



Openness and Transparency and Biomedical Research Oversight: What Your Institution Should Know

Taylor Bennett, DVM, PhD, DAACLAM, DACAW, NABR

Betty Goldentyer, DVM, USDA, APHIS, Animal Care

Maggie Snyder, PhD, OER, NIH

Axel Wolff, DVM, MS, OLAW

with

George Babcock, PhD, U. Cincinnati and OLAW

Nicole Zimmerman, BS, OLAW



Federal FOIA

- Freedom of Information Act, July 4, 1966
 - Fosters democracy
 - Empowers informed citizenry
- FOIA 5USC552, Regulations 45CFR Part 5
- NIH FOIA website: www.nih.gov/icd/od/foia

NIH Records Available Under FOIA

- Affirmative
 - RePORTER
 - PHS Assured institutions
- By written request to NIH FOIA Office or OER FOIA Office
 - US mail
 - Email
 - Fax
- Do NOT send FOIA request to OLAW

Disclosure Statute

- Responsive records will be released unless exemptions or exclusions apply
- We do not:
 - Create records; only provide documents in our possession
 - Alter records
 - Consider identity of requestor
 - Consider potential use of the record

Applicable Exemptions

Only the NIH FOIA officer may withhold information:

- 4: Trade secrets, commercial, financial info
- 5: Inter-or intra-agency memo, attorney-client communication, deliberative process
- 6: Unwarranted invasion of personal privacy
- 7: Law enforcement files

Appeal Process

If NIH issues denial of information or a no records response, requestor may:

- Appeal to HHS
- Challenge in court (up to 6 years)

States Open Records Laws

- In addition to the federal FOIA, every state has its own open records law
- Specific laws and exemptions vary by state
- Names include:
 - Sunshine
 - Freedom of Information
 - Public Records
 - Open Records

Purpose of States' Laws

- Promote transparency and openness
- Activists have used states laws to acquire info:
 - Animal care and use programs
 - Research projects
 - Researchers' personal information
 - Target researchers' homes and families
 - Request investigations
 - Seek criminal charges and enforcement actions
- Exemptions sometimes provide insufficient protection

Variation in States' Laws

- Wide variation in language, court interpretation, info protection
- Federal FOIA has 9 exemptions
 - Some states have 9
 - Some states have 50 or more
- Protect info of commercial value
 - Patentable or not
- Protect research info
- Protect personal info, health and safety

Understand Your State Laws

- Exemption of personal information?
 - Oregon
 - Utah
 - Florida

Be FOIA-Ready

- FOIA-ready documents
 - Factual
 - Do not contain extraneous info
 - Accurately reflect ACUP
- Conduct risk analysis to get FOIA-ready
 - IACUC minutes and records, protocols, medical and necropsy records, emails
 - Consider use of phone calls and conversations
 - Review records retention policies
- Required by feds vs. institutional policies

Want to Learn More?

Responding to FOIA Requests: Facts and Resources

Available at [http://orga.cofc.edu/pub/
compliance_iacuc_FOIA_Requests.pdf](http://orga.cofc.edu/pub/compliance_iacuc_FOIA_Requests.pdf)

FOIA and APHIS, AC

- All records in possession of USDA are subject to FOIA
 - Photos
 - Emails
 - Applications and renewals
 - Correspondence
- Available on Animal Care website (<https://acisearch.aphis.usda.gov/LPASearch/faces/Warning.jsp>)
 - Inspection reports
 - Annual Reports



Noncompliance Documentation

- VMOs may collect photos or records in support of noncompliance
 - Inspectors should use camera not cell phone
- You may see the records and the photos
- You have 24 to 48 hours to redact the records if necessary
- Info marked confidential or personal will not be released



APHIS FOIA Reading Room

Available from APHIS Home page

- Previously released info is posted
- Office does not have to repeatedly release same info

http://www.aphis.usda.gov/wps/portal/aphis/newsroom/news?1dmy&urile=wcm%3apath%3a%2Faphis_content_library%2Fsa_resources%2Fsa_laws_and_regulations%2Fsa_foia%2Fct_foia



Inspection Appeals

- Appealed inspection reports are not posted but they can be requested through FOIA and will be redacted and released, including:
 - Appeal letter
 - Original inspection report
 - Associated photos
- May be released before the appeal is resolved
- Clearly identify proprietary information
 - Info under investigation might be released, but will be redacted



