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Note: Text has been edited for clarity.

Developments in FOIA in the Context of Animal Research

Speakers:

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- Gorka Garcia-Malene, JD, MS, NIH FOIA Program

Broadcast Date: December 10, 2020
View Recording: https://youtu.be/Mo3wSc4MI0w (YouTube)

Slide 1: Developments in FOIA [Freedom of Information Act] in the Context of Animal Research
>> Cate: Hello. Today is Thursday, December 10th, 2020. I am Cate Pritchard, part of the Division of Policy and Education at [the Office of Laboratory Animal Welfare] OLAW, and today it is my pleasure to welcome our speakers, Dr. Axel Wolff, and Mr. Gorka Garcia-Malene to the OLAW Online Seminar series to present the seminar titled "Developments in FOIA in the Context of Animal Research."

Mr. [Dr.] Axel Wolff currently serves as Deputy Director at OLAW. Here, he also served as the Director of the Division of Compliance Oversight and as a Senior Assurance Officer. Prior to joining OLAW, Dr. Wolff was the director of the Veterinary Resources Program, in [the National Institutes of Health's] NIH's intramural biomedical research support program. His interest in unique research animals has involved him in work with armadillos, chimpanzees, and fruit bats as well as more common species.

Mr. Gorka Garcia-Malene directs the FOIA program at the NIH. Concurrently, he serves at the National Archives and Records Administration's Chief FOIA Officer's Technology Subcommittee, which studies the deployment and use of technology in FOIA programs across the executive branch to identify best practices and develop technology-based recommendations to the FOIA community. He began his career working in the litigation department of a major law firm. He then joined the FDA's [Food and Drug Administration's] Center for Drug Evaluation and Research FOIA program, specializing in FOIA litigation. He went on to assume the role of FOIA officer at FDA's Office of International Programs, where he also managed the agency's relationship with the Government of Canada and headed the FDA's successful efforts to establish information sharing frameworks and memorandums of understanding with the agency's foreign regulator[y] counterparts. Before joining NIH, he served as a FOIA officer at FDA's Center for Veterinary Medicine. He is a registered patent attorney and is barred in the District of Columbia.

And with that, it is my pleasure to welcome you to the OLAW Online Seminar, and I will now hand the microphone over to Axel.

Slide 2: As Part of a Federal Agency, OLAW Is Subject to FOIA.
>> Axel: Thank you, Cate. Let me start off by noting that the Office of Laboratory Animal Welfare, OLAW, is a component of the National Institutes of Health which is part of the Department of Health and Human Services. As such, OLAW is subject to the provisions of the Federal Freedom of Information Act, or FOIA. This differs from what institutions may be subject to in their home states, such as open records laws, sunshine laws, or other statutes similar to FOIA.

Slide 3: FOIA
FOIA was enacted in 1966 and took effect on July 4th, 1967, thus establishing an effective statutory right of public access to executive branch information in the Federal Government. The law was enacted to promote transparency and ensure accountability of government officials and agencies.

Slide 4: FOIA (Continued)
FOIA provides any person the right, which is enforceable in court, to access federal agency records, except those that are protected from public disclosure by specific Exemptions and exclusions, which will be discussed later.

Slide 5: Many Different Categories of People Request OLAW Records Through FOIA, Including:
Examples of the categories of individuals requesting OLAW records include: media representatives, attorneys, animal activist groups, students, interested citizens, and institutional employees.

Slide 6: OLAW Does Not:
The FOIA is a disclosure statute. This means that responsive records will be released unless Exemptions apply. Records within OLAW's possession are subject to release under FOIA. OLAW does not create records, alter records, consider the identity of the requester, consider the potential use of the record, [or] create ways to search for responsive records.

