Request for Records Disposition Authority

Records Schedule Number	DAA-AU-2018-0003
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	Regulatory Research Involving Human Subjects IAW the Food and Drug Administration (FDA) Regulation (0-6 year retention as stipulated by the FDA)
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Number of Total Disposition Items	Number of Permanent Disposition Items	Number of Temporary Disposition Items	Number of Withdrawn Disposition Items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

WITHDRAWN - RETURNED WITHOUT ACTION

Outline of Records Schedule Items for DAA-AU-2018-0003

Sequence Number	
1	Use of Volunteers as Subjects of Research
1.1	Regulatory Research Involving Human Subjects IAW the Food and Drug Administration (FDA) Regulation (0-6 year retention as stipulated by the FDA) - RN 70-25e/ACRS 1200B/0-6 Disposition Authority Number: DAA-AU-2018-0003-0001

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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	Regulatory Research Involving Human Subjects IAW the Food and Drug Administration (FDA) Regulation (0-6 year retention as stipulated by the FDA) - RN 70-25e/ACRS 1200B/0-6
	Disposition Authority Number: DAA-AU-2018-0003-0001
	Records created during the development and conduct of research involving human subjects that is conducted in accordance with the Food and Drug Administration (FDA) regulations. Records include, but are not limited to, (1) scientific evaluations that accompany proposals and protocols, if any; (2) documents approved by the Institutional Review Board (IRB) or Human Use committee (HUC), including, but not limited to, research proposals and protocols, approved sample consent documents and non-English translation verification(s), approved sample recruitment materials/tools, agreements, delegation of authority log(s), approved continuing review reports or progress reports submitted by investigators, approved modifications, statements of significant new findings provided to subjects, reports, deviations and injuries to subjects, reports of adverse events, and all correspondence between the IRB and the investigators, site standard operating procedures, if any, and shipping records, if any. 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

WITHDRAWN - RETURNED WITHOUT ACTION

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

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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
11/21/2017	Return to Submitter	Shirley KinsonJones	Management Analyst	Army - Records Management and Declassification Agency
11/28/2017	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

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