

Update to the Reporting Period of the Annual Report to OLAW



OLAW Special Webinar
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Eileen Morgan, Director, Division of Assurances, NIH, Office of Laboratory Animal Welfare

Jane Na, DVM, CPIA, Senior Assurance Officer, Division of Assurances, NIH, Office of Laboratory Animal Welfare

Learning Objectives

1. Provide a rationale for the change in the reporting period for the Annual Report to OLAW
2. Describe the changes in the reporting cycle
3. Identify the PHS Policy requirements for the Annual Report
4. Use the instructions to successfully prepare the Annual Report to OLAW



Background – 21st Century Cures Act

The 21st Century Cures Act, Section 2034(d), directed the NIH, in collaboration with the USDA and FDA to:

- review and revise applicable regulations and policies for the care and use of laboratory animals
- reduce administrative burden on investigators while maintaining the integrity and credibility of research findings and protection of research animals

21st Century Cures Act Working Group Recommendation

- Harmonization of the annual reporting period between the NIH OLAW and the USDA
- Federal fiscal year schedule, Oct 1 – Sept 30

REDUCING ADMINISTRATIVE BURDEN FOR RESEARCHERS: ANIMAL CARE AND USE IN RESEARCH

A Report by the

National Institutes of Health, HHS,
Animal and Plant Health Inspection Service, USDA,
and
Food and Drug Administration, HHS

August 2019

Reducing Administrative Burden
for Researchers: Animal Care and
Use in Research ([PDF](#))

Annual Report to OLAW Updates

Reporting period and due date harmonization with USDA

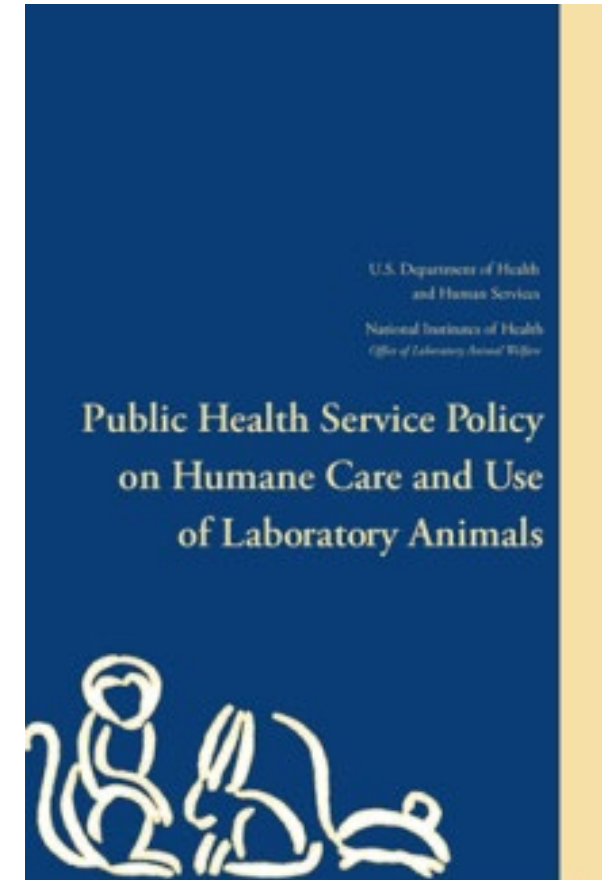
Year	Reporting Period	Due Date
2020	January 1 - September 30	December 1
2021+	October 1 - September 30	December 1

OMB-approved Annual Report form and instructions available at:

<https://olaw.nih.gov/resources/documents/annual-report.htm>

PHS Policy Requirements – Annual Report

The PHS Policy on Humane Care and Use of Laboratory Animals section **IV.F.1., 2., and 4.** requires that at least once every 12 months the IACUC, through the Institutional Official (IO), must report to OLAW **changes in the institution's program of animal care and use.**

