

THE 2012 ANNUAL REPORT TO OLAW

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PHS Policy Reporting Requirements

Annual Reporting is required of each institution with an approved Assurance

PHS Policy Part IV.F.

Reporting Periods:

Calendar Year vs. Non-Calendar Year

Due dates:

- Calendar year due to OLAW by January 31st
- Non-calendar year due to OLAW 30 days past the end of the 12 month reporting period

PHS Policy Reporting Requirements (Part IV.F.)

1. At least once every 12 months, the IACUC, through the Institutional Official, shall report in writing to OLAW:
 - a. any change in the institution's program or facilities which would place the institution in a different category than specified in its Assurance (see IV.A.2. of this Policy);
 - b. any change in the description of the institution's program for animal care and use as required by IV.A.1.a.– i. of this Policy;

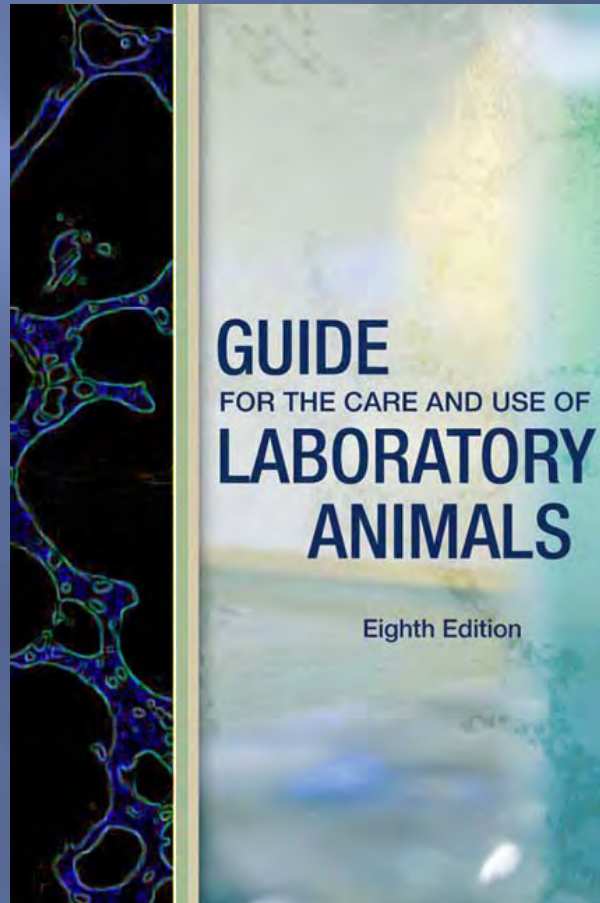
PHS Policy Reporting Requirements (Part IV.F.) cont

- c. any changes in the IACUC membership; and
- d. notice of the dates that the IACUC conducted its semiannual evaluations of the institution's program and facilities and submitted the evaluations to the Institutional Official.

PHS Policy Reporting Requirements (Part IV.F.) cont

2. At least once every 12 months, the IACUC, at an institution which has no changes to report as specified in IV.F.1.a.–c. of this Policy, shall report to OLAW in writing, through the Institutional Official, that there are no changes and inform OLAW of the dates of the required IACUC evaluations and submissions to the Institutional Official.

Adoption of the *Guide*



<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-12-020.html>

Guide Implementation

By December 31, 2012, Assured institutions must:

- Complete at least one semiannual program review using 8th Edition
- Develop reasonable plan and schedule
- All changes need not be completed, but plan and schedule must be in place

Guide Implementation

- Institutions must verify to OLAW in their 2012 annual report that they have met the required schedule for implementation of the *Guide*
- Sample annual report has added statements and check boxes to allow easy verification

2012 Annual Report

- An updated annual report sample document for 2012 is available on the OLAW website
- The annual report must be signed and dated by the Institutional Official and the IACUC Chair

Completing the Annual Report

- Download the sample document from the OLAW website at <http://grants.nih.gov/grants/olaw/sampledoc/report.htm>
- Complete the report
- Print the completed document
- Obtain signatures
- Scan to PDF
- Submit via e-mail olawarp@mail.nih.gov

2012 Annual Report

Annual Report to OLAW

Institution:
Assurance Number:
Reporting Period:

This institution's Institutional Animal Care and Use Committee (IACUC), through the Institutional Official, provides this annual report to the Office of Laboratory Animal Welfare (OLAW).

