



United States Department of Agriculture

Marketing and
Regulatory
Programs

Animal and
Plant Health
Inspection
Service

Legislative and
Public Affairs

Freedom of
Information

4700 River Road
Unit 50
Riverdale, MD
20737-1232

March 23, 2021

Russ Kick
Open Records Specialist
Rise for Animals
333 Washington Street, Ste. 850
Boston, MA 02108
russ@riseforanimals.org

RE: Your Freedom of Information Act (FOIA) request, 2020-APHIS-01337-F

SENT VIA ELECTRONIC MAIL

Dear Mr. Kick:

This letter responds to your Freedom of Information Act (FOIA) request, tracking number 2020-APHIS-01337-F, dated December 15, 2019 and received December 16, 2019. Your FOIA request seeks:

*1a). According to The Guide for the Care and Use of Laboratory Animals (The Guide), 8th edition, all entities must have a system in place for anyone (insiders or members of the public) to report concerns regarding animal welfare at a facility. These reports are either made directly to the IACUC Chair or a designated representative, or they eventually are routed to the IACUC Chair/representative. **We request all such reported concerns received by the Chair since January 1, 2019.***

(This would encompass all appendices, annexes, attachments, and accompanying documents, including photos and videos in their original formats and resolution.)

*1b). **Further, for all such reported concerns deemed supported, we request the notification sent to the Institutional Official. The time frame is January 1, 2019, to present. (This would encompass all appendices, annexes, attachments, and accompanying documents, including photos and videos in their original formats and resolution.)***

*2a). Per The Guide, all entities must have a system in place for investigators to notify the IACUC and/or attending veterinarian of adverse events, unexpected or unanticipated outcomes, violations of protocols, and other incidents involving animal welfare that occur during their studies/experiments. **We request all such notifications received by the IACUC or AV since January 1, 2019.** (This would encompass all appendices, annexes, attachments, and accompanying documents, including photos and*

videos in their original formats and resolution.)

2b). Further, we request all notifications sent to the Institutional Official regarding these reported incidents. The time frame is January 1, 2019, to present. (This would encompass all appendices, annexes, attachments, and accompanying documents, including photos and videos in their original formats and resolution.) (Date Range for Record Search: From 01/01/2019 To 12/15/2019)

Upon receipt, your request was forwarded to the Animal Care (AC), Investigative and Enforcement Services (IES), and Wildlife Services program offices including the National Wildlife Research Center (NWRC) to conduct a search of their files for records responsive to your request. On December 19, 2019, the NWRC Quality Assurance Manager returned a response stating that they do not receive notice of adverse events and therefore, would not have any records related to this request. On January 2, 2020 and February 20, 2020 AC and IES searched their electronic database to locate records potentially responsive to your request. AC and IES found no responsive records. On December 19, 2019, Wildlife Services searched their electronic database and Outlook to locate records potentially responsive to your request. After a review of the records, it has been determined that 41 pages of records are responsive to your request.

As such, APHIS must release all requested records which are not exempt under the FOIA. Therefore, the records at issue have been reviewed under the FOIA. It has been decided that 31 pages of the records contain information that is exempt from release pursuant to FOIA Exemption 3, 5 U.S.C. § 552 (b)(3)(A), FOIA Exemption 6, 5 U.S.C. § 552 (b)(5), FOIA Exemption 6, 5 U.S.C. § 552 (b)(6) and FOIA Exemption 7, 5 U.S.C. § 552 (b)(7)(C).

The following information provides justifications and precedent for our withholding of information under the applicable FOIA exemptions:

Exemption 3(A)

Exemption 3 allows the withholding of information protected by a nondisclosure provision in a federal statute other than FOIA. The applicable statute in this instance is, 15 U.S.C. § 3710(a), Trade secrets or commercial or financial information that is privileged or confidential under the meaning of section 552(b)(4) of Title 5 which is conducted of research or as a result of activities under this chapter,” which pertains to Cooperative Research and Development Agreements (CRADA) for the purpose of technological and industrial innovation. The information withheld under Exemption 3(A) is a part of a CRADA and therefore, not releasable.

Exemption 5

Exemption 5 of the FOIA protects "interagency or intra-agency memorandums or letters which would not be available by law to a party other than an agency in litigation with the agency." The courts have construed this somewhat opaque language, with its sometimes-confusing threshold requirement, to "exempt those documents, and only those documents that are normally privileged in the civil discovery context." As a threshold matter, the responsive records must be inter-agency or intra-agency documents in order to be protected from disclosure under Exemption 5.

One privilege incorporated into Exemption 5 is the deliberative process privilege, which protects the quality of agency decision making. To qualify for protection, the information must be pre-decisional and deliberative. Three policy purposes constitute the basis for the deliberative process privilege: (1) to encourage open, frank discussions on matters of policy between subordinates and supervisors; (2) to protect against premature disclosure of proposed policies before they are finally adopted; and (3) to protect against public confusion that might result from disclosure of policies and rationales that do not ultimately serve as the basis for agency action.

Specifically, the information being withheld under this exemption consists of email communications between APHIS employees reflecting pre-decisional discussions on research, some of which is a part of a CRADA. Although the emails reflect personal thoughts and opinions of the APHIS employees, the agency considered making a discretionary release of this information. However, we have determined that the disclosure of this information would chill the deliberative process of government personnel. Releasing this information would also discourage candid discussions within the agency, thereby inhibiting APHIS employees from freely exchanging their ideas, thoughts and/or opinions. Accordingly, the emails have been withheld pursuant to the deliberative process privilege of FOIA exemption 5.