Slide 7: Information Released Under FOIA May Be Used To:
Information accessed under FOIA is often used by activist groups to attempt to influence the public and end the responsible use of animals in research. Information has been used to issue misleading press releases, request investigations, and ultimately ask for enforcement actions against researchers and institutions for alleged noncompliance with animal welfare laws. Information is also used by the media in articles, by students writing position papers on animal research, by attorneys filing suit on behalf of a client, by disgruntled employees wishing to embarrass an institution by publicizing negative information or to support allegations of reprisal, by citizens looking for pets, or simply curious individuals wishing to follow up on a news article.

Slide 8: From January – September 2020, OLAW Received 209 FOIA Requests.
This chart illustrates the amount of requests submitted to NIH for OLAW records. From January to September of 2020, a total of 209 individual submissions were made. These yielded a total of 3,187 separate reports of noncompliance. These requests also led to release of 1,616 Assurances with Annual Reports. Of the 209 requests made, 204 were from activist groups.

Slide 9: It Is Very Likely That Your Institution's Records Will Be Released Under a FOIA Request to OLAW!
There is an extremely high likelihood that your institution's records, including noncompliance reports, Assurances, Annual Reports, correspondence, photographs, and other media will be released under a FOIA request to OLAW.

Over the last ten years, very broadly worded FOIA requests have been submitted seeking information for all research institutions with an animal welfare Assurance in the given state or states. In previous years, an individual may have requested [a] single case file for a single institution. This is no longer the case, and requests are now being made in the form of an ever-widening net, whereby a single request may be for all correspondence between OLAW and every institution in the state of California. This one request can yield dozens or hundreds of documents. This is compounded when the same request asks for all documents in a series of states, which may just be in alphabetical order taken from the OLAW list of Assured institutions. Based on these trends, the likelihood is very high that your institution's records on file with OLAW will be released.

Slide 10: When Reporting to OLAW, Think "Minimal, but Complete":
Ensure that information provided to OLAW is complete and accurate, but do not include information that is not required by this office, such as personal identifiers, room numbers, building plans, photos, videos, [or] graphic descriptions. We have a great website on reporting noncompliance, including what should be in the preliminary and final report. You can find it at the URL listed on this page. If you have any additional questions, you are always welcome to contact the OLAW Division of Compliance Oversight, and their information is also listed on the page linked here. Note that routine telephone inquiries about whether an item is reportable does not generate a record of call and is therefore not releasable under FOIA. Only an official record of call becomes a record and would be releasable upon closure of the case.

Slide 11: OLAW Cannot Alert Institutions About FOIA Requests We Have Received.
Note that OLAW cannot alert institutions as to whether a FOIA request has been filed for your institution's records. It is best to prepare documents anticipating that they will be released unless exempt. I will now turn the microphone over to Gorka, who will go into greater detail on how NIH handles FOIA requests.

Slide 12: The Freedom of Information Act
>> Gorka: Thank you, Dr. Wolff. My name is Gorka Garcia-Malene, I am the director of the FOIA program at the National Institutes of Health. I am delighted to have the opportunity to join this important conversation regarding the Freedom of Information Act, more commonly referred to as FOIA.

Slide 13: Purpose of FOIA
Dr. Wolff explained it well. FOIA is an important means for transparency. More specifically, it is a mechanism for disseminating agency records that enables the public to know what the government is working on. That said, not all information in government records can be released. And we'll visit that in a few moments. The Freedom of Information Act, FOIA, contains Exemptions that set out what types of information must be withheld. ~~If~~ [These] exemptions are applied judiciously, recognizing that FOIA is a vital part of our democracy.

Slide 14: Who Can File a FOIA Request?
I often receive this question: who can file a FOIA request? The answer is, virtually anybody and anything. You don't need to be a U.S. citizen. You don't need to be a human. Entities like state agencies and companies can file requests. Your attorney, with your permission, can also file a FOIA request on your behalf. There are a few exceptions to who can file a request. For example, federal agencies cannot file a FOIA request, nor can fugitives.