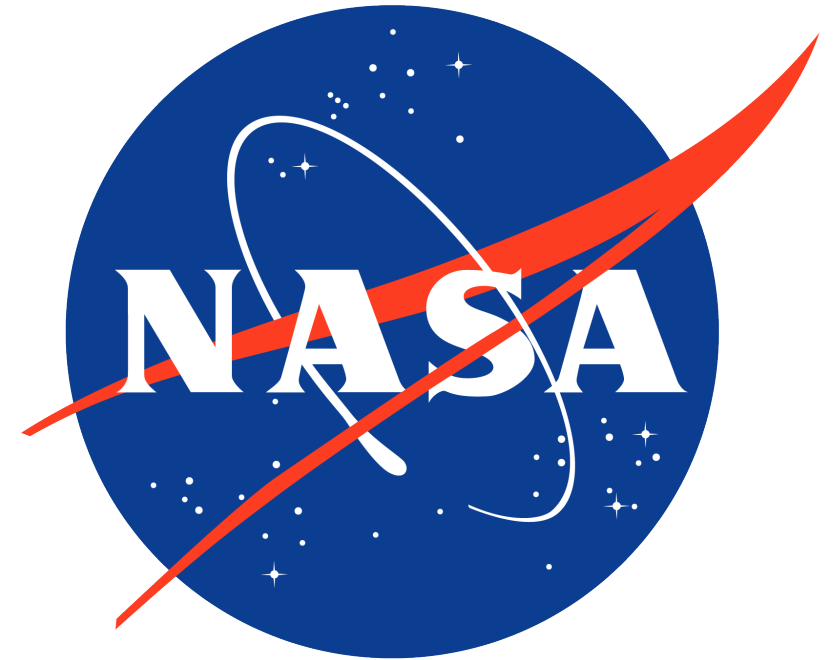


PHS Policy Program Changes *to Report*

- Any changes in the:
 - o institution's accreditation status
 - o institution's program of animal care and use or facilities
 - o Institutional Official
 - o IACUC membership
- The dates that the IACUC conducted its semiannual evaluations of the program and facilities
- Any minority views filed by members of the IACUC

2020 Annual Report Program Changes: NASA Funding

- State if your institution has National Aeronautics and Space Administration (NASA) funding for research involving animals or utilizes the International Space Station.
- MOU between OLAW and NASA in 2020



2020 Annual Report Program Changes: AAALAC Accreditation Changes

Only make a selection regarding AAALAC accreditation if there has been a change in the institution's accreditation status:

- Achieved AAALAC accreditation
- No longer AAALAC accredited

- ☐ This institution's AAALAC accreditation status has changed ([PHS Policy IV.A.2.](#)).
- ☐ [AAALAC Accredited](#) – Category 1
- ☐ Non-Accredited – Category 2

COVID-19 Pandemic Program Changes

Not to Report

Unless information in the current Assurance is impacted and needs to be updated:

- do *NOT* report temporary program changes
- do *NOT* report revisions to your institution's disaster plan

Temporary Program Change: Examples *Not to Report*

Changes adopted during the pandemic, approved by the IACUC, and updated in the disaster plan or emergency preparedness plan:

- using an expedited number of days for Designated Member Review (DMR) process
- using DMR more often than typical committee use for protocol review

Temporary Program Change: Examples *Not* to Report

Changes if *only* intended to be used during the pandemic, such as:

- using virtual methods of conducting semiannual facility inspections
- using *ad hoc* consultant(s) for conducting semiannual facility inspections for non-USDA covered species

Summary: **Temporary** Program Changes

Do *not* report **temporary**
program changes in your
Annual Report.



COVID-19 Pandemic Program Changes to Report

If your institution:

1. implemented *temporary* flexibilities (e.g., used [telecommunications](#) to conduct business)
2. are *permanently* adopting these flexibilities, and
3. these flexibilities are *not* described in your Assurance

Report these changes in your 2020 Annual Report.

Permanent Program Changes: Examples to Report

IACUC – approved changes in processes described in the Assurance document, Part III.D.1 – 10, such as:

- Veterinary Verification and Consultation (VVC)
- Designated Member Review (DMR)
- DMR subsequent to Full Committee Review (FCR)

Summary: Permanent Program Changes

- Do include in Annual Report
- Do *not* submit an **updated Assurance** document with your Annual Report. Update your Assurance at time of renewal.