Exemption 6

Exemption 6 permits the government to withhold from "personnel and medical files and similar files" information about individuals when the disclosure of such information "would constitute a clearly unwarranted invasion of personal privacy." We have determined that these records meet the definition of "similar" files, because they contain information pertaining to individuals.

In order to determine whether a document may be withheld under Exemption 6, an agency must undertake a three-step analysis. First, the agency must determine whether a significant privacy interest would be compromised by the disclosure of the record. Second, the agency must determine whether the release of the document would further the public interest by shedding light on the operations and activities of

the Government. Third, the agency must balance the identified privacy interests against the public interest in disclosure.

In this matter, we are withholding email addresses and names of private individuals. We are also withholding cell phone numbers of Wildlife Services (WS) employees.

We have determined that the private individuals have more than a *de minimis* privacy interest in the withheld information. The identifying information is being withheld because it could be used to make unwanted contact or communications with the individuals in the documents. We are withholding WS employees cell phone numbers to prevent unwanted contact or communications or harassment. Under Exemption 6, the only pertinent public interest is whether release of the information would shed light on the agency's activities and the agency's performance of its statutory duties. We have determined that the release of identifying information does not shed any light on APHIS activities. Therefore, the privacy interest of the individuals in the records you have requested outweigh the non-existent public interest in disclosure of the information.

Exemption 7(C)

FOIA Exemption 7(C) permits the government to withhold information compiled for law enforcement purposes about individuals, the disclosure of which "could reasonably be expected to constitute an unwarranted invasion of personal privacy." Under Exemption 7, law enforcement purposes cover administrative enforcement actions. APHIS is authorized under the Animal Welfare Act (AWA), (see 7 U.S.C. 2131-2159) (1) to insure that animals intended for use in research facilities or for exhibition purposes or for use as pets are provided humane care and treatment; (2) to assure the humane treatment of animals during transportation in commerce; and (3) to protect the owners of animals from the theft of their animals by preventing the sale or use of animals which have been stolen. The pertinent regulations enforcing the AWA are found at 9 CFR, Chapter 1, Subchapter A, Parts 1 – 4. The AWA ensures that all regulated commercial animal breeders, dealers, brokers, transportation companies, exhibitors, and research facilities are licensed or registered, and that his or her premises and any animals, facilities, vehicles, equipment, or other premises used or intended for use are in compliance with the AWA. In addition, the AWA authorizes APHIS to review and investigate and set civil penalties for alleged violations.

The responsive records at issue were compiled as part of the AWA regulatory compliance process and were compiled for law enforcement purposes. Exemption (b)(7)(C) is regularly applied to withhold references to individuals in law enforcement files. For the materials that have been withheld under 7(C), it has been determined that releasing them would constitute an unwarranted invasion of personal

privacy because they identify individuals referenced in law enforcement records and the release of this information would not shed light on the agency's performance of its statutory duties.

You may contact Tamara Scott, the analyst who processed your request, at (301) 851-4112 or by email, at tamara.scott@usda.gov. You may also contact Bethany Jones, our FOIA Public Liaison, at (301) 851-4100 for any further assistance and to discuss any aspect of your request. Additionally, you may contact the Office of Government Information Services (OGIS) at the National Archives and Records Administration to inquire about the FOIA mediation services they offer. The contact information for OGIS is as follows: Office of Government Information Services, National Archives and Records Administration, 8601 Adelphi Road-OGIS, College Park, Maryland 20740-6001, e-mail at ogis@nara.gov; telephone at 202-741-5770; toll free at 1-877-684-6448; or facsimile at 202-741-5769.

If you are not satisfied with this response, you may submit an administrative appeal. During the pandemic, our offices are closed. Instead of physically mailing your appeal, we ask that in the short term you submit your appeals electronically by email to FOIA.MRP.Appeals@usda.gov. Your appeal must be electronically transmitted within 90 days of the date of this response. Please reference case number 2020-APHIS-01337-F and the phrase "FOIA APPEAL" in the subject line of your email. To assist the Administrator in reviewing your appeal, please provide specific reasons why you believe modification of this determination is warranted.

If you have any questions, please do not hesitate to contact my staff at 301-851-4033.

Sincerely,

REGINALD
SHEPPARD

Digital Signature
REGINALD SHEPPARD
Date: 2021.03.23 09:42:11
+0100

For:
Tonya G. Woods
Director
Freedom of Information & Privacy Act
Legislative and Public Affairs

Enclosures

NWRC IACUC Meeting Minutes

Monday March 4, 2019; 1:00 pm MT

Committee Members Present:

Fort Collins: Jeff Chandler, Tom Gidlewski, Laurie Baeten, Amy Davis, Kevin Bentler,

Conference Call: (b) (6), (b) (7)(C) Fred Cunningham

Committee Members Absent: Stacey Brummer; Kandy Keacher was excluded due to potential conflict of interest.

Meeting Summary

An IACUC meeting was requested by the Chair (Jeff Chandler) to discuss, in accordance with NWRC institutional policy RM 00.1.00, whether or not animal mistreatment and/or non-compliance occurred at the Florida Field Station in relation to the acquisition of four additional tegu without IACUC approval (QA-2901). The IACUC was tasked with determining if animal mistreatment and/or non-compliance occurred, and if additional corrective actions were needed. In summary, the IACUC determined that animal welfare was never in jeopardy, but that protocol non-compliance did occur. The committee was in unanimous agreement that the incident was partially attributable to a new hire who was not fully familiar with the IACUC and quality assurance (QA) systems of the NWRC. Given that the incident was already discussed with the Respondent and their supervisors, that the Respondent fully recognized and accepted responsibility for their mistake, and that the Respondent assured the Chair that animal acquisition would always be done with appropriate IACUC oversight from this point forward, the IACUC voted unanimously that no additional corrective action was needed.

