

# THE 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 31<sup>st</sup>
- 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.

# The Sample Annual Report

- The annual report sample document 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](mailto:olawarp@mail.nih.gov)



# The 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).

# 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 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

# 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.]*

Date 1:	Date 2:
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# 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.]*

Date 1:	Date 2:
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# 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.

# Annual Report Part IV.

## IV. Signatures

<b>IACUC Chairperson</b>	<b>Institutional Official</b>
Name:	Name:
Signature:	Signature:
Date:	Date:

# Annual Report Part V.

## V. Change in Institutional Official

Name:	
Title:	Degree/Credential:
Name of Institution:	
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



# 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

# Annual Report Part VI. cont.

<b>IACUC Chairperson</b>	
Name:	
Title:	Degree/Credentials:
PHS Policy Membership Requirements <sup>***</sup> :	

# Annual Report Part VI. cont.

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

# 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.



# Annual Report Part VI. cont.

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

# Annual Report Part VI. cont.

\*\*\* PHS Policy Membership Requirements:

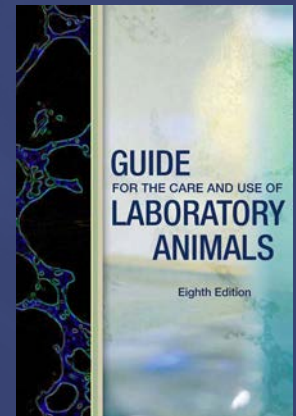
- Veterinarian*      veterinarian with training or experience in laboratory animal science and medicine or in the use of the species at the institution, who has direct or delegated program authority and responsibility for activities involving animals at the institution.
- Scientist*            practicing scientist experienced in research involving animals.
- Nonscientist*        member whose primary concerns are in a nonscientific area (for example, ethicist, lawyer, member of the clergy).
- Nonaffiliated*       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.

# Submitting the Annual Report

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

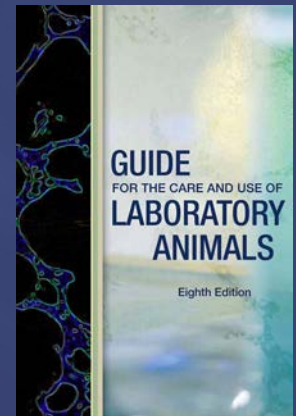
# 2012 Implementation of the *Guide*

- Complete at least one semiannual program review using 8th Edition & develop reasonable plan and schedule
- Verify in 2012 Annual Report that the *Guide* was implemented
- 2012 Annual Report included statements and check boxes to allow verification