Attention!! Annual Report Packets

- 2014 Annual Report packets contain FOIA insert
 - Explains exemptions
 - How to identify confidential business info
 - Call your inspector or AC office if you have questions:**
 - About site location information
 - Other questions



Review Your Documents

Have a process in place to ensure that your documents are FOIA-ready



Responsible Agency

- Each agency is responsible for its own records
- AC does not release OLAW records;
OLAW does not release USDA records



FOIA and NIH

- Documents requested
 - Animal Welfare Assurance
 - Annual reports
 - Compliance cases
 - Written communications
- Requestors
 - Private citizens
 - Activist groups
 - Media representatives



NIH FOIA Process

- Requests to OER not OLAW
- Request becomes official record
 - Unique identifier
 - Date of receipt, info cutoff date
 - Text of requestor message
- Requests must be:
 - Specific
 - Cannot request future information



Responsive Records

- Some requests are denied because OLAW doesn't maintain records by the requested topic
- OLAW provides responsive records to FOIA office
- OLAW and FOIA office determine what should be withheld
- OLAW requests denial of release, if indicated
- FOIA officer makes determination regarding release
- Costs are calculated and added to official record



What To Provide OLAW

- All records at OLAW are subject to FOIA release
- Provide only required information
- Do **NOT** include:
 - Personnel records or resumes
 - Name of individuals in compliance cases
 - Animal facility floor plans
- Not sure what to report? Call OLAW at **(301) 496-7163**



Why Info Is Requested

- Curiosity or interest in animal welfare
- Media interest
- Personnel issues or lawsuits
- Whistleblowers
- Interest by nonprofit organizations
- Obtaining factual information

Potential distortion of factual documents obtained under FOIA is a concern to OLAW and USDA.



Reporting Adverse Events at Research Facilities on USDA Inspection Reports

The USDA, APHIS, Animal Care will allow inspection reports to reflect the self-correction by an institution of a serious adverse event or incident so that the compliance status of the institution is accurately portrayed.



Tech Note November 2014

http://www.aphis.usda.gov/animal_welfare/downloads/Adverse%20Events%20on%20Inspection%20Reports%20-%20Tech%20Note.pdf

Serious Events

Serious adverse events or incidents are those that led to:

- Significant injury or illness,
- Unrelieved pain or distress, or
- Death of the animal.



Tech Note November 2014

http://www.aphis.usda.gov/animal_welfare/downloads/Adverse%20Events%20on%20Inspection%20Reports%20-%20Tech%20Note.pdf

Citation

A citation will be written if the incident resulted in:

- Significant injury or illness,
- Unrelieved pain or distress, or
- Death of the animal

as a result of noncompliance with a regulation or standard.

An inspector may choose to indicate OLAW's decision regarding the incident on the inspection report when there is documentation.



Tech Note November 2014

http://www.aphis.usda.gov/animal_welfare/downloads/Adverse%20Events%20on%20Inspection%20Reports%20-%20Tech%20Note.pdf

No Citation

AC will not cite an institution for an incident if the incident:

- Caused no serious adverse effects,
- Had no history of repeat noncompliance,
- Was corrected in a timely manner, and
- Led to effective preventative measures.

A citation will be issued if any one of these criteria is not met.



Tech Note November 2014

http://www.aphis.usda.gov/animal_welfare/downloads/Adverse%20Events%20on%20Inspection%20Reports%20-%20Tech%20Note.pdf

Third Party Complaints

Complaints from third parties involving previously reviewed noncompliances or events that are over 3 years old will not be revisited by AC or OLAW.



Tech Note November 2014

http://www.aphis.usda.gov/animal_welfare/downloads/Adverse%20Events%20on%20Inspection%20Reports%20-%20Tech%20Note.pdf

Why?

Memorandum of Understanding permits sharing information between OLAW and AC to:

- Foster continual improvements in animal care,
- Reduce duplication in oversight, and
- Lessen regulatory burden.



Tech Note November 2014

http://www.aphis.usda.gov/animal_welfare/downloads/Adverse%20Events%20on%20Inspection%20Reports%20-%20Tech%20Note.pdf

Question 1

1. What is Animal Care's policy regarding the review of past incidences of noncompliance?



Answer 1

1. An inspector may choose to review past incidences of noncompliance when it is determined by professional judgment to be warranted.

In the event a third party requests review of a past incident of noncompliance, the event will **not** be revisited if **previously reviewed** or occurred 3 years or more in the past.



Question 2

2. Can USDA, APHIS cite an institution for a serious adverse incident that was already investigated and the case closed by OLAW?



