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**To: Institutional Animal Care and Use (IACUC) Directors and Attending Veterinarians**

**Subject: Revision of Record Retention Guidelines for Institutional Animal Care and Use Committee (IACUC) Records and Animal Health Records**

This memo is issued to document the guidance set forth by the Research Policy Analysis and Coordination (RPAC) Office regarding the Record Retention Guidelines for Institutional Animal Care and Use Committee (IACUC) Records and Animal Health Records. This guidance is being issued via a June 2010 update to a document entitled “Administrative Records Relating to Research: Retention and Disposition Requirements” and posted to the web at the following url: [http://www.ucop.edu/research/policies/documents/retention\\_disposition\\_reqs.pdf](http://www.ucop.edu/research/policies/documents/retention_disposition_reqs.pdf)

The June 2010 update memorialized by this RPAC Operating Guidance Memo pertains only to IACUC Records and Animal Health Records, and does not amend or revise other records retention guidelines in the “Administrative Records Relating to Research: Retention and Disposition Requirements” document.

The June 2010 update makes the following changes:

- With respect to IACUC Records, the updated document clarifies that in interpreting the existing regulations (which require that records relating to ongoing activities shall be maintained for the duration of the activity and for an additional three years), UC will follow the 2010 guidance issued by the California Biomedical Research Association (CBRA) specifying that “activity” be interpreted as “protocol.”
- Adds a new section relating to Animal Health Records (also referencing CBRA guidance).

Though the web site referenced above is the best way to access the most updated version of the UC Records Retention Guidelines, a copy of the June, 2010 revision to those sections that relate to IACUC records and Animal Health Records is attached to this memo, for documentation and archiving purposes. Also attached are copies of the two CBRA guidance documents referenced in the updated UC Records Retention Guidelines: “Guidelines for Records Retention for Protocols Operating Under NIH Grants,” and “Guidelines for Record Retention Requirements Under the AWA,” both issued in 2010 by the California Biomedical Research Association as Compliance Support and Guidance documents.

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**See Window Below for Attachments**

Attachments: 1) [Administrative Records Relating to Research: Retention and Disposition Requirements](#), 2) [Guidelines for Record Retention For Protocols Operating Under NIH Grants](#), 3) [Guidelines for Record Retention Requirements Under the AWA](#)



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**JUNE 2010 update** to the sections of the University of California “Administrative Records Relating to Research: Retention and Disposition Requirements” relating to IACUC Records and Animal Health Records (For full document, see: [http://www.ucop.edu/research/policies/documents/retention\\_disposition\\_reqs.pdf](http://www.ucop.edu/research/policies/documents/retention_disposition_reqs.pdf)).

**IACUC Records Retention Guidance**  
**INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC) RECORDS**

<b>Record</b>	<b>Retention Period</b>	<b>Primary Source/ Secondary Source</b>
IACUC Records: Minutes	At least 3 years (Records that relate to ongoing activities shall be maintained for the duration of the activity* and for an additional three years)	<b>Animal Welfare Act</b> <b>9 CFR 2.35</b> NIH Institutional Animal Care and Use Committee Guidebook – p. 174 UC Contracts and Grants Manual Chapter 18-465
IACUC Records: Records of attendance	At least 3 years (Records that relate to ongoing activities shall be maintained for the duration of the activity* and for an additional three years)	<b>Animal Welfare Act</b> <b>9 CFR 2.35</b> NIH Institutional Animal Care and Use Committee Guidebook – p. 174 UC Contracts and Grants Manual Chapter 18-465
IACUC Records: Activities of the committee	At least 3 years (Records that relate to ongoing activities shall be maintained for the duration of the activity* and for an additional three years)	<b>Animal Welfare Act</b> <b>9 CFR 2.35</b> NIH Institutional Animal Care and Use Committee Guidebook – p. 174 UC Contracts and Grants Manual Chapter 18-465
IACUC Records: Committee deliberations	At least 3 years (Records that relate to ongoing activities shall be maintained for the duration of the activity* and for an additional three years)	<b>Animal Welfare Act</b> <b>9 CFR 2.35</b> NIH Institutional Animal Care and Use Committee Guidebook – p. 174 UC Contracts and Grants Manual Chapter 18-465
IACUC Records: Applications	At least 3 years (Records that relate to ongoing activities shall be maintained for the duration of the activity* and for an additional three years)	<b>NIH Institutional Animal Care and Use Committee Guidebook – p. 174</b> UC Contracts and Grants Manual Chapter 18-465
IACUC Records: Proposed activities involving animals (including documentation of IACUC approval / denial)	At least 3 years (Records that relate to ongoing activities shall be maintained for the duration of the activity and for an additional three years)	<b>Animal Welfare Act</b> <b>9 CFR 2.35</b> NIH Institutional Animal Care and Use Committee Guidebook – p. 174 UC Contracts and Grants Manual Chapter 18-465
IACUC Records: Proposed activities involving animals (including documentation of IACUC approval / denial, minutes, semi-annual inspections, and research records associated with the protocol.)	At least 3 years (Records that relate to ongoing activities shall be maintained for the duration of the activity* and for an additional three years)	<b>Animal Welfare Act</b> <b>9 CFR 2.35</b> -UC Contracts and Grants Manual Chapter 18-465 -NIH Institutional Animal Care and Use Committee Guidebook – p. 174 -PHS Policy IV.E.2. -USDA-approved CBRA Guidelines for Record Retention For Protocols Operating Under NIH Grants