Meeting Topics

- The Chair provided a summary to the committee regarding the incident and the preliminary investigation of this issue. The preliminary investigation was performed by the Chair and Attending Veterinarian (Laurie Baeten).
- A vote was taken by the IACUC to establish whether or not animal mistreatment and/or protocol non-compliance occurred.
 - The committee unanimously voted that animal mistreatment **did not** occur.
 - The committee unanimously voted that protocol non-compliance **did** occur.

- Given that protocol non-compliance was determined by the IACUC, the Chair described to the committee subsequent correspondence with the Respondent (Bryan Kluever). Per this conversation:
 - It was noted that the respondent was fully forthright and accepted responsibility for the acquisition of the animals without IACUC approval. The Chair notes that the Respondent was recently hired and not fully aware of the IACUC requirements.
 - The Respondent indicated in an e-mail to the Chair that they would now work through the NWRC QA and IACUC systems for studies using animals.
 - The AV and Chair also made it clear to the committee that this issue had been discussed with the Director's Office, and the Respondents Acting Supervisor.
 - The AV indicated that a site inspection was pending in May, at which time this issue may be informally discussed with the Respondent and their team.

- The Chair described the possible corrective actions the IACUC may choose to undertake, as described in RM 00.1.00. Per these actions, the IACUC unanimously determined and voted that no further corrective action was needed for the Respondent.

- During the course of discussions, IACUC members suggested the following:
 - It was noted that there is somewhat of a disconnect between field stations and headquarters regarding IACUC oversight. It was suggested that a letter be disseminated to field stations reminding them of IACUC oversight and function at their facilities.
 - A committee member expressed concern with communication channels at the Florida Field Station. Specifically, it was noted that several employees at this Field Station should have known that acquisition of animals without IACUC approval would be non-compliance, and that they should have communicated this with the Respondent.
 - Additional discussion during the Veterinary Consultation related to the availability of contingency animals.

NWRC IACUC Meeting Minutes

June 27, 2019; 2:00 pm MT

Committee Members Present:

Fort Collins: Laurie Baeten, Tom Gidlewski, Kevin Bentler, Jeff Chandler

Conference Call: Amy Davis, Fred Cunningham

Committee Members Absent: Kandy Keacher, (b) (6), (b) (7)(C) Stacey Brummer

Meeting Summary

An IACUC meeting was requested by the Chair (Jeff Chandler) to discuss, in accordance with NWRC institutional policy RM 00.1.00, whether or not animal mistreatment and/or non-compliance occurred in relation to QA-2840 and QA-2674. Additional topics to be covered at this meeting included requested feedback on the Protocol Review and Protocol Amendment Process, and any other animal care and use topic the committee wished to discuss.

Meeting Topics

- The Chair provided a summary to the committee regarding the potential non-compliance incidents associated with QA-2840 and QA-2674 and the preliminary investigation of this issue. The preliminary investigations were performed by the Chair and Attending Veterinarian (Laurie Baeten). Responses from the study participants regarding the incident are available to the committee upon request and have been filed. In both instances, the preliminary investigations suggested that both potential non-compliances were due to administrative oversight, and that at no time was animal welfare compromised.
- A vote was taken by the IACUC to establish whether or not animal mistreatment and/or protocol non-compliance occurred (quorum established).
 - QA-2840 – Committee unanimously voted that non-compliance occurred.
 - QA-2674 – Committee unanimously voted that non-compliance occurred.
- Action to be taken for noncompliance (quorum established)..
 - QA-2840 – The Committee unanimously voted that no further disciplinary action was needed.
 - QA-2674 – The Committee unanimously voted that no further disciplinary action was needed.

- The Chair informed the committee that in collaboration with the Quality Assurance unit, that Study Director's will be notified when IACUC approval is set to expire. The Chair also noted that the ultimate responsibility of IACUC compliance remains with the Study Director
- Protocol Review and Amendment Review
 - The Chair described the current Protocol and Amendment Review process, the members present agreed with the current system and did not recommend any modification. In essence, all committee members can see any Protocol / Amendment at their request. All new protocols will be disseminated to all Committee members. All amendments will be processed by the AV / Chair, and at their discretion, additional committee members will be asked to review if the proposed modifications are deemed 'significant' by the AV and/or Chair.
- Other issues
 - Fred Cunningham identified that the Mississippi Field Station was due for inspection. This activity will be coordinated through the Attending Veterinarian.
 - The Attending Veterinarian and Chair discussed the new post approval monitoring policy which is under development.
 - The Chair brought to the Committee's attention the recent animal care and use issues which occurred at the U.S. Meat Animal Research Center (ARS). Documentation related to this incident will be provided to the Committee. The objective of this exercise is to inform the Committee of the possible escalation which can occur due to animal care and use issues and to prepare/think of strategies which could prevent this type of incident from occurring at the NWRC.

NWRC IACUC Meeting Minutes

June 27, 2019; 2:00 pm MT

Committee Members Present:

Fort Collins: Laurie Baeten, Tom Gidlewski, Kevin Bentler, Jeff Chandler

Conference Call: Amy Davis, Fred Cunningham

Committee Members Absent: Kandy Keacher, (b) (6), (b) (7)(C) Stacey Brummer

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An IACUC meeting was requested by the Chair (Jeff Chandler) to discuss, in accordance with NWRC institutional policy RM 00.1.00, whether or not animal mistreatment and/or non-compliance occurred in relation to QA-2840 and QA-2674. Additional topics to be covered at this meeting included requested feedback on the Protocol Review and Protocol Amendment Process, and any other animal care and use topic the committee wished to discuss.