Answer 2

2. Yes. APHIS can cite if the incident:

- Resulted in serious adverse effects;
- Was not corrected in a timely manner;
- Effective measures were not put into place; or
- Involved a history of repeated noncompliance.



Question 3

2. Will self-reporting an adverse event to USDA, APHIS, Animal Care prevent the issuance of a citation?



Answer 3

3. No, self-reporting has no bearing on whether a citation will be issued but may be taken into consideration as evidence of 'good faith' during an enforcement action.



Question 4

4. Is it a requirement to report serious adverse events and incidents to the USDA?



Answer 4

3. No. The following are required by the Animal Welfare Act Regulations to be reported:

- Change of operations: 9 CFR §2.30 (c)(1);
- Protocol suspension: 9 CFR §2.31 (d)(7);
- Uncorrected significant deficiencies from a semiannual inspection: 9 CFR §2.31 (c)(3); and
- Annual Report: 9 CFR §2.36.



OLAW Requires Self-reports

The PHS Policy (IV.F.3.) requires Assured institutions to self-report any serious or continuing noncompliance to OLAW.

Institutions may also choose to share self-reports of noncompliance with AC as a demonstration of their commitment to continual animal welfare improvement, timely correction of noncompliance, and prevention of reoccurrence.



NIH-OD-15-028

<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-028.html>

OLAW Shares Self-reports

Under the MOU, OLAW frequently shares self-reports of serious animal welfare concerns involving USDA regulated species with AC.



NIH-OD-15-028

<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-028.html>

OLAW Shares Self-reports Continued

Serious animal welfare concerns may include unanticipated death of animals, and unexpected and unrelieved pain or distress to animals.

OLAW will contact AC to share serious animal welfare concerns and issues of interest to both agencies.

Institutional self-reports are shared with AC after OLAW's investigation is completed.



NIH-OD-15-028

<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-028.html>

USDA Citations

Animal Care will not cite an institution for past self-reports to OLAW if the incident:

- Did not cause serious adverse effects;
- Had no history of repeat noncompliance;
- Was corrected in a timely manner; and
- Led to effective preventative measures.

AC will cite the institution if any of the above criteria are not met.

USDA Tech Note November 2014

http://www.aphis.usda.gov/animal_welfare/downloads/Adverse%20Events%20on%20Inspection%20Reports%20-%20Tech%20Note.pdf

NIH-OD-15-028

<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-028.html>



Time Limit

Complaints from third parties involving previously reviewed noncompliance or any events over 3 years old will not be reexamined by AC or OLAW.



NIH-OD-15-028

<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-028.html>

OLAW Shared Animal Welfare Concerns Policy

OLAW's Shared Animal Welfare Concerns Policy is in accordance with the MOU that was designed to foster continual improvements in animal welfare, reduce redundancy in oversight, and reduce regulatory burden.



NIH-OD-15-028

<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-028.html>

Question 5

5. What are examples of serious animal welfare concerns that OLAW will share with USDA?



Answer 5

5. OLAW will share serious noncompliance that involves regulated species such as death from weather extremes, death from going through cage wash, and death as a result of HVAC failure.



Question 6

6. Will OLAW share concerns about non-regulated species?



Answer 6

6. No, OLAW will not share concerns about mice, rats, or birds



Question 7

7. What happens when AC gets a report from OLAW and OLAW has already worked with the institution to resolve the concern and closed the case?



Answer 7

7. In this situation, OLAW has already handled the concern, so it is not an emergency. There's no need for AC to deploy a VMO to the situation immediately but the concern will be reviewed at the next routine inspection.



Being Prepared is the Key

- Identify a knowledgeable point person
 - Familiar with research
 - Understands laws and regs
 - Keeps everyone informed of process
- Ensure all documents are FOIA-ready

Process

- Counsel reviews response to determine exemptions
- Accurately account for cost of responding

Question 8

8. We would like the USDA to comment on the practice of issuing citations for incidents that were already reported to the relevant agency.

Our institution self-reported a serious noncompliance to OLAW and also provided a courtesy notice to USDA.

After the case was closed, OLAW released a report of the case in response to a FOIA request.



Question 8 Continued

We found and immediately corrected the problem. The IACUC instituted a plan to prevent recurrence. OLAW agreed that the corrective plan was appropriate. Nevertheless, USDA cited us and posted the citation on their website.

Although we took immediate action, the USDA visit and citation occurred 2-3 years after the incident and the citation read 'from this date forward'. We appealed unsuccessfully to have that phrase changed or removed. This makes it appear as though we did not take action.