Slide 15: Who is Subject to FOIA?
Another important distinction is: "Who is subject to FOIA?" Only one of the three branches of government is subject to FOIA. Neither the legislative nor the judicial branch are subject to this law. Instead, FOIA applies to agencies in the federal executive branch, independent regulatory agencies, and some components in the Executive Office of the President. States tend to have their own sunshine laws, as they're called, permitting requesters to seek state records directly from state offices.

Slide 16: FOIA or Privacy Act?
It is important that requests are filed appropriately when seeking records. We see with some frequency that requestors will file a FOIA request for records that really ought to be processed under the Privacy Act. These are two distinct programs, and it behooves the requestor to distinguish between the two. FOIA provides a right of access to agency records for anyone who asks. That means that the information will typically be reviewed as though the requestor is any person or any entity. In contrast, the Privacy Act allows individual people to seek access to records about themselves, so these will tend to release more information to the requestor, given that the records are about them. You can file Privacy Act requests with the privacy program of each agency. I would consult agency websites for instructions on how to do so.

Slide 17: What Is an Agency Record?
We know that FOIA is a mechanism for accessing agency records. The natural question arises: "What is an agency record?" Records generally are any handwritten, typed, or printed documents, or any documentary material in other forms. That includes electronic information, like emails. Whether they are agency records turns on whether they satisfy two categories: that they are either created or obtained by the agency, and that they are under the agency's control at the time of the request.

Slide 18: Does FOIA Cover Records Sent to an Agency by Institutions?
From the previous slide, we can linger for a moment on the phrase "obtained by the agency." Does that mean, for example, that FOIA covers records sent to NIH by institutions? The answer is yes, so long as they meet the definition of an agency record. However, this does not mean that requesters have unfettered access to copies of these submissions. FOIA provides for categories of information that cannot be released, and that information will be redacted prior to their release. When the institution is a federal agency, NIH may send the request along with the records to that federal agency for their review, redaction, and release.

Slide 19: How We Process Requests:
I'd like to take a moment to provide some perspective into all the work that goes on when we receive a FOIA request. Agencies typically have 20 working days to process a request. And the clock begins to tick when the correct office receives the request. In that time there are several steps that take place. First, we ensure that the request is perfected. In other words, that NIH staff can reasonably ascertain exactly

which records are being sought, and where to locate them with a reasonable amount of effort. It's important to note that FOIA was not intended to make agency staff spend countless hours seeking difficult-to-find records.

Slide 20: How We Process Requests (continued)
If a request is unclear, agency FOIA staff will seek clarification from the requestor. This stops the processing clock until the agency receives a satisfactory clarification from the requestors. It is common for FOIA staff to reach out to a requestor to help shape the scope of the request, in order to help the requestor receive the information they need while reducing the work that the agency has to do. After all, our work is funded with taxpayer dollars, and we do not relish dedicating those funds to unnecessary processing.

Slide 21: How We Process Requests (continued)
Our FOIA staff typically lacks access to the records sought by the requestor, so the next step is for the FOIA staff to seek the records from specific staff members. If the records sought do not exist, we simply inform the requestor of the fact and close the request. It bears noting that FOIA does not require an agency to create a record to respond to a request. It's a mechanism to provide existing records to requestors.

Slide 22: How We Process Requests (continued)
Once we have the records, FOIA staff will review the records to determine whether they are the correct records. In other words, we make sure that the requestor receives what they asked for. In addition, we determine whether the information included in the records is protected from disclosure by any of the Freedom of Information Act's Exemptions. We'll cover these next. However, before we turn to the Exemptions, I should note that the review process can be quite demanding. Depending on the complexity of the request, multiple layers of review may be necessary, and submitters of the information and agency subject matter experts may need to be consulted during the review.

Now is a good time to cover those Exemptions.

