

Request for Records Disposition Authority

Records Schedule Number DAA-AU-2015-0032
Schedule Status Approved

Agency or Establishment Department of the Army
Record Group / Scheduling Group Army Undifferentiated
Records Schedule applies to Agency-wide
Schedule Subject THE CARE AND USE OF LABORATORY ANIMALS IN DOD PROGRAMS

Internal agency concurrences will be provided No

Background Information

The US Army Medical Research and Materiel Command (USAMRMC) sets forth policies, procedures and responsibilities for the care and use of laboratory animals within Department of Defense (DoD) programs. This is supported by Army research and development. The program covers any live vertebrate animal that is being used or is intended for use in research, training, testing or for experimentation purposes. However, this does NOT cover animals used for ceremonial or recreational purposes; military working animals or farm animals, such as, but not limited to, livestock or poultry, used or intended for use as food, or fiber, or livestock, or poultry used or intended for use in improving animal nutrition, breeding, management, or production efficiency, or for improving the quality of food for fiber. Military, civilian and contract personnel assigned to all organizations create these records. All offices conducting research-related programs/studies maintain such records. Inclusive dates are 1930-present, the volume is indefinite.

The USAMRMC believes research-related data identified for retention is beyond the scope of the general correspondence files addressed in disposition authority N1-AU-00-28. The research-related data 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. The USAMRMC provides research-related support for Army and DoD's top joint development programs, the retention of research-related data will allow the organization to maximize research activities to continue

supporting development, transition, technologies and integration
across Army/DoD research and development communities

Item Count

Number of Total Disposition Items	Number of Permanent Disposition Items	Number of Temporary Disposition Items	Number of Withdrawn Disposition Items
3	0	3	0

GAO Approval

Outline of Records Schedule Items for DAA-AU-2015-0032

Sequence Number	
1	Laboratory Animal Medical Research Involving Animal Subjects Conducted IAW FDA Regulations – Good Laboratory Practices (GLP) / RN 40-33a/1200B-06 Disposition Authority Number: DAA-AU-2015-0032-0001
2	Laboratory Animal Medical Research Involving Animal Subjects NOT Conducted IAW FDA Regulations/ RN 40-33b/1200-06 Disposition Authority Number: DAA-AU-2015-0032-0002
3	Institutional Animal Care and Use Committee (IACUC) Records/ RN 40-33c/1200B-06 Disposition Authority Number: DAA-AU-2015-0032-0003

Records Schedule Items

Sequence Number

1

Laboratory Animal Medical Research Involving Animal Subjects Conducted IAW FDA Regulations – Good Laboratory Practices (GLP) / RN 40-33a/1200B-06

Disposition Authority Number DAA-AU-2015-0032-0001

GLP laboratory animal medical records are the records of animal treatment and care, food given, medical condition, treatments, and observed mental and physical health of animal subjects in GLP studies. These records are duplicates of the animal's veterinary medical record created specifically for GLP or reference purposes as part of the scientific project and include entries describing specific animal use. They may be audited as part of the GLP. Outside agencies sometimes ask to see the animal medical records of previous studies to verify results.

Final Disposition Temporary

Item Status Active

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)
AR 40-33	THE CARE AND USE OF LABORATORY ANIMALS IN DOD PROGRAMS;

Disposition Instruction

Cutoff Instruction KE5. Event is 5 years following the date in which the study is submitted to the FDA in support of an application for a research or marketing permit. Keep in the CFA 5 years after the event occurs, then destroy, unless otherwise stated in the protocol. Digitization is authorized unless prohibited by the government agency.

Retention Period Destroy 5 year(s) after following the date in which the study is submitted to the FDA in support of an application for a research or marketing permit.

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Additional Information

GAO Approval **Not Required**

Laboratory Animal Medical Research Involving Animal Subjects NOT Conducted IAW FDA Regulations/ RN 40-33b/1200-06

Disposition Authority Number **DAA-AU-2015-0032-0002**

Laboratory animal medical records are the records of animal treatment and care, food given, medical condition, treatments, and observed mental and physical health of animal subjects in scientific studies. (Record creation begins with animal ownership and ends when the animal expires and/or leaves the facility.)

Final Disposition **Temporary**

Item Status **Active**

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 Mangement System (ARIMS)
AR 40-33	THE CARE AND USE OF LABORATORY ANIMALS IN DOD PROGRAMS

Disposition Instruction

Cutoff Instruction **KE3. Event is 3 years after disposition of the animal. Keep in CFA until event occurs, then destroy, unless otherwise stated in the protocol. Digitization is authorized unless prohibited by the government agency. Destroy the record in the CFA 3 years after disposition of the animal.**

Retention Period **Destroy 3 year(s) after disposition of the animal.**

Additional Information

GAO Approval **Not Required**

Institutional Animal Care and Use Committee (IACUC) Records/ RN 40-33c/1200B-06

Disposition Authority Number **DAA-AU-2015-0032-0003**

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The protocol provides the processes and procedures which become the approved test plan framework for the study. These are not records of the actual investigation, but of the processes signed as approved by the IACUC Committee. Each process for handling the laboratory animals during a scientific investigation is summarized. Legal and ethical issues regarding animal handling are addressed. There are often additional amendments, such as a change of animal species, a change in dosage or a change in research team leadership. Every procedure used as part of the investigations must have an approved protocol or approved protocol amendment. As described here, the protocol file includes the IACUC approved version of the protocol, documentation of IACUC approval, and all amendments and continuing reviews conducted throughout the life of the protocol. Also considered, IACUC records are administrative files supporting oversight of the animal care and use program. This includes IACUC meeting minutes, IACUC policies, semi-annual facility inspections, program review reports, investigative documents related to adverse events, animal welfare concerns and reports on animal usage.

Final Disposition Temporary

Item Status Active

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)
AR 40-33	THE CARE AND USE OF LABORATORY ANIMALS IN DOD PROGRAMS;

Disposition Instruction

Cutoff Instruction KE3. Event is 3 years after expiration or completion of protocol. Keep in the CFA until event occurs, then destroy. Digitization is authorized unless prohibited by the government agency.

Retention Period Destroy 3 year(s) after expiration or completion of protocol.

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
06/08/2015	Certify	Shirley KinsonJones	Management Analyst	Army - Records Management and Declassification Agency
04/07/2016	Submit for Concurrence	Sebastian Welch	Appraiser	National Archives and Records Administration - Records Management Services
04/14/2016	Concur	Margaret Hawkins	Director of Records Management Services	National Records Management Program - ACNR Records Management Services
04/14/2016	Concur	Laurence Brewer	Director, National Records Management Program	National Archives and Records Administration - National Records Management Program
04/17/2016	Approve	David Ferriero	Archivist of the United States	Office of the Archivist - Office of the Archivist