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*Note: Text has been edited for clarity.*

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

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<https://www.youtube.com/watch?v=PKPbl4duGUE> (YouTube).

Slide 1 (Openness and Transparency and Biomedical Research Oversight: What Your Institution Should Know)

>>*Babcock*: Hello, today is December 4, 2014. Welcome to the OLAW Online Seminar, **Openness and Transparency and Biomedical Research Oversight: What Your Institution Should Know**. OLAW and USDA share information about animal welfare concerns under the [Memorandum of Understanding](#). Today we would like to explain to you how the two agencies work together in our shared mission to ensure the humane care and use of animal models at the Nation's research institutions. For our webinar today, OLAW has assembled a panel of experts to consider many aspects of open records and sharing information. Maggie Snyder will start us off with a review of the federal Freedom of Information Act and Taylor Bennett will comment on states open records requirements. Betty Goldentyer and Axel Wolff will discuss the impact of these laws and regulations on animal care and use programs at USDA-regulated and PHS-Assured institutions. Following the presentation of this background information, Betty and Axel will discuss their agencies' shared animal welfare policies in the context of documents published by

their agencies during the last quarter of calendar 2014, a [USDA Tech Note](#) [PDF] and NIH Guide Notice [NOT-OD-15-028](#). Now that I have introduced the webinar, I'm going to introduce the speakers.

Dr. Taylor Bennett has been the Senior Scientific Advisor for NABR, the National Association for Biomedical Research, since 2007. Prior to that, he spent 36 years at the University of Illinois at Chicago involved with the Animal Care and Use Program, serving as the Associate Vice Chancellor for Research Resources for the last 10 years of that time.

Dr. Betty Goldentyer is the Director of Animal Welfare Operations for the APHIS [Animal and Plant Health Inspection Service] Animal Care program at USDA. Betty has been with the Animal Care program since its organization as a stand-alone program in 1988.

Dr. Maggie Snyder is the Freedom of Information Act Coordinator for the NIH Office of Extramural Research [OER]. She also serves as the OER Privacy Act Coordinator and the senior advisor to the Deputy Director of OER.

Dr. Axel Wolff has been the director of the Division of Compliance Oversight at the Office of Laboratory Animal Welfare at the National Institutes of Health since 2005. He has also served as a Senior Assurance Officer at OLAW.

Nicole Zimmerman is OLAW's newest staff member. She graduated with honors in 2014 from St. Mary's College of Maryland where she majored in Public Policy and Economics and minored in Anthropology and Environmental Studies. Nicole joined the Division of Policy and Education as a volunteer high school student in 2009, continued her service as an NIH Pathways Intern, and was converted to full time federal service upon her graduation.

Now, let's begin with a review of the FOIA statute by Dr. Snyder.

Slide 2 (Federal FOIA)

>>*Snyder*: Thank you, the Freedom of Information Act, referred to as FOIA, was signed into law on July 4, 1966 making it the first law that gave the right to access documents of federal agencies to members of the public. The FOIA fosters democracy and empowers an informed citizenry. A copy of the Freedom of Information Act (5 USC 552) and its Regulations 45 CFR Part 5, Public Information may be found at the [NIH FOIA website](#) at the address shown on your screen.

Slide 3 (NIH Records Available Under FOIA)

FOIA requires federal agencies to make records available to the public either affirmatively or upon written request. Affirmative releases are repeatedly requested

documents or documents the agency makes available on its website or in a public reading room. Affirmative release of documents makes the activities of an agency transparent to the public. An example of an affirmative release is the Office of Extramural Research online Research Portfolio Reporting Tool commonly called RePORTER which provides information about NIH grants. Another example is the list of PHS Assured Institutions available on the OLAW website.

There are many FOIA coordinators at NIH, several institutes have their own FOIA coordinator and I am the FOIA coordinator for the Office of Extramural Research. NIH has one FOIA officer and each of the coordinators works with the NIH FOIA officer.