Meeting Topics

- The Chair provided a summary to the committee regarding the potential non-compliance incidents associated with QA-2840 and QA-2674 and the preliminary investigation of this issue. The preliminary investigations were performed by the Chair and Attending Veterinarian (Laurie Baeten). Responses from the study participants regarding the incident are available to the committee upon request and have been filed. In both instances, the preliminary investigations suggested that both potential non-compliances were due to administrative oversight, and that at no time was animal welfare compromised.
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 - The Chair described the current Protocol and Amendment Review process, the members present agreed with the current system and did not recommend any modification. In essence, all committee members can see any Protocol / Amendment at their request. All new protocols will be disseminated to all Committee members. All amendments will be processed by the AV / Chair, and at their discretion, additional committee members will be asked to review if the proposed modifications are deemed 'significant' by the AV and/or Chair.
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From: [Snow, Nathan P - APHIS](#)
To: [Vercauteren, Kurt C - APHIS](#); [Chandler, Jeffrey C - APHIS](#); [Baeten, Laurie - APHIS](#)
Subject: RE: Revised QA's for IACUC review
Date: Monday, June 17, 2019 7:56:13 AM

Hello,

I apologize for the issue created by my lack of amending this protocol in a timely manner, and I appreciate you all working through this while I was on leave. I am really glad that Jeff asked for suggestions on how to avoid this from happening again, and I agree that Kurt's suggestions would be extremely helpful.

Please let me know how I can help at this point,

Nathan

From: Vercauteren, Kurt C - APHIS
Sent: Thursday, June 13, 2019 2:27 PM
To: Chandler, Jeffrey C - APHIS <jeffrey.c.chandler@usda.gov>; Baeten, Laurie - APHIS <laurie.baeten@usda.gov>; Snow, Nathan P - APHIS <nathan.p.snow@usda.gov>
Subject: RE: Revised QA's for IACUC review

Jeff and Laurie,

Appreciate those suggestions – see attached.

Kurt

From: Chandler, Jeffrey C - APHIS
Sent: Thursday, June 13, 2019 10:32 AM
To: Baeten, Laurie - APHIS <laurie.baeten@usda.gov>; Vercauteren, Kurt C - APHIS <kurt.c.vercauteren@usda.gov>; Snow, Nathan P - APHIS <nathan.p.snow@usda.gov>
Subject: RE: Revised QA's for IACUC review

Also, suggestions for preventing this from happening again would be appreciated (what could help you, as well as the rest of the Center).

From: Baeten, Laurie - APHIS
Sent: Thursday, June 13, 2019 10:29 AM
To: Vercauteren, Kurt C - APHIS <kurt.c.vercauteren@usda.gov>; Chandler, Jeffrey C - APHIS <jeffrey.c.chandler@usda.gov>; Snow, Nathan P - APHIS <nathan.p.snow@usda.gov>
Subject: Re: Revised QA's for IACUC review

Kurt,

I think this looks good but I suggest a sentence or two on the location choice since TN was not listed in the original protocol.

Thanks,

Laurie

Laurie A. Baeten, DVM, PhD

Attending Veterinarian

laurie.baeten@usda.gov | office 970-266-6364 | cell 970-893-0204

USDA/APHIS/WS/National Wildlife Research Center

4101 LaPorte Avenue | Fort Collins, CO 80521

From: Vercauteren, Kurt C - APHIS
Sent: Thursday, June 13, 2019 10:17:59 AM

To: Chandler, Jeffrey C - APHIS; Baeten, Laurie - APHIS; Snow, Nathan P - APHIS

Subject: RE: Revised QA's for IACUC review

Jeff,

Here is the summary. Let me know if this doesn't suit the need and you think I should provide more detail (my excuses).

Kurt

From: Chandler, Jeffrey C - APHIS

Sent: Wednesday, June 12, 2019 8:40 PM

To: Baeten, Laurie - APHIS <laurie.baeten@usda.gov>; Vercauteren, Kurt C - APHIS <kurt.c.vercauteren@usda.gov>; Snow, Nathan P - APHIS <nathan.p.snow@usda.gov>

Subject: RE: Revised QA's for IACUC review

Thank you everyone for getting this taken care of quickly.

I just spoke to Laurie, and she filled me in on the meeting today. We both agreed that we shouldn't need to meet on Monday (6/17) to discuss further.

---Kurt and Nate, if you could be send me the brief write-up by Monday the 24th that would be great. Thanks and just let me know if questions/concerns.

Best,

jeff

From: Baeten, Laurie - APHIS

Sent: Wednesday, June 12, 2019 12:56 PM

To: Chandler, Jeffrey C - APHIS <jeffrey.c.chandler@usda.gov>; Vercauteren, Kurt C - APHIS <kurt.c.vercauteren@usda.gov>; Snow, Nathan P - APHIS <nathan.p.snow@usda.gov>

Subject: Re: Revised QA's for IACUC review

Jeff,

I met with Kurt this morning to discuss QA-2674. (b)(3)Federal Technology Transfer Act 15 U.S.C. 3710a, (b)(5)

(b)(3)(A) Federal Technology Transfer Act 15 U.S.C. 3710a, (b)(5)



Otherwise, I find the activities outlined in the amendment to be acceptable and would recommend approval.

I will keep the proposed meeting time for next week open in case we need to discuss this further as a group (6/17/19 9:30am).