[*Regarding the text in the last bullet for slide 22: “OD FOIA Officer” refers to the presenter, who is the Office of the Director Freedom of Information Act Officer at the National Institutes of Health]

Slide 23: FOIA Exemptions
FOIA provides that a person has the right to access federal agency records, except to the extent that the information in those records is protected from disclosure by any of the nine Exemptions contained in that law. I will describe these briefly; though please note that there is a rich history in case law further defining the contours of each Exemption.

Slide 24: Exemption 1 and 2
You'll find that some of the Exemptions don't particularly apply to NIH. For instance, Exemption 1 covers national security information or classified information. Exemption 2 protects from disclosure information relating to internal personnel rules and practices.

Slide 25: Exemption 3
Exemption 3 is a placeholder and sets out that information identified by other legislation is recognized and protected under FOIA. One such example is 15 U.S.C. Section 3710, which restricts what royalty information agencies are permitted to release. This law is not affiliated with FOIA, but we would cite to Exemption 3 and to 15 U.S.C when withholding that information.

Slide 26: Exemption 4
Exemption 4 is commonly used at NIH. Folks are typically surprised to learn that a large proportion of the FOIA requests we receive are for grant records. These and other types of records are submissions to the agency that tend to contain a good deal of trade secrets or confidential commercial information. That is what Exemption 4 is meant to protect.

Slide 27: Exemption 4 (Continued)
So why are these types of information protected? This Exemption is intended to protect the interests of both the government and the submitters of the information. It affords protection to those submitters who furnish commercial or financial information to the government by safeguarding them. In so doing, it encourages submitters to furnish useful commercial or financial information to the government and it correspondingly provides the government with an assurance that such information will be reliable, so it can conduct its business.

Slide 28: Exemption 4 – Trade Secrets
The first category of information covered by Exemption 4 are trade secrets. These typically relate to the manufacturing process. I've listed some examples below to help conceptualize what it covers. For example, it includes product formulations, chemical compositions, quality control procedures, sterilization and cleaning procedures, production procedures, blueprints, or design specifications. But this is by no means an exhaustive list.

Slide 29: Exemption 4 – Confidential Commercial Information
The second category of information covered by Exemption 4 is confidential commercial information. That is, information that is commercial or financial, obtained from a person, and is privileged or confidential. All three of these must be satisfied for information to benefit from protection under Exemption 4.

Slide 30: Exemption 4 – Confidential Commercial Information
Let's go through these one-by-one. Commercial or financial means related to business or trade. Examples include information related to leases, prices, quantities, reserves, business decisions, names of key personnel, statements of work, financial situations, etcetera.

Slide 31: Exemption 4 – Confidential Commercial Information
Obtained from a person. This requirement simply means that information generated by the Federal Government is not typically protected by Exemption 4. It’s typically meant to protect information that is provided by a party outside of the Federal Government.

Slide 32: Exemption 4 – Confidential Commercial Information
And the last requirement, privileged or confidential. This is fairly intuitive. For information to be protected as confidential commercial information, it must be customarily and actually treated as private. Sometimes, submitters of information will insist that we redact certain information from their

records prior to release, when a cursory search of their public-facing website shows the information is posted for everyone to see. In that case, typically the information would not be confidential. Another important aspect of this requirement is that there were no express or implied indications at the time the information was submitted to the government, that the government would publicly disclose the information. For example, if NIH informs submitters that it typically posts a particular type of record, submitters are on notice that their submissions would likely be released.

Slide 33: Exemption 4 – Confidential Commercial Information
I've included some examples of confidential commercial information that you might find useful. These include: SOPs, sales data, unit pricing, future business plans, customer or supplier relationships, consultants or contractor relationships, clinical trial data gathered by a drug company, or, for example, pending product approval records, and that might also fall under Trade Secrets. Again, this is by no means an exhaustive list, but I hope that it helps conceptualize what confidential commercial information covers.

Slide 34: Exemption 5
Exemption 5 protects the internal, pre-decisional deliberations of government staff. At the heart of this Exemption is the protection of our internal deliberations, so that the specter of release under FOIA does not chill internal discussions. This Exemption also protects advice sought from or provided by government attorneys, as well as those attorneys' work product.