Written FOIA requests may be submitted by mail, FAX or email by U.S. citizens and non-citizens seeking records, data, or documents in the possession of the agency to either the NIH FOIA officer or to the appropriate FOIA coordinator. FOIA requests for OLAW documents may either be sent to the NIH FOIA Office or to my office as the OER FOIA Coordinator. However, they should not be sent to OLAW. If I am aware of responsive records in a different office or institute within NIH, I am obligated to forward that request to the other office immediately. For example, if I get a request for a specific grant that is funded by an NIH institute, then I will forward that request to the FOIA coordinator for that institute.

#### Slide 4 (Disclosure Statute)

FOIA is a disclosure statute, in other words, the law presumes that all responsive records and information will be released unless one of 9 exemptions and 3 exclusions applies. Additionally our regulations state:

- We do not “create a record.” This is particularly noteworthy when the Office of Extramural Research gets requests for application and/or grant award data. We do not create records. We only provide those documents in our possession. Also we do not perform data analysis for requesters.
- We do not alter a record. That is why it is best that correspondence with a federal agency not include personal information, such as medical conditions or employment situation or non-professional or inappropriate material.
- In responding to a request, we may not consider the identity of the requester or the use the requester intends to make of the records when deciding whether to release or withhold records. All requesters are treated in a professional manner.

#### Slide 5 (Applicable Exemptions)

The NIH FOIA officer is the only person within NIH that may withhold information using one of the 9 exemptions listed in the law. For OLAW and Office of Extramural Research documents, 4 exemptions are often invoked:

- Exemption 4: protects trade secrets and commercial or financial information;

- Exemption 5: protects inter-agency or intra-agency memoranda and incorporates certain privileges such as attorney-client communication or deliberative process;
- Exemption 6: protects certain information if disclosure would constitute a clearly unwarranted invasion of personal privacy, for example, personnel actions; and
- Exemption 7: protects certain information in law enforcement files.

#### Slide 6 (Appeal Process)

The law allows for an appeal if a no records response or a denial of information is sent to the requester. An appeal must be sent to the Department of Health and Human Services following procedures that are posted at the NIH FOIA website. If that appeal does not resolve the issue, then the individual has up to 6 years to pursue the matter through the courts. Court challenges to the use of an exemption or a denial of information have increasingly defined the uses of the exemptions. For FOIA, any exemption is an assertion of harm, thus an exemption must be specific and be the type of harm anticipated by the Congress in creating the exemption. For example exemption 4, financial harm, has been tested in the court. The court determined that there would be financial harm from the release of the information denied by the agency; however, the information was ordered to be released because the original intent was to protect against the theft of intellectual property. I recognize that the community is concerned about what is appropriate to release without risking safety, loss of security or confidentiality. I also recognize that I review well-written reports of noncompliance that do NOT compromise safety, security or confidentiality. I encourage those submitting their reports to review them line-by-line and word-by-word, making them FOIA-ready.

To make our webinar about open access to information more comprehensive, now we're going to hear from Taylor Bennett about states open record laws.

#### Slide 7 (States Open Records Laws)

>>*Bennett*: Thank you, Maggie. As Dr. Snyder mentioned, the federal Freedom of Information Act governs access to records in the possession of federal agencies. However, in addition to the federal FOIA, every state has a law that governs access to records in the possession of state and local governments and other public bodies, such as public universities. Like the federal FOIA, these state laws have specific exemptions intended to protect sensitive information from disclosure. However, the extent of the information protected and the names of these laws vary by state. These state laws go by names such as: Sunshine Laws, Freedom of Information Laws, Public Records Laws, Open Records Laws and others.

#### Slide 8 (Purpose of States' Laws)

Also like the federal FOIA, state open records laws are intended to promote government transparency and openness by permitting individuals to request information from state entities. Many state open records laws permit any person to request records; however, some states only permit citizens to make such requests.

So why should those involved with animal care and use programs care about laws that are intended to promote transparency? You should care about your state's open records law because animal rights activists have increasingly turned to such laws to acquire information about animal care and use programs, research projects and the personal information of researchers using animals. As Dr. Snyder mentioned, in some cases, it is difficult to determine what information is appropriate to be released without risking safety, loss of security or confidentiality.