Laurie

Laurie A. Baeten, DVM, PhD

Attending Veterinarian

laurie.baeten@usda.gov | office 970-266-6364 | cell (b) (6), (b) (7)(C)

USDA/APHIS/WS/National Wildlife Research Center

4101 LaPorte Avenue | Fort Collins, CO 80521

From: Chandler, Jeffrey C - APHIS

Sent: Tuesday, June 11, 2019 6:29:06 PM

To: Vercauteren, Kurt C - APHIS

Cc: Baeten, Laurie - APHIS

Subject: RE: Revised QA's for IACUC review

Thanks, Kurt. Please note that I've cc'd Laurie on this e-mail.

First, let me say thanks, I appreciate your upfront response.

Secondly, I'll send an e-mail to QA shortly clearing the QA-2179 and QA-2521, as there is no animal work immediately planned for these studies, and an amendment will be submitted should animal work be necessary. The other amendments will go out for IACUC review.

As for, QA-2674, based on the information you provided below, this is potentially protocol noncompliance. I see that Nate is the Study Director for this protocol, and based on my understanding, he is ultimately responsible for IACUC compliance. Kurt, could you please loop him into this conversation, I do not want him to be blindsided.

Moving forward, we will proceed as specified in the RM001.00 policy document. Per this policy, the first step is to meet with Laurie. Laurie, could you please schedule this meeting with Kurt and Nate, and please wait to schedule until Nate has been looped in. I also note that per our regulations and best practices, time is of the essence here, so please schedule this as soon as possible. Further, it's my interpretation that this meeting will also serve as the 'preliminary review.' Kurt, if this preliminary review suggests noncompliance, I would ask you and Nate write a brief description of the incident, which includes why it happened and what the animal impacts were (to be shared with the full IACUC).

All this said, based on the information I know thus far, (b) (5)

(b) (5)

(b) (5)

I'm specifically interested in knowing what actions could be implemented in the future to prevent noncompliance issues related to lapse in study approval dates. Thanks, and please let me know if you have questions/concerns.

From: Vercauteren, Kurt C - APHIS

Sent: Tuesday, June 11, 2019 1:51 PM

To: Chandler, Jeffrey C - APHIS <jeffrey.c.chandler@usda.gov>

Subject: RE: Revised QA's for IACUC review

Jeff,

I'll answer your questions below in blue and I've attached better amendments. Let me know how you want to move forward.

Kurt

From: Chandler, Jeffrey C - APHIS

Sent: Monday, June 10, 2019 8:11 PM

To: Vercauteren, Kurt C - APHIS <kurt.c.vercauteren@usda.gov>

Subject: Revised QA's for IACUC review

Hi Kurt,

Thanks for the revised QAs. A couple of questions for you.

1. For QA-2179 you indicated that additional work would involve data analysis and manuscript preparation. However, you did not specifically state that no more animal work would be performed. Can you confirm that this is the case? [No, following some analyses we may desire to do more animal work and would write an amendment \(or new protocol, depending\) to address any next step.](#)
2. Regarding QA-2674, QA-2617, and QA-2620 additional details are requested by the IACUC for the proposed replication of studies that will involve animal use. As such please provide the specific details for each of these studies, just as you would have done when constructing the original protocol. The specific details for each of these studies are needed for the IACUC to judge appropriateness. [More detailed amendments attached. I apologize, I clearly see that I did not provide enough justification on these, sorry to have created extra headaches for you.](#)
3. Finally, the IACUC requests a specific answer to the following two questions listed below for each of the four aforementioned QA protocols as well as QA-2521. Given our previous discussion (6/6/19) and to provide context to why these questions are being asked, please review the following information provided by USDA regarding protocol noncompliance (<https://www.nal.usda.gov/awic/protocol-noncompliance-overview>). I will also direct you to two of our internal policy documents which are attached.
 - a. Were personnel involved in live animal use (of any type) who were not approved by the IACUC? If so, whom and for which studies?
[QA-2674 Bear - WS TN Hyle and Tussing baited their trap sites, they would have if our stations were present or not.](#)
[QA-2617 DIFFS - no](#)
[QA-2620 Bait - no](#)
[QA-2521 Tejon - no](#)
 - b. Was research involving live animals conducted at any time beyond the IACUC-approved study data (defined as the study completion date specified in the approved protocol)? If so, which studies and what activities were conducted.
[QA-2674 Bear – proposed study completion date was 3/19, I'm guilty of not realizing this and putting pig specific bait stations in the field in 5/19](#)
[QA-2617 DIFFS - no](#)
[QA-2620 Bait - no](#)
[QA-2521 Tejon - no](#)

Thank you very much for looking into these items, and please let me know if there are any issues you'd like to discuss. I've got some training at the hub all this week from 8-5, but I'm happy to talk in the evening after that wraps up.

Best,

jeff

Jeff Chandler

BioLabs
IACUC Chair
USDA/APHIS/WS National Wildlife Research Center
4101 Laporte Avenue
Fort Collins, Colorado 80521-2154
970-266-6090 (phone)
(b) (6), (b) (7)(C) (cell)
Jeffrey.C.Chandler@usda.gov

From: (b) (6), (b) (7)(C) @aol.com
To: Chandler, Jeffrey C - APHIS
Subject: Re: IACUC protocol noncompliance incidents / meeting
Date: Wednesday, June 26, 2019 8:06:41 AM

Jeffrey, I will be traveling and unable to attend a group meeting during the dates available. I believe that if

(b) (5)

(b) (5) I also do not have other issues to raise with the Committee. I hope the Committee can meet its quorum and have a successful meeting, and will be back and available on July 5. Best,

(b) (6), (b) (7)(C)