Question 8 Continued

This practice uses USDA time and resources and makes institutions question the validity of reporting to OLAW.

It misrepresents our program to the public and does not support OLAW and USDA's mission of improving animal welfare and reducing regulatory burden.



Answer 8

8. It is critical that we all use our time and resources wisely. Our partnership with OLAW helps us do that. You are also correct that we need to provide an accurate picture of the compliance at each facility to the public. Noncompliance, impacting an animal, occurred at the facility. Identifying and documenting noncompliance is USDA's job and the public expects those noncompliances to be reflected on the inspection report for transparency and tracking purposes.



Answer 8 Continued

We were inconsistent in early 2013 when several complaints came in about incidents that were 3 or even more years old.

We now have clear guidance and inspectors will not be reviewing incidents over 3 years old or any incident that has already been reviewed by USDA.



Answer 8 Continued

We recognize and appreciate the efforts that went into preventing a recurrence and have advised the inspectors to acknowledge that in the report. Please take the opportunity to make sure the report reflects that effort.

We also recognize these efforts when we consider the need (or lack there of) for enforcement action. The institution demonstrated good faith and that is vital to good animal welfare.



Question 9

9. Within the last year, an animal protectionist, obtained a copy of a Final Report regarding a noncompliance instance via a FOIA request to OLAW. As far as we are aware, all other federal agencies will provide the institution the opportunity to make allowable redactions pursuant the FOIA before the federal agency releases the document to the requester. Our institution routinely does this. Additionally, the federal agency will notify the institution as to who requested the document pursuant to the FOIA. In this case, OLAW did not give us the opportunity to make redactions to the Final Report before OLAW released the Final Report to the requestor.



Question 9 Continued

Why does OLAW not allow institutions to request that redactions be made to documents generated by the institution before the document is released pursuant to a FOIA request?

Even if the institution would not make any further redactions to the document, at least the institution would be put on notice as to who is requesting a document pursuant to the FOIA and what document is being requested pursuant to the FOIA, before the document is released to the public.



Answer 9

9. As per Executive Order 12600, agencies do not provide pre-disclosure notifications for **all** documents requested by FOIA.

Pre-disclosure notification is used for information believed to be of the type protected under Exemption 4 (Trade Secrets, commercial or financial information).

Executive Order 12600

<http://www.archives.gov/federal-register/codification/executive-order/12600.html>



Summary

- Federal FOIA requires federal agencies to make records available to the public either affirmatively or upon written request.
- Records are not created or altered, they are simply released.
- There are, however, 9 exemptions and 3 exclusions which may be invoked
- It is strongly suggested that institutions carefully review their records to make them FOIA-ready so safety, loss of security, or confidentiality are not comprised.



Summary

- In addition to federal FOIA, every state has a law that governs access to records.
- Institutions should be aware of the open records laws in their state which differ widely in the amount of information protected from disclosure.
- Institutions should also insure their documents related to state laws are FOIA-ready, that is documents that are factual, devoid of extraneous information and accurately reflective of the institutions animal care and use program.
- Having in place a records retention policy that meets the requirements is also important.



Summary

- Federal FOIA laws also apply to USDA records including photos and emails. Annual Reports are available directly through the Animal Care website without making a request under FOIA.
- Complaints from third parties involving previously reviewed noncompliances or events that are over 3 years old will not be revisited by AC or OLAW.
- Under a MOU, OLAW frequently shares self-reports of serious animal welfare concerns with AC when USDA regulated species are



Resources

- NIH FOIA Office
<http://www.nih.gov/icd/od/foia/>
- NIH OER FOIA Office
http://grants.nih.gov/grants/oer_offices/subopac_foia.htm
- NIH Guide Notice NIH-OD-15-028
<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-028.html>
- USDA ACIS Search Tool
<https://acissearch.aphis.usda.gov/LPASearch/faces/Warning.jspx>
- USDA APHIS FOIA
http://www.aphis.usda.gov/wps/portal/aphis/newsroom/news?1dmy&uril e=wcm%3apath%3a%2Faphis_content_library%2Fsa_resources%2Fsa_laws_and_regulations%2Fsa_foia%2Fct_foia
- USDA Tech Note November 2014
http://www.aphis.usda.gov/animal_welfare/downloads/Adverse%20Events%20on%20Inspection%20Reports%20-%20Tech%20Note.pdf





Next OLAW Online Seminar
IACUC Review of Aquatics
March 2015