Changes to the Institutional Official and IACUC Roster

- If a change in IO occurred since January 1, 2020, provide the information for the *current* IO (the IO signing the Annual Report to OLAW) in Item V.
- If the IACUC membership has changed since January 1, 2020, provide an updated roster that reflects *current* membership (members as of the day of Annual Report submission) in Item IV.

2020 Annual Report Semiannual Program Review

- Provide program review date(s) conducted during the partial year reporting period (January 1 – September 30)
- If only one review was conducted, *include only one* semiannual review date

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: Provide date(s) the program review
was completed

Date 2: Provide date(s) of the second program
review if completed

Leave blank if only one program
review was completed due to the
partial year

Institutions Granted Waivers for the Semiannual Facility Inspection

Due to the COVID-19 pandemic:

- institutions may only have *one* or *no* date for facility inspections between January 1 and September 30
- list dates of completed inspections and state if your institution received a waiver from OLAW
- institutions with approved waivers should conduct postponed inspections as soon as the IACUC can safely do so

Visit OLAW's [COVID-19 page](#)

2020 Annual Report

Semiannual Facility Inspections

- Provide any facility inspection date(s) conducted during the partial year reporting period (January 1 – September 30)
- State if your institution was granted a waiver from OLAW

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 evaluations of each site during the reporting period, please attach a list showing the dates.]

Date 1: Provide date(s) of facility inspections that were completed

Leave blank if no facility inspections were completed due to the COVID-19 pandemic with approved OLAW waiver.

Date 2: Provide date(s) of the second facility inspection if completed

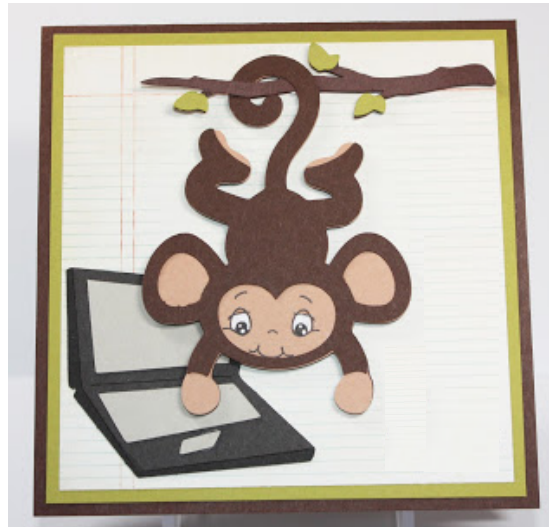
Leave blank if only one inspection was completed due to the COVID-19 pandemic with approved OLAW waiver or due to the partial reporting year.

Minority Views

- Attach the minority view(s) by the IACUC member(s) *exactly as submitted*.
- If the minority view is part of the meeting minutes, submit *only* the minority view portion of the minutes.
- If the minority view is part of the semiannual report, submit *only* the minority view portion of the report.

Completed the Annual Report, Next Steps?

- Have the completed report signed by the Institutional Official and IACUC Chair
- Email the report to the OLAW Annual Reports email box olawarp@mail.nih.gov



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Summary

Year	Reporting Period	Due Date
2020	January 1 - September 30	December 1
2021+	October 1 - September 30	December 1

- Review the OLAW Annual Report [website](#) and [Instructions](#)
- Contact OLAW if you have questions



Call or email the OLAW Division of Assurances
301-496-7163 or olawdoa@mail.nih.gov

OLAW Resources for Annual Report

- [NOT-OD-20-109](#) Notice of Update to the Reporting Period of the Annual Report to OLAW
- Annual Report to OLAW [website](#)
- Submit the Annual Report to olawarp@mail.nih.gov



Learning Objectives

- ✓ Provide a rationale for the change in the reporting period for the OLAW Annual Report
- ✓ Describe the changes in the reporting cycle
- ✓ Identify the PHS Policy section and required reporting elements
- ✓ Use the instructions to successfully prepare the Annual Report to OLAW

Questions?



