Records governed from 0-6 years as defined by the signed copy of the Protocol / Consent Form) / RN 70-25b/1200B-06 Disposition Authority Number: DAA-AU-2018-0001-0001

Records Schedule Items

Sequence Number	
1	Use of Volunteers as Subjects of Research The U.S. Army Medical Research and Material Command (USAMRMC) provides research-related data that contains significant information on problems and conditions that the organization has been tasked with solving. This data is frequently used by the organizations engineers, scientists, and researchers as resources for the continuation of computational analyses and further study of problems and issues in support of the Army Research and Development programs, both current and future. Input records covered by DAA-GRS-2013-0001-0001 Item 10 for hard copy and analog, and by DAA-GRS-2013-0001-0004 Item 20 for electronic input/source records. Output ad-hoc records are covered by DAA-GRS-2013-0001-0005 Item 30, and output data file records are covered by DAA-GRS-0001-0006 Item 31.
1.1	Research Involving Human Subjects IAW the Food and Drug Administration (FDA) Regulations (Records governed from 0-6 years as defined by the signed copy of the Protocol / Consent Form) / RN 70-25b/1200B-06

Disposition Authority Number: DAA-AU-2018-0001-0001

Documents generated as (1) a result of subject enrollment into and participation in research, including, but not limited to, screening and enrollment log(s), signed consent documents, source documentation, case report forms, completed surveys, questionnaires, screening assessments, injury assessments, Health Insurance Portability Accountability Act (HIPPA) waivers and reports of adverse events; (2) records as specified in Title 21 Food and Drugs, Chapter 1 FDA, Department of Health and Human Services, Subchapter D Drugs for Human Use; (5) records as specified in Title 21 Food and Drugs, Chapter 1 FDA, Department of Health and Human Services, Subchapter H Medical Devices. Digitization is authorized unless prohibited by the governing agency.

Final Disposition	Temporary
Item Status	Withdrawn
Is this item media neutral?	Yes
Do any of the records covered by this item currently exist in electronic format(s) other than e-mail and word processing?	No

Manual Citation	Manual Title
AR 25-400-2	Army Records Information Management System (ARIMS)

Disposition Instruction	
Cutoff Instruction	KE6. Keep in CFA until event occurs then destroy. Event is 2 years after the date the investigation is completed or terminated, records are no longer required to support a Pre-Market Application (PMA) or Product Development Protocol (PDP), whichever date is later; 2 years after a marketing application is approved, or 2 years after delivery of a drug for investigational use is discontinued and the FDA is notified.
Retention Period	Destroy 6 year(s) after event occurs.
Additional Information	
GAO Approval	Not Required

Agency Certification

I hereby certify that I am authorized to act for this agency in matters pertaining to the disposition of its records and that the records proposed for disposal in this schedule are not now needed for the business of the agency or will not be needed after the retention periods specified.

Signatory Information

Date	Action	By	Title	Organization
12/07/2017	Certify	Shirley KinsonJones	Management Analyst	Army - Records Management and Declassification Agency
01/31/2018	Return Without Action	Sebastian Welch	Appraiser	National Archives and Records Administration - Records Management Services