-----Original Message-----

From: Chandler, Jeffrey C - APHIS <jeffrey.c.chandler@usda.gov>
To: (b) (6), (b) (7)(C) @aol.com' (b) (6), (b) (7)(C) @aol.com>; Baeten, Laurie - APHIS <laurie.baeten@usda.gov>; Bentler, Kevin T - APHIS <kevin.t.bentler@usda.gov>; Brummer, Stacey P - APHIS <stacey.p.brummer@usda.gov>; Cunningham, Frederick L - APHIS <fred.l.cunningham@usda.gov>; Davis, Amy J - APHIS <amy.j.davis@usda.gov>; Gidlewski, Thomas - APHIS <thomas.gidlewski@usda.gov>; Keacher, Kandy L - APHIS <kandy.l.keacher@usda.gov>
Sent: Tue, Jun 25, 2019 2:15 pm
Subject: RE: IACUC protocol noncompliance incidents / meeting

Hello IACUC,

Doodle poll link to discuss recent noncompliance issues and other IACUC business (apologies for the delay in getting this out): <https://doodle.com/poll/vxqz2grg5dbfkgg8>

Best,

jeff

From: Chandler, Jeffrey C - APHIS

Sent: Thursday, June 13, 2019 7:09 PM

To: (b) (6), (b) (7)(C) @aol.com' (b) (6), (b) (7)(C) @aol.com>; Baeten, Laurie - APHIS <laurie.baeten@usda.gov>; Bentler, Kevin T - APHIS <kevin.t.bentler@usda.gov>; Brummer, Stacey P - APHIS <stacey.p.brummer@usda.gov>; Cunningham, Frederick L - APHIS <fred.l.cunningham@usda.gov>; Davis, Amy J - APHIS <amy.j.davis@usda.gov>; Gidlewski, Thomas - APHIS <thomas.gidlewski@usda.gov>; Keacher, Kandy L - APHIS <kandy.l.keacher@usda.gov>

Subject: IACUC protocol noncompliance incidents / meeting

Dear IACUC,

Over the last two weeks it came to my attention that two NWRC study protocols were potentially out of compliance. Specifically these protocols are: QA-2840 (John Humphry/Bryan Kluever) and QA-2674 (Nate Snow/Kurt VerCauteren). In both instances the presumptive noncompliance resulted from conducting animal work beyond the approved study date.

For both instances, as soon as the issue was identified, Laurie and myself intervened with the study directors and conducted a preliminary investigation. Long story short, it's our opinion that (b) (5)

(b) (5) Nonetheless, we will convene an IACUC meeting to discuss these incidents and determine the course of action related to noncompliance. I'd like to schedule a meeting for this sometime the week of the 24th (I'll send out a doodle poll in the next couple of days). On another note, I'd like to use this IACUC meeting to discuss any issues, observations, or concerns you may have.

Best,

jeff
Jeff Chandler
BioLabs
IACUC Chair
USDA/APHIS/WS National Wildlife Research Center
4101 Laporte Avenue
Fort Collins, Colorado 80521-2154
970-266-6090 (phone)
(b) (6), (b) (7)(C) (cell)
Jeffrey.C.Chandler@usda.gov

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From: [Chandler, Jeffrey C - APHIS](#)
To: [Vercauteren, Kurt C - APHIS](#); [Snow, Nathan P - APHIS](#)
Subject: QA-2674 noncompliance IACUC decision
Date: Thursday, June 27, 2019 5:01:18 PM

Hi Kurt and Nate,

The IACUC met today to discuss the potential noncompliance with QA-2674. The Committee unanimously voted that noncompliance occurred. As such, a subsequent discussion/vote was held regarding potential disciplinary actions. The Committee unanimously voted that no further action would be required. Thus, I consider this issue to be closed.

I also met with the QAU to develop an administrative process which will hopefully prevent this type of incident from occurring again, Center-wide. Specifically, the QAU will disseminate a monthly report to the IACUC for currently active studies with IACUC oversight. I will then review this document and send the Study Directors a warning that their IACUC approval is set to expire soon.

Please note that ensuring compliance still officially rests in the hands of the Study Director.

As for the Amendment to this study protocol which you recently submitted, it is my intention to clear that through the system tomorrow. Also note that the IACUC is not allowed to administratively extend approval if the study has expired (ie. it would have to go through this process again if animal work occurred beyond the approved study date).

Please let me know if you have any questions or concerns.

Best,

jeff

Jeff Chandler

BioLabs

IACUC Chair

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(b) (6), (b) (7)(C) (cell)

Jeffrey.C.Chandler@usda.gov

From: [Chandler, Jeffrey C - APHIS](#)
To: [Chandler, Jeffrey C - APHIS](#)
Subject: RE: Agenda for 2840 non-compliance meeting
Date: Thursday, June 6, 2019 1:48:18 PM

On 6-6-19, myself and Laurie Baeten met with John Humphry and Bryan Kluever to discuss the potential non-compliance issue with QA-2840. We discussed each point described in the items below.

Per this meeting, we inquired to animal welfare, no problems were suspected or identified. Thus, this incident was just an administrative lapse. As such, Laurie Baeten and I will prepare a report to the IACUC committee and present the incident as such. All documentation provided by the study personnel will be provided in the report.

From: Chandler, Jeffrey C - APHIS
Sent: Tuesday, June 4, 2019 10:16 AM
To: Baeten, Laurie - APHIS <laurie.baeten@usda.gov>
Subject: Agenda for 2840 non-compliance meeting
Hi Laurie,

For this conference call on Thursday with John and Bryan, are you satisfied with the information provided? It's my view they have provided everything we need.