<p><b>(NEW) Animal Health Records:</b> Health records associated with an animal needed to convey necessary information to all those involved in the animal's care, in contemplating utilizing these animals in research, and to share with regulatory agencies responsible for verifying the appropriate provision of veterinary care.</p>	<p>For NIH-funded research: At least 3 years after completion of the activity*. (For protocols operating on an NIH grant, all <i>relevant animal records</i> should be maintained as a unit with the associated IACUC protocol and records, and share the same destroy date.)</p> <p>Regardless of funding source: For USDA-covered species, throughout an animal's life and at least one year after the animal's death.</p>	<p><b>USDA-approved CBRA Guidelines for Record Retention For Protocols Operating Under NIH Grants (June 2010)</b>  <b>CBRA Guidelines for Record Retention Requirements Under the AWA (June 2010)</b>          -NIH Institutional Animal Care and Use Committee Guidebook – p. 174          -UC Contracts and Grants Manual Chapter 18-465</p>
<p>IACUC Records: Proposed significant changes in activities involving animals (including documentation of IACUC approval / denial)</p>	<p>At least 3 years (Records that relate to ongoing activities shall be maintained for the duration of the activity* and for an additional three years)</p>	<p><b>Animal Welfare Act 9 CFR 2.35</b>          - NIH Institutional Animal Care and Use Committee Guidebook – p. 174          UC Contracts and Grants Manual Chapter 18-465</p>
<p>IACUC Records: Information as specified on any live dog or cat acquired, purchased or otherwise held</p>	<p>At least 3 years (Records that relate to ongoing activities shall be maintained for the duration of the activity* and for an additional three years)</p>	<p><b>Animal Welfare Act 9 CFR 2.35 NIH Institutional Animal Care and Use Committee Guidebook – p. 174</b></p>
<p>IACUC Records: Information as specified on any dog or cat sold, euthanized or otherwise disposed of</p>	<p>At least 3 years (Records that relate to ongoing activities shall be maintained for the duration of the activity* and for an additional three years)</p>	<p><b>Animal Welfare Act 9 CFR 2.35 NIH Institutional Animal Care and Use Committee Guidebook – p. 174</b></p>
<p>IACUC Records: Semi-Annual IACUC reports and recommendations</p>	<p>At least 3 years (Records that relate to ongoing activities shall be maintained for the duration of the activity* and for an additional three years)</p>	<p><b>Animal Welfare Act 9 CFR 2.35 NIH Institutional Animal Care and Use Committee Guidebook – p. 174</b></p>
<p>IACUC Records: Any reports and recommendations as forwarded to the institutional official</p>	<p>At least 3 years (Records that relate to ongoing activities shall be maintained for the duration of the activity* and for an additional three years)</p>	<p><b>UC Contracts and Grants Manual Chapter 18-465</b></p>
<p>IACUC Records: Records of accrediting body determinations</p>	<p>At least 3 years (Records that relate to ongoing activities shall be maintained for the duration of the activity* and for an additional three years)</p>	<p><b>UC Contracts and Grants Manual Chapter 18-465 NIH Institutional Animal Care and Use Committee Guidebook – p. 1</b></p>