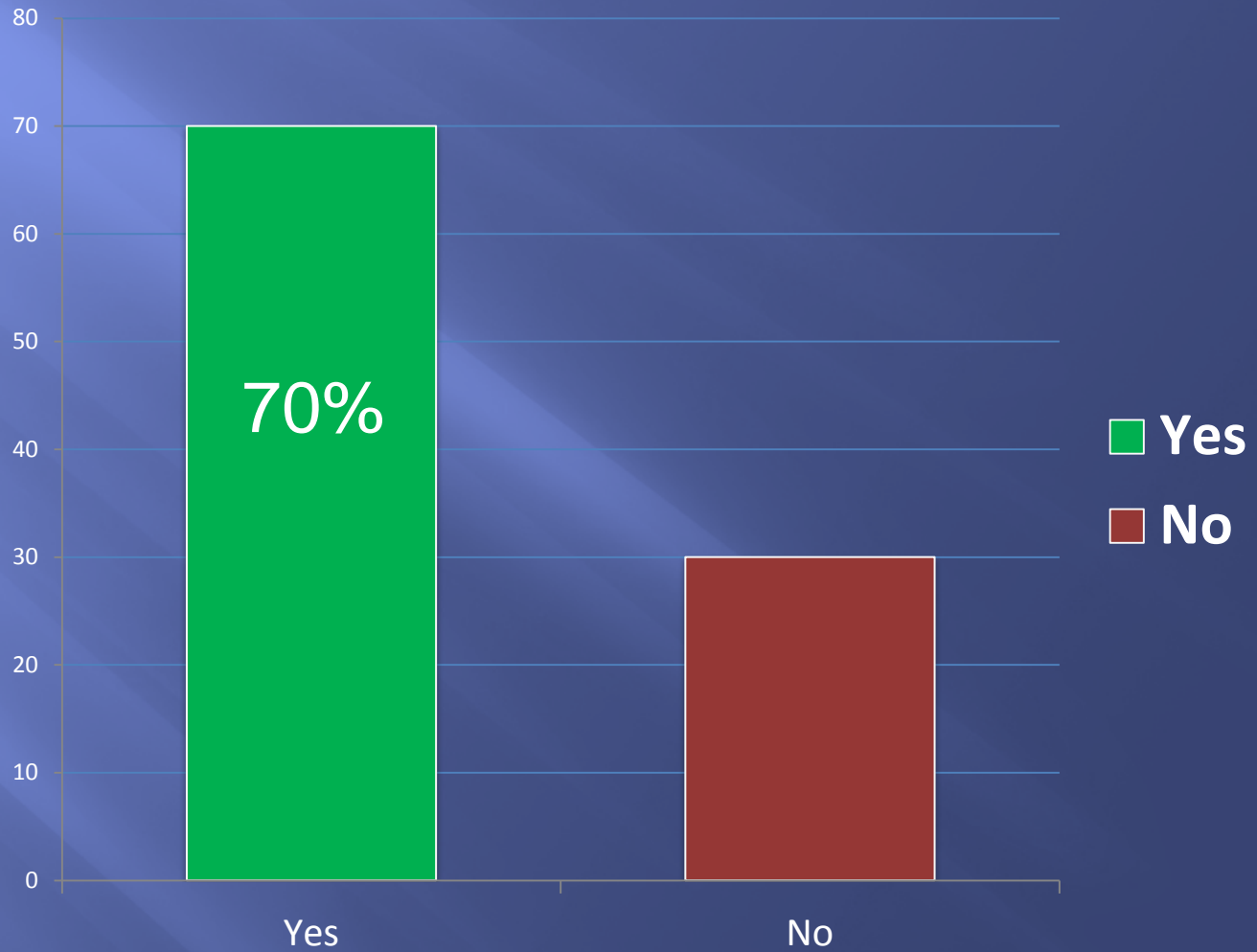
# Analysis of *Guide* Implementation

- Reviewed responses from over 1000 annual reports
- 98.5 % of the responses were complete in all sections of the report