This is especially true as applied to information related to research. Information obtained under the FOIA and state open records laws has been used to inaccurately label researchers as "animal abusers," target individuals and families at their homes, request baseless investigations, seek criminal charges for alleged animal cruelty, and ask for enforcement actions to be taken for alleged issues involving noncompliance. While many state's laws include exemptions intended to protect proprietary information, these exemptions have often proven insufficient to protect research data, sensitive photographs, and the personal information of researchers.

#### Slide 9 (Variation in States' Laws)

Some state open records laws are modeled after the federal FOIA. However, important differences exist based on the language used by the statute, court interpretations, and the extent of the information protected by exemptions. For example, some state courts have held that IACUC minutes are subject to disclosure while courts in other states have held that IACUCs are not public bodies and their records are therefore not subject to disclosure.

Perhaps one of the most striking differences between the various states' open records laws is the amount of information protected from disclosure by exemptions. The federal FOIA has only 9 exemptions and some states, similarly, have a limited number. Other states, however, have a much broader array, with some state open records laws containing 50 or more exemptions. These exemptions can be very important to research facilities as some are specifically intended to prevent sensitive research information and personal information from being disclosed.

In cases where the requested documents are of commercial value, the information is likely to be protected because many states have exemptions designed to protect trade secrets and commercial and proprietary information.

However, non-patentable research information is often not protected under a trade secrets exemption. Recognizing this fact, at least 18 states have enacted exemptions specifically designed to protect research information and other data from disclosure. Public universities have also used exemptions for health and safety and commercial and financial information to try and protect sensitive research. These exemptions have proven effective at preventing the public disclosure of research information in some cases.

#### Slide 10 (Understand Your State Laws)

In addition to exemptions for research information, over the last decade a few states have enacted exemptions specifically designed to prevent the disclosure of the personal information of individuals involved in research. Oregon has such an exemption which protects from disclosure the name, home address, professional address or location of a person that is engaged in, or that provides goods or services for, medical research at Oregon Health and Science University that is conducted using animals other than rodents. Utah enacted a similar exemption in 2008 to protect the name, home and work addresses, and telephone numbers of individuals who use animals in medical or scientific research conducted within the state's higher education system. And recently, Florida amended its Sunshine Law to exempt any identifying information of a person employed by, under contract with, or volunteering for, a publicly-funded research facility conducting animal research.

State open records laws generally require that information must be released unless the information is protected by an exemption. In some cases the personal information of individuals involved in research has been disclosed because the state did not have an exemption. One example of this occurred when a major research university provided requested documents, but redacted the names and addresses of individual researchers for security reasons. The university argued that the identity of the animal research scientists and their contact information did not constitute records for the purposes of the state's Public Records Act. However, the university's withholding was challenged and the court rejected the arguments holding that there was no specific statutory or constitutional exemption in the state's law that protects public employee's names and addresses.

#### Slide 11 (Be FOIA-Ready)

For those involved with animal care and use programs at public institutions, it's very important to be aware of the laws in your state and ensure that any documents which might be released are FOIA-ready. FOIA-ready is a term I frequently use, but not without first giving credit to Betty Goldentyer who mentioned it in a telephone conversation we were having. "FOIA-ready" documents are ones that are factual, devoid of extraneous information, and accurately reflect an institution's animal care and use program.

As information obtained under the FOIA or a state open records law is often posted online, research facilities should consider doing a risk analysis to determine what consequences would ensue if the information in their records were to be posted on a website. The FOIA-ready standard would apply to IACUC minutes, protocols, medical and necropsy records, and any other records maintained in support of the institution's animal care and use program. Remember that emails are considered records and as such should be FOIA-ready when conducting animal care and use program business. Nothing beats a face-to-face meeting or even a phone call when it comes to discussing protocol-related issues or unexpected events that can occur in an animal care and use program.

In addition to ensuring that your documents are FOIA-ready, you need to have in place, a records retention policy that meets the requirements of your state's open records act but does not unnecessarily retain records that could be requested. This is particularly true for health and necropsy records which are not required by the Animal Welfare Act but are necessary to manage a program of veterinary care. Requests for health and necropsy records often result in the need to release thousands and even tens of thousands of pages of information.