Question #1

How do I submit the Annual Report?

Answer #1

How do I submit the Annual Report?

To submit the Annual Report (AR):

- *Download the AR form from the OLAW website*
- *Complete the AR form*
- *Have the report signed by the Institutional Official and IACUC Chair*
- *Email the report to olawarp@mail.nih.gov*

Question #2

Are there any updates regarding the shared portal with USDA that was mentioned with the 21st Century Cures Act recommendations?

Answer #2

Are there any updates regarding the shared portal with USDA that was mentioned with the 21st Century Cures Act recommendations?

Not at this time.

Question #3

What if I don't have NASA funding? Should I indicate that I don't have any?

Answer #3

What if I don't have NASA funding? Should I indicate that I don't have any?

Only report NASA funding if your program:

- *has funding by NASA involving animals, or*
- *uses the International Space Station to conduct animal activities*

Question #4

Which institutions are eligible for requesting a waiver for the conduct of the semiannual facility inspections?

Answer #4

Which institutions are eligible for requesting a waiver for the conduct of the semiannual facility inspections?

*Assured institutions that are unable to safely conduct facility inspections within the **6 month plus 30 day** timeframe because of COVID-19 restrictions may request a waiver (see [NOT-OD-20-088](#)).*

Question #5

How can I request a waiver if my institution is unable to safely conduct the semiannual facility inspections within the 6 months plus 30 day timeframe?

Answer #5

How can I request a waiver if my institution is unable to safely conduct the semiannual facility inspections within the 6 months plus 30 day timeframe?

An authorized institutional representative (IO, IACUC Chair, IACUC Coordinator or Attending Veterinarian) may request a waiver for the semiannual inspections by submitting a request with justification related to the COVID-19 pandemic to olawdpe@mail.nih.gov.

Question #6

Can we get a waiver to submit the 2020 Annual Report late?

Answer #6

Can we get a waiver to submit the 2020 Annual Report late?

Waivers will not be considered for Annual Report submission at this time.

Question #7

I have *many* program changes to report. It would be easier to submit a revised Assurance to capture all my changes. May I submit an updated Assurance instead of providing *all these updates* in my Annual Report?

Answer #7

I have *many* program changes to report. It would be easier to submit a revised Assurance to capture all my changes. May I submit an updated Assurance instead of providing *all these updates* in my Annual Report?

The Annual Report process was intended to collect changes to your animal care and use program that occur throughout the 4-year approval period of your Assurance. Please provide the updates in your Annual Report. Keep a record of the changes to include in the next renewal of the Assurance.

Question #8

Does the update to the Annual Report reporting period and due date change when I submit my Assurance renewal?

Answer #8

Does the update to the Annual Report reporting period and due date, change when I submit my Assurance renewal?

No, the update in reporting period and due date for the Annual Report does not change when you submit your Assurance for renewal. Domestic Assurance renewals are submitted once every four years, and the Annual Report is submitted every year.

Answer #9

If I just renewed my Assurance do I have to submit an Annual Report?

Answer #9

If I just renewed my Assurance do I have to submit an Annual Report?

Yes, the Annual Report includes the dates of your semiannual program review and facility inspections, which are only reported to OLAW during the Annual Report process.

Question #10

Last year our semis occurred in April and October. This year we would only have one semiannual date to report, April 2020. Our next program review and inspections are scheduled to occur in October, which would be after the September 30 cut-off date.

To accommodate the new reporting period, should we move our program review and inspections to September or should we maintain our current schedule?

Answer #10

To accommodate the new reporting period, should we move our program review and inspections to September or should we maintain our current schedule?

Your current schedule can be maintained. It is acceptable for the 2020 Annual Report to OLAW to list one date for the program review and one date for the facility inspections to follow your regular semiannual schedule.

Only report dates of program reviews or facility inspections that occur January 1 – September 30, 2020.

Thank you!