2012 Annual Report Requirement: Verification of implementation of the 8th Edition of the *Guide for the Care and Use of Laboratory Animals (Guide)*

[Effective January 1, 2012, NIH required Assured institutions to base their animal care and use programs on the standards of the 8th Edition of the Guide. Assured institutions must complete at least one (of the two required) semiannual program review and facility inspection using the 8th Edition of the Guide as the basis for evaluation by December 31, 2012. It is not required that all necessary changes be completed by December 31, 2012, but rather that an evaluation must be conducted and a plan and schedule for implementation of the standards in the 8th Edition of the Guide must be developed by December 31, 2012. See [NOT-OD-12-020](#)]

2012 Annual Report cont

Implementation of the 8th Edition of the *Guide* [*Select A or B*]

- ☐ A. This institution has fully implemented the standards of the 8th Edition of the *Guide*. [*Skip to Item I.*]
- ☐ B. This institution has not completed all the necessary changes to fully implement the standards of the 8th Edition of the *Guide*.

An evaluation was conducted and a plan and schedule for implementing the 8th Edition of the *Guide* was developed by December 31, 2012. [*Select Yes or No*]

☐ Yes

☐ No: [*Provide a paragraph describing the reason(s) for the delay and how the institution will meet this requirement, but do not attach a plan and schedule.*]

2012 Annual Report Part I.

I. Program Changes *[Select A or B]*

- ☐ A. There have been **no changes** in this institution's program for animal care and use as described in the Assurance. *[Skip to Item II.]*
- ☐ B. Change(s) in this institution's program for animal care and use as described in the Assurance have occurred during this reporting period. ([FAQ 6](#))

Select all that apply:

- ☐ This institution's AAALAC accreditation status has changed ([PHS Policy IV.A.2.](#)).
 - ☐ [AAALAC Accredited](#) – Category 1
 - ☐ Non-Accredited – Category 2
- ☐ This institution's program for animal care and use has changed ([PHS Policy IV.A.1.a-i.](#)). *[Attach a full description of the changes.]*
- ☐ The individual designated by this institution as the Institutional Official has changed. *[Provide name, title(s), address, e-mail, phone, and fax numbers in Item V.]*

- ☐ The membership of this institution's IACUC has changed. *[Provide current roster of members in Item VI.]*

What to Report: Changes in the Animal Care and Use Program

- Changes to the animal care and use program as described in the Animal Welfare Assurance
- Change in the lines of authority or administrative reporting channels
- Modification of IACUC procedures (Part III.D. of the sample Assurance)
- Modifications to the occupational health or training programs

What to Report: Changes in the Animal Care and Use Program cont

- Change in the veterinarian
- Change in the veterinarian's authority or responsibility
- Changes in buildings, species, or approximate numbers of animal housed

2012 Annual Report Part II.

II. Semiannual Evaluations

This IACUC has conducted semiannual evaluations of the institution's program and inspections of the institution's facilities (including satellite facilities) on the dates below. Reports of the evaluations and inspections have been submitted to the Institutional Official. The reports include any IACUC-approved departures from the *Guide* with a reason for each departure, any deficiencies (significant or minor) that were identified, and a plan and schedule for correction of each deficiency. *[Do not provide semiannual reports unless they include a minority view.]*

A. Program Evaluations

[Two dates (month/day/year) must be provided to satisfy the PHS Policy requirement that evaluations be done at 6 month intervals. If the IACUC conducted more than 2 evaluations of the program during the reporting period, please attach a list showing the dates. Institutions must use the 8th Edition of the Guide as the basis for evaluation for at least one (of the two required) semiannual program review.]

Date 1:	Date 2:
Guide used: [Select one] <input type="checkbox"/> 7 th Edition <input type="checkbox"/> 8 th Edition	Guide used: [Select one] <input type="checkbox"/> 7 th Edition <input type="checkbox"/> 8 th Edition
Method used: [Select all that apply] <input type="checkbox"/> OLAW Checklist <input type="checkbox"/> Relevant <i>Guide</i> Chapter headings <input type="checkbox"/> Other: [Briefly describe] _____ _____	Method used: [Select all that apply] <input type="checkbox"/> OLAW Checklist <input type="checkbox"/> Relevant <i>Guide</i> Chapter headings <input type="checkbox"/> Other: [Briefly describe] _____ _____

2012 Annual Report Part II. cont

B. Facility Inspections

[Two dates (month/day/year) must be provided to satisfy the PHS Policy requirement that facility inspections be done at 6 month intervals. If the IACUC conducted more than 2 inspections of each site during the reporting period, please attach a list showing the dates. Institutions must use the 8th Edition of the Guide as the basis for evaluation for at least one (of the two required) semiannual facility inspection.]