Some institutions have adopted the language in a previous USDA policy and maintain such records for a year following an animal's disposition or death but each institution needs to establish a policy that meets the requirements of their state's open records act. A retention policy for other records that are not required by the federal statute or policy should also be established. Such records include those associated with internal regulatory compliance activities, quality assurance issues, and correspondence with accrediting bodies.

Slide 12 (Want to Learn More?)

For those of you interested in learning more about dealing with FOIA requests, I would recommend a document entitled ["Responding to FOIA Requests: Facts and Resources"](#) [PDF] which provides information on best practices for dealing with both FOIA and state open records acts requests. Working in conjunction with the Society for Neuroscience and the Federation of American Societies for Experimental Biology, NABR developed this document for investigators whose grants are subject to FOIA. When a request is made for information on grants, investigators are often contacted by the funding agency and they need to know what to do. That said, this document contains a lot of information applicable to anyone dealing with FOIA or states open records acts.

>>*Babcock*: Thank you, Taylor. Now we are going to leave the state laws and return to our discussion of the federal FOIA. Betty Goldentyer will talk about the impact of the federal FOIA on records from registered research facilities in possession of Animal Care. Betty?

### Slide 13 (FOIA and APHIS, AC)

>>Goldentyer: Thanks, the federal Freedom of Information Act, as Dr. Snyder described, applies to all federal programs including USDA APHIS Animal Care. Records that are in the possession of USDA, to include photos and emails, are subject to the FOIA and will be made public on request unless exemptions apply.

Documents that are already available to the public, such as anything on [our website](#) like the inspection reports and the Annual Reports, have been affirmatively released, and are available without going through the FOIA office. If you need help finding those documents, you can contact Animal Care regional offices directly.

So what does Animal Care have in our possession? Animal Care maintains the inspection reports, applications for registration and renewals, the Annual Reports, and correspondence like a letter appealing a report or advising us of a personnel change.

### Slide 14 (Noncompliance Documentation)

Documents and photos may be collected by the inspector in support of noncompliance. The Required Inspection Procedures chapter, chapter 2, of the Inspection Guide provides guidance to you and the inspectors on what should be collected and how it should be collected. Only photos or records in support of a failure to comply will be collected. The inspector will show you the records being collected and provide a 24 – 48 hour window of time for you to redact the documents if you think it's necessary. We've asked the inspectors to use a camera, not a cell phone to take photographs. You can make copies of documents if you prefer that to photographing a document.

FOIA requests to APHIS all go through a central FOIA point-of-contact and are reviewed as Dr. Snyder described. If you have identified correspondence or other documents as confidential business information, FOIA will contact you prior to releasing that information. Correspondence, photos, records, not marked confidential, may be released without first advising you, but always – if they do see confidential or personal information – it will be redacted.

### Slide 15 (APHIS FOIA Reading Room)

APHIS maintains a [FOIA Reading Room](#) which is accessible from the APHIS homepage. Previously released material is posted periodically which relieves the FOIA office of the task of releasing the same information multiple times. The requester can just be referred to the Reading Room. This previously released information may include photos even though photos associated with an inspection are not posted on the Animal Care Inspection Report website.

#### Slide 16 (Inspection Appeals)

Inspection reports that have been appealed are not posted to the website. They may, however, be requested and released (after redaction) through the FOIA office. The appeal letter, the original inspection report, and any associated photos, if requested through the FOIA office, may be released even before the appeal is resolved. If a facility is under investigation by Investigative and Enforcement Services, information still might be released after redaction. This is a good reminder to clearly identify confidential business information.

#### Slide 17 (Attention!! Annual Report Packets)

This year your Annual Report packets contained an insert from the FOIA office. There is good information in the packet regarding the exemptions and identifying your confidential business information. We did get some questions about the block on the Annual Report that asks for site locations, as a physical address may pose a security concern. Please call the inspector or the office with these or any other concerns, as there may be options for reporting that provide appropriate information but don't pose the same concern.

#### Slide 18 (Review Your Documents)

All the inspection reports and Annual Reports, just about every application for registration, all the correspondence and enforcement actions can be, and are, requested through the FOIA. So it is important to have a process in place to review those documents.