*\*In accordance with the June 2010 Guidance issued by the California Biomedical Research Association, UC will interpret "activity" as protocol. Thus, the retention period is at least 3 years from the protocol's end date or termination, whichever later occurs. (If the initial protocol approval is followed by a de novo review and approval, this does not change the paperwork retention time frame associated with the initial protocol. Specifically, the initial protocol needs to be retained for only 3 years following the end-date of the initial protocol, as indicated in the approval, regardless of subsequent de novo review and approval. )*

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# Guidelines for Record Retention For Protocols Operating Under NIH Grants

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## 1. Purpose

The purpose of this SOP is to provide guidance and insight into the requirements for IACUC record retention for protocols operating on NIH grants, and under PHS Policies, and subject to the oversight and standards of the Office of Laboratory Animal Welfare, NIH. The recommendations in this document are consistent with OLAW guidance.

## 2. Retention of IACUC Paperwork and Protocols

PHS Policy states that “all records shall be maintained for at least three years; records that relate directly to applications, proposals, and proposed significant changes in ongoing activities reviewed and approved by the IACUC shall be maintained for the duration of the activity and for an additional three years after completion of the activity. All records shall be accessible for inspection and copying by authorized OLAW or other PHS representatives at reasonable times and in a reasonable manner.” (PHS Policy IV.E.2.)

PHS Policy also specifies that *relevant animal records* need to be held for three years after completion of the activity (the protocol on which the animal was active).

The “clock” on this three-year retention period begins on the end-date as indicated in the approved protocol or at the termination of a protocol. The IACUC minutes, semi-annual inspections and evaluations, and research records that are associated with this protocol can likewise be discarded three years after the end-date/termination of the protocol.<sup>1</sup>

If the initial IACUC protocol approval is followed three years later by a de novo review and approval, this **does not** change the paperwork retention time frame associated with the **initial** protocol. Specifically, the initial protocol only needs to be retained for three-years following the end-date of the initial protocol, as indicated in the approval, regardless of subsequent de novo review and approval. The retention clock for the subsequent de novo review and approval begins at the end-date/termination date indicated in **this** approved protocol, and is also for three years.

### Examples

- A. An IACUC protocol (#20001) was approved on Jan. 4, 2000, and three years later (Jan. 4, 2003) it was followed by a de novo review and approval (IACUC protocol #20001A) with an end date of Jan. 4, 2006.

All paperwork associated with initial protocol (#20001) can be discarded three years after it ends, even though the protocol was re-newed. (Specifically, three years **after** #20001A was approved). #20001 has a destroy date then of Jan. 5, 2006. The IACUC minutes, semi-annual inspections and evaluations, and any research records that are associated with #20001 can be discarded on Jan. 5, 2006 as well.

The subsequent protocol (#20001A) can be discarded three years after it ends on Jan. 4,

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<sup>1</sup> In regard to hand-written notes such as IACUC minutes, notes from an investigation or inspection, etc., if there is a transcribed document (typed or computer generated) that covers what is in the hand-written notes, there is no need to keep the original hand-written notes past the moment of transcription.

2006 . Specifically, a destroy date of Jan. 5, 2009). The IACUC minutes, semi-annual inspections and evaluations, and any research records that are associated with #20001A can be discarded at this as well.

- B. An IACUC protocol (#200309) was approved on Sept. 10, 2003, followed two-year years later by termination (on Oct. 1, 2005) because all animal procedures were complete.

The paperwork associated with protocol #200309 can be discarded three years after its termination (Destroy Date – Oct 2, 2008). The IACUC minutes, semi-annual inspections, evaluations, and research records that are associated with #200309 can be discarded at the same time.

### **3. Retention of Animal Health Records**

The health records associated with an animal are needed to convey necessary information to all those involved in the animal's care, in contemplating utilizing these animals in research, and to share with the regulatory agencies that are responsible for verifying the appropriate provision of veterinary care.