Date 1:	Date 2:
Guide used: [Select one] <input type="checkbox"/> 7 th Edition <input type="checkbox"/> 8 th Edition	Guide used: [Select one] <input type="checkbox"/> 7 th Edition <input type="checkbox"/> 8 th Edition
Method used: [Select all that apply] <input type="checkbox"/> OLAW Checklist <input type="checkbox"/> Relevant <i>Guide</i> Chapter headings <input type="checkbox"/> Other: [Briefly describe] _____ _____	Method used: [Select all that apply] <input type="checkbox"/> OLAW Checklist <input type="checkbox"/> Relevant <i>Guide</i> Chapter headings <input type="checkbox"/> Other: [Briefly describe] _____ _____

2012 Annual Report Part III.

III. **Minority Views** [*Select A or B*]

- ☐ A. There were **no minority** views during this reporting cycle.
- ☐ B. Any minority views submitted by members of the IACUC regarding reports filed under [PHS Policy IV.F.](#) for this reporting cycle are attached.

2012 Annual Report Part IV., V.

IV. Signatures

IACUC Chairperson	Institutional Official
Name:	Name:
Signature:	Signature:
Date:	Date:

V. Change in Institutional Official

Name:	
Title:	Degree/Credential:
Address: [<i>street, city, state, zip code</i>]	
E-mail:	
Phone:	Fax:

What to Report: Change in the IO

- Please provide:
 - Name, title, degree/credentials
 - Mailing address
 - Telephone number
 - Fax number
 - E-mail address

2012 Annual Report Part VI.

VI. Change in IACUC Membership [*Current roster*]

Institution:

IACUC Contact Information

Address: [*street, city, state, zip code*]

E-mail:

Phone:

Fax:

What to Report: IACUC Office Contact

Please provide IACUC office contact information:

- IACUC office mailing address
- IACUC office telephone number
- IACUC office fax number
- IACUC office e-mail address

NOT information for the IACUC Chair

2012 Annual Report Part VI. cont

VI. Change in IACUC Membership [*Current roster*]

Institution:	
IACUC Contact Information	
Address: [<i>street, city, state, zip code</i>]	
E-mail:	
Phone:	Fax:
IACUC Chairperson	
Name:	
Title:	Degree/Credentials:

2012 Annual Report Part VI. cont

PHS Policy Membership Requirements***:			
IACUC Roster [<i>Provide below or attach</i>]			
Name of Member/ Code*	Degree/ Credentials	Position Title**	PHS Policy Membership Requirements***

2012 Annual Report Part VI. cont

* Names of members, other than the chairperson and veterinarian, may be represented by a number or symbol in this report to OLAW. Sufficient information to determine that all appointees are appropriately qualified must be provided and the identity of each member must be readily ascertainable by the institution and available to authorized OLAW or other PHS representatives upon request.

** List specific position titles for all members, including nonaffiliated (e.g., banker, teacher, volunteer fireman; not "community member" or "retired").

*** [PHS Policy](#) Membership Requirements:

<i>Veterinarian</i>	veterinarian with training or experience in laboratory animal science and medicine or in the use of the species at the institution, who has direct or delegated program authority and responsibility for activities involving animals at the institution.
<i>Scientist</i>	practicing scientist experienced in research involving animals.
<i>Nonscientist</i>	member whose primary concerns are in a nonscientific area (for example, ethicist, lawyer, member of the clergy).
<i>Nonaffiliated</i>	individual who is not affiliated with the institution in any way other than as a member of the IACUC, and is not a member of the immediate family of a person who is affiliated with the institution. This member is expected to represent general community interests in the proper care and use of animals and should not be a laboratory animal user. A consulting veterinarian may not be considered nonaffiliated.

[Note: all members must be appointed by the CEO (or individual with specific written delegation to appoint members) and must be voting members. Non-voting members and alternate members must be so identified.]

Submitting the Annual Report

- Convert the signed annual report to a PDF document
- E-mail the report to:
olawarp@mail.nih.gov
- No online submission for the 2012 report
- Do not FAX
- Do NOT send hard copy (US Mail, FedEx, etc.)

Please send questions
to OLAW via the
question box on your screen



Question 1

Our last report covered the non calendar year ending March 31, 2012, and we were informed that our next report was due by April 30, 2013. More recently, we received an e-mail stating that the due date for all annual reports was January 31, 2013.

Could you clarify which of those two dates applies to our institution?

Question 2

Does the institution have to submit an annual report if they have recently renewed their Animal Welfare Assurance?