#### Slide 19 (Responsible Agency)

Each agency remains the responsible office for its own records. If we get a request for NIH or FDA records, the request is referred to the agency that maintains the record but the FOIA applies to all federal agencies. Now, Axel is going to discuss how it works at OLAW.

#### Slide 20 (FOIA and NIH)

>> *Wolff*: Yes, thank you, Betty. I'm going to explain how OLAW addresses FOIA requests. Documents in possession of the NIH and OLAW are subject to the federal Freedom of Information Act. Private citizens, activist groups, and media representatives are examples of the types of individuals who commonly file FOIA requests for documents in the possession of OLAW. The types of documents requested range from copies of an institution's Assurance or annual report to compliance cases or written communications.

#### Slide 21 (NIH FOIA Process)

Requests should not be made directly to OLAW but rather to Dr. Snyder in her capacity as the Office of Extramural Research FOIA coordinator. The request is given a unique identifier, date of receipt at NIH, and the text of the message from

the requestor. The identification number is necessary for tracking and maintenance as an official record. The date of receipt is important because this is the cutoff or end date for the search of a record. Requests cannot be made for future records – only those responsive to the request up to the date of request. The request must be for specific records in the possession of OLAW. The text from the requestor defines the types of records, dates of the records, and specificity of the information desired, such as a record from a named institution or records within defined dates.

#### Slide 22 (Responsive Records)

Some requests are made for information such as noncompliance cases sorted by species or investigator. But because OLAW does not maintain records arranged in this fashion, the FOIA request cannot be fulfilled. OLAW staff evaluates the request and determines whether the material requested is present. If so, all responsive records are forwarded to the NIH OER FOIA office for review. In consultation with OLAW, if it is determined that part or all of the documents should be withheld, then a request for denial of release is sent by OLAW and the OER FOIA coordinator to the NIH Freedom of Information [Act] officer, who makes a determination as to whether the records can be released. In other words, OLAW staff does not apply the FOIA withholding exemptions. This action is performed by the NIH FOIA officers and legal staff. However, OLAW always requests that the FOIA officers withhold information about open noncompliance cases.

Once the responsive documents have been identified, the search time, pay grade of individual conducting the search, and number of responsive pages is recorded. This is for calculating any costs charged to the requestor and this information becomes part of the official file record.

#### Slide 23 (What To Provide OLAW)

Because any records in OLAW's possession could be subject to FOIA release, institutions should provide OLAW with only that information that is required and used for official business. Do not include personnel records or resumes or animal facility floor plans sent with an Assurance or names of individuals involved in a noncompliance report. If you are not sure what to include, you can telephone my office at (301) 496-7163 and we can discuss what you need to include in the report. Then just send only that information. Do not include additional information in your report.

#### Slide 24 (Why Info Is Requested)

Individuals request information from OLAW under FOIA for a variety of reasons such as:

- curiosity or interest in animal welfare;
- media interest;
- personnel issues or lawsuits;

- whistleblowers who want to see the results of their efforts;
- interest by nonprofit organizations; and
- to obtain factual information that may, however, be subsequently misrepresented to the media or public.

The potential distortion of factual documents obtained under FOIA is a concern to OLAW and USDA and that is why we are sharing our policies regarding how we share information between our two agencies. First, Betty will explain the USDA policy.

#### Slide 25 (Reporting Adverse Events at Research Facilities on USDA Inspection Reports)

>>*Goldentyer*: In order to accurately reflect the compliance status at each inspection, Animal Care recently released a [Tech Note](#) [PDF] outlining the process when inspecting reports of adverse events. Animal Care Veterinary Medical Officers will acknowledge, on the report, the self-correction by an institution of a serious adverse event or incident so that the current compliance status of the institution is accurately portrayed.

These are usually adverse events that were self-reported, in other words your institution communicates with a member of Animal Welfare Operations, the VMO, Supervisor or one of the Regional Offices, regarding the event. That communication could be by email, telephone or letter.

#### Slide 26 (Serious Events)

Let me define what I mean by serious events. Serious adverse events or incidents are those that led to significant injury or illness, unrelieved pain or distress, or the death of the animal. And we're talking about incidents here, not pain or distress associated with research.