The USDA recommends that health records for USDA-covered species be maintained throughout an animal's life, and for at least one year after the animal's death.

PHS Policy specifies that *relevant animal records* need to be held for three years after completion of the activity (the protocol on which the animal was active). In the majority of cases, this will *exceed* the above one-year minimum recommended retention period.

In practice, for protocols operating on an NIH grant, all *relevant animal records* should be maintained as a unit with the associated IACUC protocol and records, and share the same destroy date.

# Guidelines for Record Retention Requirements Under the AWA

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## 1. Purpose

The purpose of this SOP is to provide guidance and insight into the requirements for record retention under the Animal Welfare Act (AWA), and to convey the standards and expectations of the USDA, APHIS.<sup>1</sup>

## 2. General Information

Records retention policies vary among federal agencies, and from research facility to facility. A standardized retention policy across research facilities is advantageous to all, both for practicality and perception. It ensures ease of regulatory compliance, and will assist facilities in refuting any future accusations by animal extremist groups that facilities are destroying “evidence” when they are, in fact, acting in accordance with industry standards and with federal policies and regulations.

## 3. Retention of IACUC Paperwork and Protocols

The AWA requires a three-year retention policy for IACUC paperwork, proposals, etc. The “clock” on this three-year retention period begins on the end-date as indicated in the approved protocol or at the termination of a protocol. The IACUC minutes, semi-annual inspections and evaluations, and research records that are associated with this protocol can likewise be discarded three years after the end-date/termination of the protocol.<sup>2</sup>

If the initial IACUC protocol approval is followed three years later by a de novo review and approval, this **does not** change the paperwork retention time frame associated with the *initial* protocol. Specifically, the initial protocol only needs to be retained for three-years following the end-date of the initial protocol, as indicated in the approval, regardless of subsequent de novo review and approval. The retention clock for the subsequent de novo review and approval begins at the end-date/termination date indicated in **this** approved protocol, and is also for three years.

### Examples

- A. An IACUC protocol (#20001) was approved on Jan. 4, 2000, and three years later (Jan. 4, 2003) it was followed by a de novo review and approval (IACUC protocol #20001A) with an end date of Jan. 4, 2006.

All paperwork associated with initial protocol (#20001) can be discarded three years after it ends, even though the protocol was re-newed. (Specifically, three years **after** #20001A was approved). #20001 has a destroy date then of Jan. 5, 2006. The IACUC minutes, semi-annual inspections and evaluations, and any research records that are associated with #20001 can be discarded on Jan. 5, 2006 as well.

The subsequent protocol (#20001A) can be discarded three years after it ends on Jan. 4, 2006. Specifically, a destroy date of Jan. 5, 2009). The IACUC minutes, semi-annual

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<sup>1</sup> This SOP has been reviewed and approved by the USDA

<sup>2</sup> In regard to hand-written notes such as IACUC minutes, notes from an investigation or inspection, etc., if there is a transcribed document (typed or computer generated) that covers what is in the hand-written notes, there is no need to keep the original hand-written notes past the moment of transcription.

inspections and evaluations, and any research records that are associated with #20001A can be discarded at this as well.

- B. An IACUC protocol (#200309) was approved on Sept. 10, 2003, followed two-year years later by termination (on Oct. 1, 2005) because all animal procedures were complete.

The paperwork associated with protocol #200309 can be discarded three years after its termination (Destroy Date – Oct 2, 2008). The IACUC minutes, semi-annual inspections, evaluations, and research records that are associated with #200309 can be discarded at the same time.

#### **4. Retention of Health Records**

The health records associated with animals are needed to convey necessary information to all those involved in the animal's care, in contemplating utilizing these animals in research, and to share with the regulatory agencies that are responsible for verifying the appropriate provision of veterinary care.

While there are no specific paperwork retention requirements regarding animal health records (the records retention requirements under Section 2.35 do not apply here), every research facility should have a system of retention and maintenance of such health records so that they are comprehensive and adequate to demonstrate both the delivery of adequate health care, and to create the much needed overview of the animal's overall health thought-out its life.

The USDA, APHIS recommends that health records be maintained throughout an animal's life, and for at least one year after the animal's death.