Question 3

If there are programmatic changes after the annual report has been submitted to OLAW, how should the institution report these?

Question 4

For the semiannual program review and facility inspections, does the institution have to list all of the facilities and the dates they were inspected?

Question 5

If the inspections are performed throughout the six-month period, does the report have to identify which facilities were reviewed at which times?

Question 6

What happens if the semiannual dates are more than six months apart?

Question 7

Can we submit the annual report prior to December 31?

Question 8

What if the annual report is submitted late?

Question 9

What is considered noncompliance regarding information contained in the annual report?

Question 10

Do the minority views need to be explained in the annual report, or just report the dates?

Question 11

Is a “no” vote by a member when the IACUC is voting on acceptance of a protocol a minority view?

Question 12

What if the IO is not available to sign the annual report?

Question 13

What if the Chair is not available to sign the annual report?

Question 14

If a new program component is added, and it's not AAALAC accredited, does that change the status of the institution from category one to category two?

Question 15

If we open a new building that becomes part of our existing AAALAC accredited animal program, does this change our category designation?

Question 16

Should changes in the Assurance be reported in the annual report or as they occur?

Question 17

In preparing our OLAW annual report we have identified some major changes that have occurred in our program including:

- an updated PI and IACUC member training policy
- a newly developed occupational health and safety program
- new IACUC members

Is it correct that we include these major changes in our upcoming annual report?

Question 18

The following changes do not alter our animal program as much as they change the mechanism used to comply with the requirements. Do we need to include these in our upcoming annual report?

- Creating a new subcommittee of the IACUC to follow up on animal use concerns
- Adding the harm/benefit analysis of animal use in research during our protocol review
- Correcting a sentence in our Assurance concerning how we conduct Designated Member Review.

Question 19

If an institution had to make tons of program changes to implement the standards of the new *Guide*, how much info should they report?

The instructions under program changes indicate: “This institution’s program for animal care and use has changed (PHS Policy IV.A.1.a–i.). [Attach a full description of the changes.]”

Question 20

Can you please clarify the species change notification requirement? What kind of changes are we talking about?

Question 21

Our IACUC has created a policy to use designated member review subsequent to full committee review in our IACUC review process. Should we report this as a program change in our annual report?

Question 22

Should Interinstitutional Assurances approved by OLAW be included in the annual report?

Question 23

If our Assurance has substantially changed, but is not due for renewal for two years, would OLAW prefer to receive the changes via the annual report or a completely new Assurance?

Question 24

Since our programs have been updated to implement the *Guide* 8th Edition and the OLAW Sample Animal Welfare Assurance was revised earlier this year, is it expected that we submit an updated Assurance for approval?

Question 25

We have a disaster plan completed but the IACUC has not yet completed reviewing the document and may require more revisions. How should this be reported?

Question 26

You have mentioned that our institution should have a reasonable plan and schedule for implementing the changes that are required to meet the *Guide* 8th Edition standards. What does OLAW consider a reasonable plan and schedule?

Question 27

Our agreements with collaborating institutions are being written but since this requires both IACUCs to review the changes it has taken longer than expected and we do not have them completed. How do we report this?

Question 28

It is my understanding that if an institution has undergone an AAALAC site visit during the year – that it would suffice for the annual report. Is this correct?

Question 29

If our PHS Assurance is being evaluated for renewal, would the renewal Assurance document complete the requirements of the annual report?

Question 30

Are the completed annual reports to OLAW posted online or available via FOIA?

Question 31

Can you clarify the requirements for the IACUC Chair and members' addresses, phone numbers, et cetera?

Do those need to be reported if it is not the address and phone number for the IO or the IACUC Office?

Question 32

What if the IACUC office does not have an e-mail address?

Question 33

Is e-mail submission of a PDF document the only accepted method this year?

Question 34

Does OLAW recognize the category of non-voting member of an IACUC and if so what responsibilities could such a member have?

Question 35

Do minority views of nonvoting members of the IACUC need to be provided in the annual report?

Question 36

Do nonvoting IACUC members need to sign the **semiannual** report?

Question 37

If the AAALAC site visit doesn't coincide with our semiannual inspection date, will it still be acceptable as one of our inspections?

Question 38

If we are not required to list IACUC member names, how does OLAW track and review the IACUC members?

Question 39

What's the earliest date that annual reports can be submitted?

Question 40

What protects IACUC members from having their contact information used by animal activist organizations?

Question 41

What does OLAW do with the annual reports?

Upcoming Webinars

Disaster Planning

Stephen Durkee

March 7, 2013

Training Issues

Sara Munro

June 20, 2013