#### Slide 27 (Citation)

Inspection procedures regarding self-corrected serious adverse incidents or events are currently outlined in the Inspection Guide and the 2012 Stakeholder Announcement. I have supplied OLAW with a copy of those procedures. You can find it on the [OLAW website](#) in the supporting material that accompanies the recording of this webinar [See [November 2014 Tech Note](#) (PDF)]. A citation will be written if the incident resulted in significant injury or illness, unrelieved pain or distress, or death of an animal as a result of noncompliance with a regulation or standard. In accordance with the Memorandum of Understanding which permits information sharing between OLAW and Animal Care, an inspector may choose to indicate OLAW's decision regarding the incident on the inspection report when there is documentation.

Slide 28 (No Citation)

Animal Care 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 of those criteria are not met.

Slide 29 (Third Party Complaints)

Lastly, complaints from third parties involving previously reviewed noncompliances will not be revisited. And any event over 3 years old will not be revisited by Animal Care or OLAW.

Slide 30 (Why?)

This decision is also in accordance with the Memorandum of Understanding which was designed to foster continual improvements in animal welfare, reduce duplication in oversight, and lessen regulatory burden.

Slide 31 (Question 1)

>>*Zimmerman*: Hello everyone, this is Nicole. We have some questions about this USDA policy for Betty to review now. What is Animal Care's policy regarding the review of past incidences of noncompliance?

Slide 32 (Answer 1)

>>*Goldentyer*: An inspector may choose to review past incidences of noncompliance when it is determined by their professional judgment to be warranted. For example, new information may become available. In the event that a third party requests review of a past incident of noncompliance, the event will not be re-visited if it was previously reviewed or if it occurred 3 years or more in the past.

Slide 33 (Question 2)

>>*Zimmerman*: Can USDA APHIS cite an institution for a serious adverse incident that was already investigated and the case was closed by OLAW?

Slide 34 (Answer 2)

>>*Goldentyer*: Yes. APHIS can cite the incident if:

- it resulted in serious adverse effects;
- was not corrected in a timely manner;
- effective preventative measures were not put into place; or
- there was a history of repeated noncompliance.

Slide 35 (Question 3)

>>*Zimmerman*: Will self-reporting an adverse event prevent the issuance of a citation?

Slide 36 (Answer 3)

>>*Goldentyer*: No. Self-reporting has no bearing on whether a citation will be issued but may be taken into consideration as evidence of “good faith” in the event of an enforcement action.

Slide 37 (Question 4)

>>*Zimmerman*: Is it a requirement to report serious adverse events and incidents to the USDA?

Slide 38 (Answer 4)

>>*Goldentyer*: No, it's not required. The following are required and these are the only things that are required:

- 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 of course
- the Annual Report [9 CFR §2.36].

>>*Zimmerman*: Thank you for answering those questions. Now Axel will explain OLAW's policy on sharing animal welfare concerns with USDA which was published on December 1, 2014 as NIH Guide Notice [NOT-OD-15-028](#), Notice of Office of Laboratory Animal Welfare Policy on Shared Animal Welfare Concerns.

Slide 39 (OLAW Requires Self-reports)

>>*Wolff*: Thank you, Betty and Nicole. PHS-Assured institutions are required by the PHS Policy ([IV.F.3.](#)) to self-report any serious or continuing noncompliance to OLAW. Institutions may also choose to share self-reports of noncompliance with Animal Care as a demonstration of their commitment to continual animal welfare improvement, timely correction of noncompliance, and prevention of recurrence.

Slide 40 (OLAW Shares Self-reports)

Under a Memorandum of Understanding, OLAW frequently shares self-reports of serious animal welfare concerns involving USDA regulated species with Animal Care Animal Welfare Operations (formerly called AC Regional Offices).

Slide 41 (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 Animal Care to share serious animal welfare concerns and issues of interest to both

agencies. Institutional self-reports are shared with Animal Care after OLAW's investigation is completed.

#### Slide 42 (USDA Citations)

As they describe in their Tech Note, 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.