The topics I think we should hit on:

1. Remind them of IACUC oversight responsibilities and rules.
2. Make it clear that this effort is a fact-finding endeavor that is required by our institutional policy.
3. Inform them that we will have a committee meeting to discuss this issue and vote on the non-compliance aspect, which may or may not be associated with additional disciplinary actions.

What I'd like this discussion to achieve:

1. Review all active protocols at the Field Station, and make sure that these are in compliance.
2. If they have a question about policy / procedure, please ask us.

Please add or modify anything here as you see appropriate.

Jeff Chandler

BioLabs

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USDA/APHIS/WS National Wildlife Research Center

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(b) (6), (b) (7)(C) (cell)

Jeffrey.C.Chandler@usda.gov

From: [Keacher, Kandy L - APHIS](#)
To: [Chandler, Jeffrey C - APHIS](#)
Subject: IACUC protocol noncompliance incidents / meeting...back from dentist; cannot talk, mouth numb all the way to eyelid!
Date: Thursday, June 27, 2019 3:22:06 PM

Hi Jeff,

I am not familiar with QA-2674 (Nate Snow/Kurt VerCauteren) lack of compliance, so cannot really comment.

I can only discuss QA-2840 (John Humphry/Bryan Kluever) , since I have some knowledge with it occurring at Florida Field Station. Bottom line: our previous Project Leader, Mike Avery, handled all QA protocol deadlines. Without someone overseeing these details and in combination with having a new PL learning the ropes of the job, the observance of the deadline fell through the cracks.

Not sure what the standard action is by IACUC for lack of compliance.

My recommendation I will be making to Bryan Kluever is to have posted either by our organizational calendar or in his office a list of all active QAs, start date, ending date and archive deadline to keep everyone informed.

From: Chandler, Jeffrey C - APHIS

Sent: Tuesday, June 25, 2019 2:15 PM

To: (b) (6), (b) (7)(C)@aol.com' (b) (6), (b) (7)(C)@aol.com>; Baeten, Laurie - APHIS <laurie.baeten@usda.gov>; Bentler, Kevin T - APHIS <kevin.t.bentler@usda.gov>; Brummer, Stacey P - APHIS <stacey.p.brummer@usda.gov>; Cunningham, Frederick L - APHIS <fred.l.cunningham@usda.gov>; Davis, Amy J - APHIS <amy.j.davis@usda.gov>; Gidlewski, Thomas - APHIS <thomas.gidlewski@usda.gov>; Keacher, Kandy L - APHIS <kandy.l.keacher@usda.gov>

Subject: RE: IACUC protocol noncompliance incidents / meeting

Hello IACUC,

Doodle poll link to discuss recent noncompliance issues and other IACUC business (apologies for the delay in getting this out): <https://doodle.com/poll/vxqz2grg5dbfkkgg8>

Best,

jeff

From: Chandler, Jeffrey C - APHIS

Sent: Thursday, June 13, 2019 7:09 PM

To: (b) (6), (b) (7)(C) aol.com' (b) (6), (b) (7)(C)@aol.com>; Baeten, Laurie - APHIS <laurie.baeten@usda.gov>; Bentler, Kevin T - APHIS <kevin.t.bentler@usda.gov>; Brummer, Stacey P - APHIS <stacey.p.brummer@usda.gov>; Cunningham, Frederick L - APHIS <fred.l.cunningham@usda.gov>; Davis, Amy J - APHIS <amy.j.davis@usda.gov>; Gidlewski, Thomas - APHIS <thomas.gidlewski@usda.gov>; Keacher, Kandy L - APHIS <kandy.l.keacher@usda.gov>

Subject: IACUC protocol noncompliance incidents / meeting

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will convene an IACUC meeting to discuss these incidents and determine the course of action related to noncompliance. I'd like to schedule a meeting for this sometime the week of the 24th (I'll send out a doodle poll in the next couple of days).

On another note, I'd like to use this IACUC meeting to discuss any issues, observations, or concerns you may have.

Best,

jeff

Jeff Chandler

BioLabs

IACUC Chair

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970-266-6090 (phone)

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jeff.chandler@usda.gov

From: [Chandler, Jeffrey C - APHIS](#)
To: [Humphrey, John S - APHIS](#); [Kluever, Bryan M - APHIS](#)
Cc: [Baeten, Laurie - APHIS](#)
Subject: RE: Potential IACUC Protocol Non-Compliance, QA-2840
Date: Tuesday, June 4, 2019 10:07:07 AM

Hi John,
I think this is sufficient, thank you.
We'll see you guys on Thursday.
Best,
jeff

From: Humphrey, John S - APHIS
Sent: Monday, June 3, 2019 2:25 PM
To: Kluever, Bryan M - APHIS <bryan.kluever@usda.gov>; Chandler, Jeffrey C - APHIS <jeffrey.c.chandler@usda.gov>
Cc: Baeten, Laurie - APHIS <laurie.baeten@usda.gov>
Subject: RE: Potential IACUC Protocol Non-Compliance, QA-2840

Hello Jeff,
In advance of tomorrows call to discuss QA-2840, I'd like to try and make sure you have all the information you need.
Relative to your initial questions:
"Additionally, please provide me with a written summary containing the following information for QA-2840 by 5-29-19 at 7:00 pm EST.

1. Provide all available information regarding the number of traps used, trapping days, and number of animals captured (targets and non-targets) after 2-28-18 .
2. Describe any other animal use that occurred under this protocol beyond 2-28-18.
3. Describe this potential protocol non-compliance issue as you see it, and how/why it occurred."

I believe I've provided you with all the information in my description of events, except the trap days, which was 610 (10 traps x 61 days).

