

# WITHDRAWN - RETURNED WITHOUT ACTION

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION  
Request for Records Disposition Authority

Records Schedule: DAA-AU-2018-0002

## Request for Records Disposition Authority

Records Schedule Number      DAA-AU-2018-0002  
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 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 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Number of Total Disposition Items	Number of Permanent Disposition Items	Number of Temporary Disposition Items	Number of Withdrawn Disposition Items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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NATIONAL ARCHIVES AND RECORDS ADMINISTRATION  
Request for Records Disposition Authority

Records Schedule: DAA-AU-2018-0002

## Outline of Records Schedule Items for DAA-AU-2018-0002

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 6+ years as defined by the signed copy of the Protocol / Consent Form) - RN 70-25c/ACRS 1200B/6+ Disposition Authority Number: DAA-AU-2018-0002-0001

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NATIONAL ARCHIVES AND RECORDS ADMINISTRATION  
Request for Records Disposition Authority

Records Schedule: DAA-AU-2018-0002

## Records Schedule Items

Sequence Number

1 Use of Volunteers as Subjects of Research  
The U.S. Army Medical Research and Materiel 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 6+ years as defined by the signed copy of the Protocol / Consent Form) - RN 70-25c/ACRS 1200B/6+

Disposition Authority Number DAA-AU-2018-0002-0001

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 Management Information Management System (ARIMS)

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## Executive Summary

Summary

Permanent Item Numbers

Federal Register Notice

Publication Date

Copies Requested 0

Comments Received 0

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NATIONAL  
ARCHIVES

Sebastian Welch &lt;sebastian.welch@nara.gov&gt;

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**Return Without Action DAA-AU-2018-0001 thru DAA-AU-2018-0008**

1 message

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**Sebastian Welch** <sebastian.welch@nara.gov>  
To: "shirley.a.jones48.civ@mail.mil" <shirley.a.jones48.civ@mail.mil>

Wed, Jan 31, 2018 at 10:37 AM

Shirley,

Please accept this email as the official notice that NARA is returning without further actions the following schedules:

DAA-AU-2018-0001  
DAA-AU-2018-0002  
DAA-AU-2018-0003  
DAA-AU-2018-0004  
DAA-AU-2018-0005  
DAA-AU-2018-0006  
DAA-AU-2018-0007  
~~DAA-AU-2018-0008~~

A handwritten signature in blue ink, appearing to be 'S' or 'SW', written over the crossed-out schedule number DAA-AU-2018-0008.

Per my email dated 7 December 2017, the schedules are being withdrawn because they do not adequately reflect the actual records that exist in the creating office. As you may recall, we visited the creating office (US Army Medical Research and Materiel Command) and reviewed examples of that office's files back in 2015. At the conclusion our visit, I stated that the proposed schedule (DAA-AU-2015-0034) did not adequately reflect the records that we reviewed. It appears that schedules DAA-AU-2018-0001 through DAA-AU-2018-0008 merely reflect a breakout of the items that were submitted under DAA-AU-2015-0034. As such, they still do not adequately describe records.

If you require any further assistance, please don't hesitate to call. As always, I look forward to working with you and your staff.

Sincerely,

SEBASTIAN (SAM) WELCH  
Supervisor, Appraisal Team 4  
Records Management Services  
National Archives and Records Administration  
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"It's a short journey from cradle to grave--don't hasten it by worrying over trivial matters".