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

#### Slide 43 (Time Limit)

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

#### Slide 44 (OLAW Shared Animal Welfare Concerns Policy)

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

#### Slide 45 (Question 5)

>>*Babcock*: Axel, What are examples of serious animal welfare concerns that OLAW will share with USDA?

#### Slide 46 (Answer 5)

>>*Wolff*: OLAW will share serious noncompliance that involves regulated species such as death from weather extremes, death from an animal going through the cage washer, and death as a result of a heating, ventilation or air conditioning failure.

#### Slide 47 (Question 6)

>>*Babcock*: Will you share concerns about non-regulated species?

#### Slide 48 (Answer 6)

>>*Wolff*: No, OLAW will not share concerns about mice, rats or birds.

#### Slide 49 (Question 7)

>>*Babcock*: What happens when Animal Care gets a report from OLAW and OLAW has already worked with the institution to resolve the concern and closed their case?

Slide 50 (Answer 7)

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

>>*Babcock*: Betty and Axel have given us a lot of information about what goes on within our federal agencies. Now Taylor is going to provide practical information for our audience from the perspective of the institution. Taylor?

Slide 51 (Being Prepared is the Key)

>>*Bennett*: Yes, George, preparedness is the key to a proper and efficient response to a FOIA or open records request. What do you need to be prepared for? In 2013, almost half of the 110 FOIA requests to NIH from national animal rights groups were for information on grants, with only 12 of the requests involving information from OLAW. In 2014, information on grants is still the most frequently requested item, but the number of requests for information from OLAW has doubled and many of those requests are for information from multiple institutions.

The other thing that's interesting is that before releasing a funded grant application, NIH will ask the grantee for advice concerning patent rights and other confidential commercial or financial information. NIH will consider that advice and, if they agree, they will remove that information from the application before they release it. In addition, they will remove information that would be an invasion of personal privacy if released. Therefore, research institutions should identify a point person within the institution to keep all relevant parties informed and coordinate an orderly response to FOIA or state open records laws. The point person should be familiar with the sensitive nature of animal research documents and have a full understanding of all relevant laws and regulations. Depending on the administrative structure of the institution, the point person may be someone within the legal counsel's office or someone within the research administration office. All relevant individuals should know who the point person is and the appropriate institutional procedure for responding to a federal FOIA or state open records requests.

In proactively preparing for a FOIA or open records request, a research facility should consider ensuring that their documents – especially frequently requested documents – are, as stated repeatedly, FOIA-ready and that records and reports contain only that information required by the regulatory and funding agencies. I mention reports because whether an institutions is subject to state open records act or not, any correspondence or reports to federal agencies are subject to being obtained under FOIA and should only contain the required information. Also do not forget publications are by definition public documents and thus need to be reviewed in light of how others will perceive what is stated and/or depicted.

#### Slide 52 (Process)

After receiving an inquiry about a federal grant FOIA request from NIH or a state open records request, the institution's counsel should review all exemptions to determine whether sensitive information falls within the scope of an exemption. Research institutions responding to a FOIA or state open records request should also accurately estimate the cost of their response. In the case of open records requests, state law usually dictates what costs public institutions can require the requestor to pay. Some states allow public institutions to charge the actual costs of responding to records requests. Other states, however, are more limited and may only permit certain costs to be recouped. If state law does not allow the research institution to charge the actual cost of responding to the request, it should nevertheless consider keeping a log of the expenses to determine if it is responding in the most efficient manner possible. Federal regulations also permit certain costs to be recouped in some situations when information is requested from a federal agency under the FOIA.

Animal rights organizations increasingly turn to the federal Freedom of Information Act and state open records acts to obtain information about research using animal models. Research facilities should ensure that they understand and comply with all relevant laws and regulations related to the disclosure of such information. In particular, a research facility should carefully assess whether exemptions for research information or personal information can be used to protect sensitive information from disclosure.

>>*Babcock*: Now we have some comments that OLAW received from a PHS-Assured institution prior to this webinar. We have covered some of this material in a global fashion in the webinar. Now our panel will address these issues in this specific context.