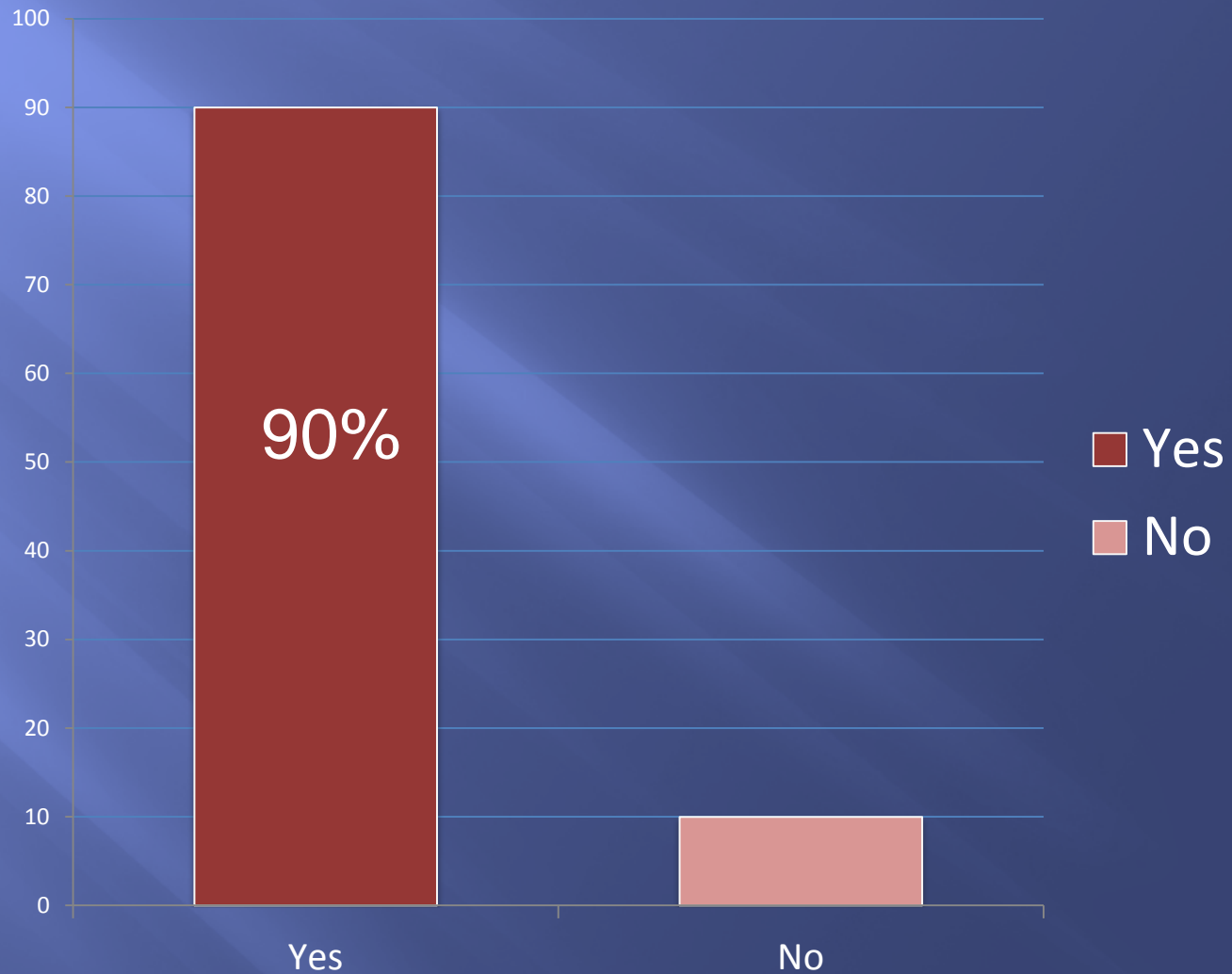


# Implementation of the *Guide*

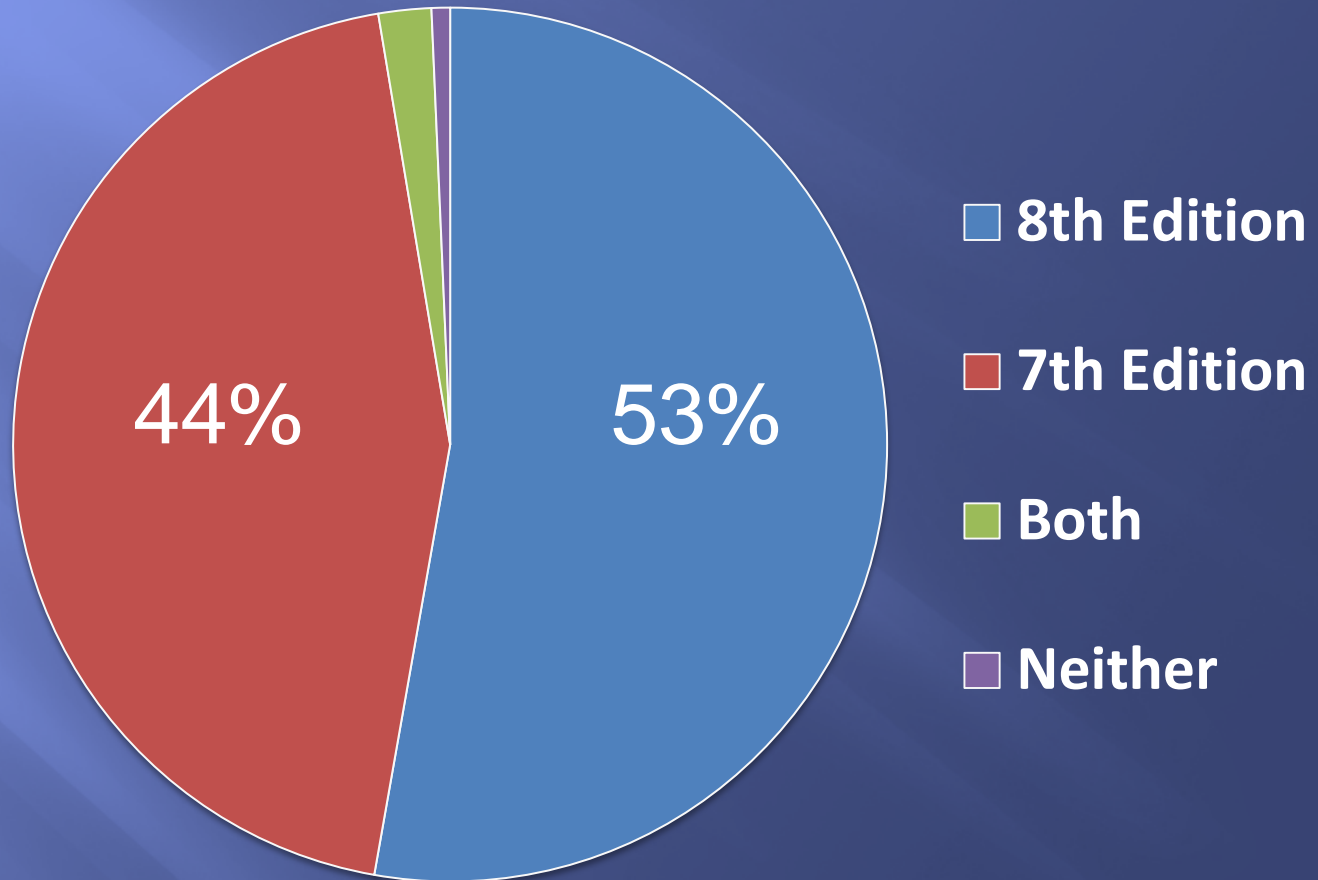




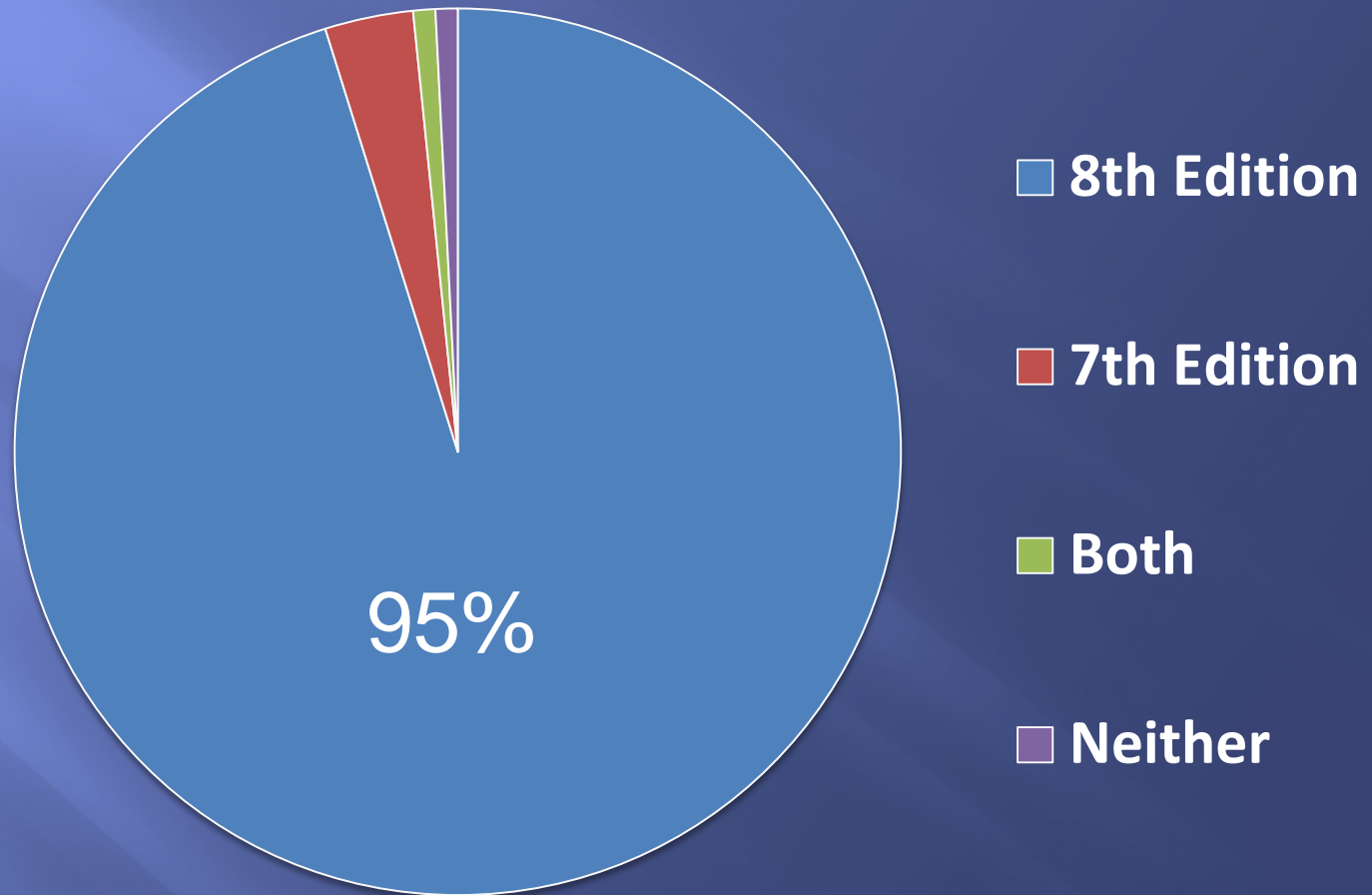
# Not Implemented, Plans in Place



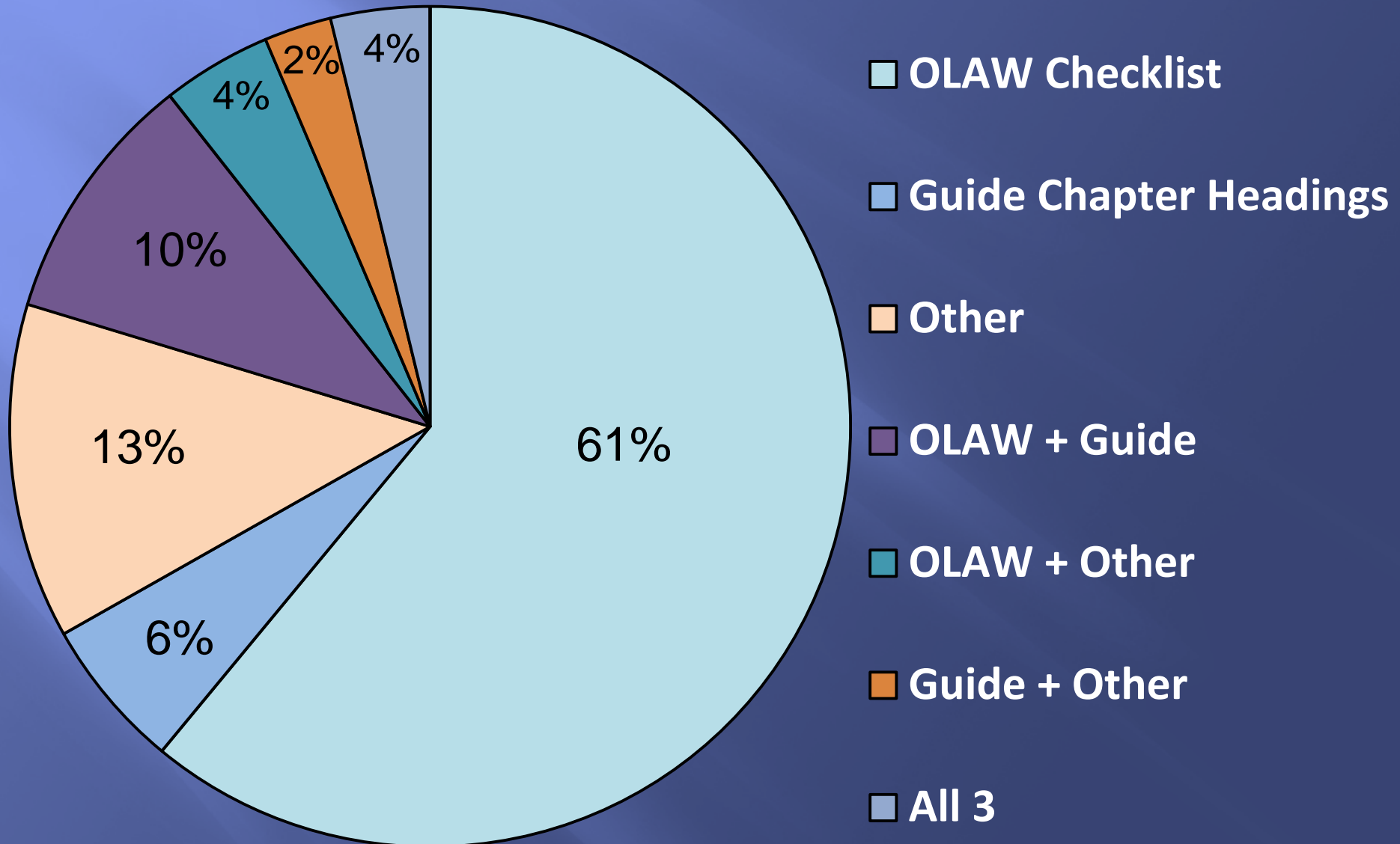
# First Program Evaluation



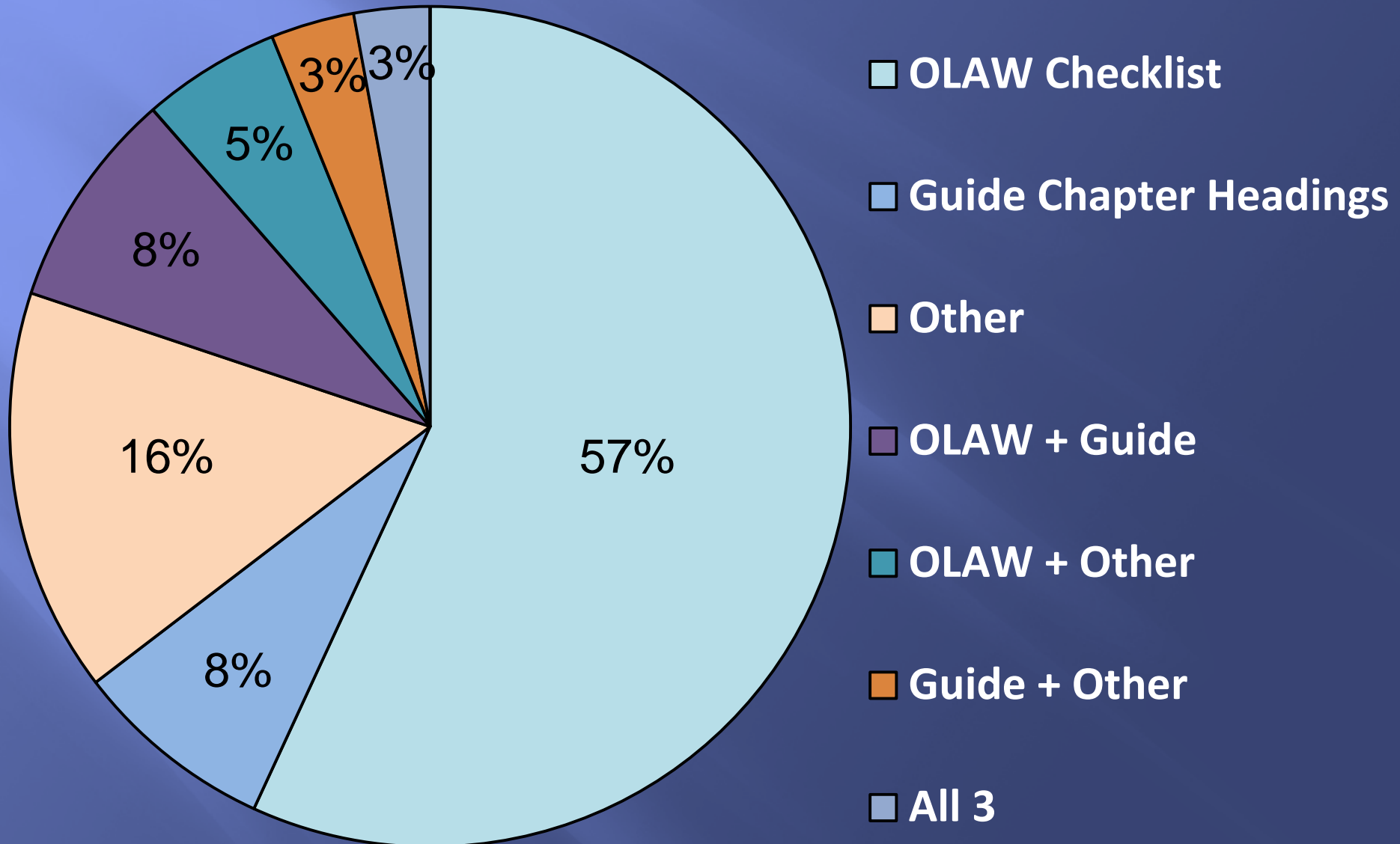
# Second Program Evaluation



# Methods Used for Evaluations



# Methods Used for Inspections



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





# Question 1

**Who must file the annual report?**

**Does it have to be the IACUC Chair or the IO?**

## 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 6-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 6 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 1 to category 2?

# 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

Can you please clarify the species change notification requirement?

What kind of changes are we talking about?

# Question 20

Our IACUC just 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 21

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

## Question 22

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 23

If an institution has undergone an AAALAC site visit during the year would that suffice in place of the annual report?

# Question 24

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



# Question 25

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

# Question 26

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 27

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

# Question 28

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

# Question 29

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

# Question 30

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



# Question 31

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

# Question 32

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

# Question 33

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

# Question 34

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

# Question 35

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

# Question 36

**What does OLAW do with the annual reports?**



# Upcoming Webinars

Webinars will continue to be held quarterly on **Thursdays** at **1PM eastern time** in 2014: **March, June, September, December**

OLAW will announce topic and day prior to the webinar via our listserv and RSS feed

Please send topic suggestions to [olawdpe@mail.nih.gov](mailto:olawdpe@mail.nih.gov)