Slide 35: Exemption 6
Exemption 6 is not typically controversial. It seeks to protect information that, if released, would result in a clearly unwarranted invasion of privacy. This extends to, for example, all personal phone numbers, all personal emails, personal addresses, personal plans, the names of family members, etcetera. This is particularly relevant in this day and age, where passionate members of the public take it upon themselves to interrupt the personal lives of public servants and institutional staff. And this is also why NIH is particularly careful to guard against the release of any information that would identify whistleblowers, including, for example, their title, their position, their supervisor, anything that would help anyone ascertain their identity.

Slide 36: Exemptions 7, 8 and 9
Exemptions 7, 8, and 9 protect certain information in law enforcement files, information held by financial regulators, which NIH isn't, and geological and geophysical information, which I haven't seen in my tenure.

Slide 37: Exemptions Most Often Applied to OLAW Records, and Examples
I wanted to take a moment to discuss the Exemptions that we see most frequently at NIH. Those are Exemptions 4, 5, 6, and 7. When dealing with OLAW records, Exemption 4 is frequently used to protect private sources of funding. We use Exemption 5 to protect, for instance, information regarding a pending grant application or some other pending decision that has not been finalized by the agency. We usually use Exemption 6 to protect personal phone numbers and email addresses, the names of secondary staff (and that would include IACUC coordinators, graduate students, or clinical vets). Exemption 7 is cited to when the records relate to a pending investigation, so for example, where NIH is investigating noncompliance reports. During the pendency of that investigation, that information is protected.

Slide 38: Practical Considerations
Having considered the nine Exemptions, it may prove helpful to discuss some practical considerations for institutions to take into account. The first and second most important considerations are these: that most of the information submitted to OLAW by institutions is released upon request under FOIA. That said, all records are reviewed for redaction prior to release.

I hope the previous slide will also prove helpful in fine tuning your submissions to OLAW. To the extent permissible by OLAW, it's helpful for everyone involved if that information is not included in your submissions to OLAW, and the reason for this is that it minimizes the risk of an accidental release, and it helps us at the FOIA program to get records to the requesters as quickly as possible, because there's less to redact and less layers of review.

The reason we redact contact information, by the way, and that's the contact information of secondary individuals, for example, is that by releasing that information, requestors might simply pick up the phone and call a number to ascertain the name of the person on the other side of the line, negating the redaction of their names. So, it would just defeat the purpose of redacting just their names, and that's why we redact their contact information.

Slide 39: Recent Trends in FOIA
I also wanted to take a moment to discuss recent trends in FOIA requests arriving at OLAW. The number of requests for OLAW records has more than doubled in the last four years. Increasingly, the requestors also seek pictures submitted to the agency. There are other trends that I want to share with you in the next slide.

Slide 40: Recent Trends in FOIA (continued)
And please take this with a grain of salt. These are general perceptions we've gleaned over the past few years. Until about two years ago, requests for OLAW records were sporadic, they focused on specific institutions, and on specific species. It's difficult for me to put myself in the shoes of the requestors, but perhaps the goal at that time was to gather information rather narrowly for direct action, that is, for lobbying or for commenting on certain records publicly, posting those individual records. Something more akin to an informal oversight function over how OLAW conducted its work.

Now, requestors tend to systematize requests. So, for example, every few weeks, we'll receive a request for Annual Reports and Assurances for the next batch of Assured institutions. What that means is eventually, information is provided to requestors for all Assured institutions on a rolling basis. So, in addition to the work these requestors were conducting in the past, requestors appear to be building libraries of materials for further dissemination. Perhaps to amass a broader scope of information to empower local grass roots efforts.