#### Slide 53 (Question 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.

#### Slide 54 (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.

Slide 55 (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's and USDA's mission of improving animal welfare and reducing regulatory burden. Betty?

Slide 56 (Answer 8)

>>*Goldentyer*: It is critical that we all use our time and resources wisely. And our partnership with OLAW helps us do that. The questioner is also correct that we need to provide an accurate picture of the compliance at each facility to the public. So there's the rub. Noncompliance, impacting an animal, occurred at the facility. Identifying and documenting noncompliance is our job and the public expects those noncompliances to be reflected on the inspection report for transparency and tracking.

Slide 57 (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.

Slide 58 (Answer 8 Continued)

We recognize and appreciate the efforts that went into preventing a recurrence and we have advised the inspectors to acknowledge that on 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.

Slide 59 (Question 9)

>>*Babcock*: 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.

Slide 60 (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?]

Slide 61 (Answer 9)

>>*Snyder*: FOIA coordinators from other units of NIH will make pre-disclosure notifications of grant applications and other documents that may contain information protected under Exemption 4 – Trade Secrets, or commercial information. Since OLAW has advised the institutions not to include such information in their reports, OLAW documents are not routinely forwarded to the submitter for review. However, I sometime seek clarification from an institution if I have questions regarding the contents of a document. The Regulations and [Executive Order 12600](#) have provided for pre-disclosure notification where it is reasonable to believe that the release of the information in the records could be considered to cause competitive commercial harm. Additionally, I note, in litigation where an institution is a nonprofit it is hard to demonstrate commercial harm.

Slide 62 (Summary)

>>*Babcock*: I would like to thank our speakers for this excellent webinar. So Axel, Betty, Maggie, Taylor and Nicole, thank you. Before we sign off, I would like to briefly summarize some of the important points brought out in this informational filled webinar.

- [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.

Slide 63 (Summary)

- In addition to federal FOIA, every state has a law that governs access to records.
- Institutions should be aware of the FOIA laws in their state which may 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 institution's animal care and use program.
- Having in place a records retention policy that meets the requirements is also important.

#### Slide 64 (Summary)

- Federal FOIA laws also apply to USDA records including photos and emails. However 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 over 3 years old will not be revisited by Animal Care or OLAW.
- Under a Memorandum of Understanding, OLAW frequently shares self-reports of serious animal welfare concerns with Animal Care when USDA-regulated species are involved.

#### Slide 65 (Resources)

On this slide, we have provided [links to resources] you may find useful. You can download a PDF copy of the slides or the transcript of this webinar from [the OLAW website.]

- *NIH FOIA Office:* <http://www.nih.gov/icd/od/foia/>
- *NIH OER FOIA Office:*  
[http://grants.nih.gov/grants/oer\\_offices/subopac\\_foia.htm](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.jsp>
- *USDA APHIS FOIA:*  
[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](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)
- *USDA Tech Note November 2014:*  
[http://www.aphis.usda.gov/animal\\_welfare/downloads/Adverse%20Events%20on%20Inspection%20Reports%20-%20Tech%20Note.pdf](http://www.aphis.usda.gov/animal_welfare/downloads/Adverse%20Events%20on%20Inspection%20Reports%20-%20Tech%20Note.pdf)

#### Slide 66 (Next OLAW Online Seminar)

Please remember to email any questions concerning today's webinar to OLAW, which we will answer and add to the transcript of this webinar. Thanks to all of you for participating and we look forward to our next webinar in March 2015, which will be on IACUC Review of Aquatic species. Thank you and good bye.

## Additional Submitted Questions Not Addressed During the Webinar

Question 10. Are progress reports for P40 grants and others considered in the public domain once they have been submitted?

>>*Snyder*: Once submitted, the progress report would be considered the property of the government and thus subject to FOIA. The FOIA coordinator, in consultation with the program officer (the source of the document), would review its contents and decide if they have “reason to believe that disclosure of the information could reasonably be expected to cause substantial competitive harm.” [[Ex. Order 12600 Sec. 3\(a\) \(ii\)](#)] I can’t speak for the other FOIA coordinators, but a telephone call to the program officer would be helpful if the submitter has included intellectual property within the report.

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