

# WITHDRAWN - RETURNED WITHOUT ACTION

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION  
Request for Records Disposition Authority

Records Schedule: DAA-AU-2018-0004

## Request for Records Disposition Authority

Records Schedule Number      DAA-AU-2018-0004  
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) Regulations (6+ years retention as stipulated by the FDA)

Internal agency concurrences will be provided      Yes

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 Materiel 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Number of Total Disposition Items	Number of Permanent Disposition Items	Number of Temporary Disposition Items	Number of Withdrawn Disposition Items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

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Records Schedule: DAA-AU-2018-0004

## Outline of Records Schedule Items for DAA-AU-2018-0004

Sequence Number	
1	Use of Volunteers as Subjects of Research
1.1	Regulatory Research Involving Human Subjects IAW the Food and Drug Administration (FDA) Regulations (6+ years retention as stipulated by the FDA) - RN 70-25f/ACRS 1200B/6+ Disposition Authority Number: DAA-AU-2018-0004-0001

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## Records Schedule Items

Sequence Number			
1	<p><b>Use of Volunteers as Subjects of Research</b> 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.</p>		
1.1	<p><b>Regulatory Research Involving Human Subjects IAW the Food and Drug Administration (FDA) Regulations (6+ years retention as stipulated by the FDA) - RN 70-25f/ACRS 1200B/6+</b></p> <p>Disposition Authority Number      DAA-AU-2018-0004-0001</p> <p>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.</p> <p>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</p>		
	<table border="1"><tr><td data-bbox="358 1889 930 1936">Manual Citation</td><td data-bbox="930 1889 1477 1936">Manual Title</td></tr></table>	Manual Citation	Manual Title
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AR 25-400-2

Army Records Information Management  
System (ARIMS)

## Disposition Instruction

### Cutoff Instruction

TE10. Keep in CFA until event occurs then retire to RHA/AEA. The RHA/AEA will destroy the record 10 years after the event. Event is 2 years after the date the investigation is completed or terminated, records are no longer required to support a PMA or 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 10 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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