Slide 41: Recent Trends in FOIA - Grants
I'd like to take a moment to revisit grant records. If only to emphasize that they are sought with great frequency, directly from NIH Institutes and Centers. To do so, requestors identify the grants sought using ~~OLAW's~~ [NIH's] online RePORTER tool. Frequent requestors usually sought records guided by species of interest. So, for example, they might seek specific grants regarding canines. However, of late, these frequent requestors are beginning to focus on animal use by field of research. So, for example, sepsis, regardless of species. Again, requestors appear to be building libraries of materials for further

dissemination. However, please note that the existence or information related to unawarded grants is never released by NIH.

Slide 42: NIH FOIA Program Contacts
In this last slide, I've included a link to the NIH FOIA program page. I also include my office's contact number [Phone: (301) 496-5633] and email [E-mail: nihfoia@mail.nih.gov] should you have any questions. I hope these remarks proved useful. With that, I'll hand the microphone back to Cate. Thank you, Cate.

Slide 43: Question 1
>> Cate: Great, thank you so much, Axel and Gorka. We do have a few questions that we received prior to the webinar. The first one is: "What information is redacted by OLAW?" Axel?

Slide 43: Question 1 Answer
>> Axel: Information is never redacted by OLAW. All responsive documents are forwarded to the NIH FOIA office for appropriate application of redactions and Exemptions.

>> Cate: Thank you. And Gorka?

>> Gorka: That's right, Dr. Wolff. All redactions are carried out by FOIA professionals, familiar with the materials, and experienced in FOIA Exemptions.

>> Cate: And this was discussed throughout a lot of the webinar, so if you have any questions, you can likely find it previously.

Slide 44: Question 2
>> Cate: Our second question is: "How can institutions limit the information provided to OLAW but still satisfy reporting requirements?" Axel?

Slide 44: **Question 2 Answer**
>> Axel: We addressed this in the webinar, but specifically for noncompliance reports, we need sufficient information that's required by OLAW to determine what occurred and the corrective and preventive measures taken. But individuals' names, contact information, and floor plans are not to be included.

>> Cate: Thank you. And Gorka?

>> Gorka: I would just second what Dr. Wolff's said. Not submitting that information increases efficiency on my end for our program for processing requests, and it also reduces the risk of releasing protected information.

Slide 45: Question 3
>> Cate: Great. The next one is an interesting one: "Are text messages subject to FOIA?" Axel?

Slide 45: Question 3: Answer
>> Axel: I am not exactly sure. I assume if one can be retrieved and is pertinent to official actions, it would constitute a record. But bottom line is, OLAW does not conduct official business with text messages.

Slide 46: Question 4
>> Cate: Great. And the last question is: "Does OLAW release AAALAC Program Descriptions under FOIA, given that it's a voluntary program and not a legal compliance requirement?" Axel?

Slide 46: Question 4 Answer
>> Axel: OLAW does not maintain AAALAC Program Descriptions. However, if portions of the Program Description are used to answer questions in the Assurance, then these would be releasable.

>> Cate: Thank you. And Gorka?

>> Gorka: I typically try to address these questions on a case-by-case basis. Generally speaking, I would say that AAALAC elements that are incorporated into Assurances probably don't benefit from protection under FOIA. However, I would have to evaluate that on a case-by-case basis.

Slide 47: Additional FOIA Resources Available From OLAW
>> Cate: All right. Thank you so much, Dr. Wolff and Mr. Garcia-Malene for your discussions. We truly appreciate your time and efforts to discuss FOIA as it relates to animal research, OLAW, and NIH.

At this point, I'd like to mention that OLAW has two additional resources available on FOIA: an OLAW webinar from 2008, and a podcast from 2016. They can both be found on the page listed at the bottom of this slide.

Slide 52: Next OLAW Online Seminar: 21st Century Cures Act Progress Updates
Our next online seminar will be on the 21st Century Cures Act Progress Updates in the spring of 2021. Until then, thank you for listening. Stay safe and healthy, and goodbye.

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