Only the one opossum was captured, though on 4 successive occasions, and in the same trap adjacent to the refuge bunkhouse. Following notification to Laurie as required, I had a conversation with the trap manufacturer, Tomahawk Trap Co., and it was determined via photos of the trap, that it had not been properly maintained by the volunteer. This trap, and eventually all others via a rolling swap out with spares, were modified by Tomahawk to more easily set the trap with a single pull of a handle to set the triggers, versus manually setting both. We had no further captures at this site or in any other traps, but had 990 animals caught on camera at, in, or under the trap.

Does this cover the information you wanted, given my previous description of events? I highlighted my description of events below to make it easier to find.

John S Humphrey
Wildlife Biologist
USDA/APHIS/WS
National Wildlife Research Center
FL Field Station
2820 East University Ave.
Gainesville, FL 32641
Phone: 352-375-2229 ext. 3

Cell: 352-278-2266

Fax: 352-378-4925

John.S.Humphrey@aphis.usda.gov

From: Kluever, Bryan M - APHIS

Sent: Thursday, May 30, 2019 3:49 PM

To: Chandler, Jeffrey C - APHIS <jeffrey.c.chandler@usda.gov>

Cc: Baeten, Laurie - APHIS <laurie.baeten@usda.gov>; Humphrey, John S - APHIS <john.s.humphrey@usda.gov>

Subject: RE: Potential IACUC Protocol Non-Compliance, QA-2840

Hi Jeff,

I am scheduled to be off next Friday.

Would it be possible to have this call on June 6th rather than June 7th?

Best,

Bryan

From: Chandler, Jeffrey C - APHIS

Sent: Tuesday, May 28, 2019 7:05 PM

To: Humphrey, John S - APHIS <john.s.humphrey@usda.gov>

Cc: Kluever, Bryan M - APHIS <bryan.kluever@usda.gov>; Baeten, Laurie - APHIS <laurie.baeten@usda.gov>

Subject: RE: Potential IACUC Protocol Non-Compliance, QA-2840

Hi John,

Thank you for this information, and letting me know that no work is currently being performed via QA-2840. I appreciate the upfront response.

As it stands currently, it's my interpretation that this incident was not a willful disregard of IACUC policy. This is evidenced in that you reported non-target captures (as you were directed) even though this occurred beyond the approved study date. Rather, this incident seems to have occurred due to problems associated with administrative function and training as it pertains to NWRC IACUC policy.

We will discuss this and other details next week after you have had the opportunity to compile the additional information requested. Let's plan to have this discussion Friday, June 7.

Regards,

jeff

From: Humphrey, John S - APHIS

Sent: Tuesday, May 28, 2019 1:25 PM

To: Chandler, Jeffrey C - APHIS <jeffrey.c.chandler@usda.gov>

Cc: Kluever, Bryan M - APHIS <bryan.kluever@usda.gov>

Subject: RE: Potential IACUC Protocol Non-Compliance, QA-2840

Jeff,

The study has not had any activity since the end in March 2018.

The short and the long of it, was that that the study protocol was prepared in the late Spring or so of 2017 when the opportunity became available under the supervision of Dr. Michael Avery, the project leader until retiring that December. I had never done a study protocol before, and it was a project that the state stakeholders had encouraged me to conduct given the unique and patented features of the Large Reptile Trap, so Mike offered to help me through the process.

After the protocol was approved that summer, and while the study was being conducted at the Refuge, the state game agency put out a solicitation for grant proposals which we were also encouraged to apply for given our expertise and the need to fund python projects outside of our Field Station budget, and which were due in October 2017. We were notified that the proposal was approved very early in January, however at the same time, I was hospitalized with an extended illness that delayed the project.

With the retirement of Dr. Avery, we had temporary Project Leaders that were in rotation for about 5 months while the selection process was conducted for a new PL was in place. As I had no experience in doing anything administrative relative to the study protocols, I wasn't aware that the study timeline needed to be amended when the project resumed following my release from the hospital, and hence the capture date being beyond the February 28 study end date due to the study running until the end of March.

At the same time, we were trying to figure out how to get the grant award/agreement processed by the state's deadline in February to accept the funds, and why one amendment was initiated at the suggestion of one of the temporary project leaders. It was thought that it would be more prudent to amend the current study protocol, as the study proposal to the state was essentially the same study, but expanded into areas where pythons were known to exist.

The study at the Refuge was complete by the end of March, however in hindsight and with all the knowledge I've learned since first putting the QA-2840 study protocol together, the timeframe for the study to be run and archived, was far too short to accommodate unforeseen circumstances. At the same time all this was happening, the agreements section was having issues getting them through the system, and we lost the opportunity to accept the grant funds due to missing several deadlines which I was unaware of due to being naïve in how those things work, as well as not having a Project Leader to follow through to ensure the deadlines were met. It was decided to wait until the new PL was in place to finish the amendment due to the uncertainty of any projects moving forward in the area of invasive species.

When Bryan Kluever arrived at the Field Station around October, we were in discussion as to whether to again apply for the state grant. We decided to apply for the same grant in October 2018 with the same proposal, and again had the proposal accepted. However as our new project leader was also new to the system, he thought it best to contract with a university entity to run the study due to their long experience with the state grant system, as well as the problem and the study area. We then had the office fire that disrupted pretty much all activities as we were displaced from the building for about 1 month, having to move items out for cleaning and storage while the office was decontaminated and cleaned. There was then the furlough which caused the issue of missing the date for the study archive as you became aware, which I quickly tried to get educated on.

This has been a very long and arduous process for me that I am finally getting the grasp of, but which was extremely hampered by inexperience, loss of continuity in leadership, a severe hospitalization, and an office fire, all while we all tried to keep the Field Station moving in a somewhat forward direction.

I'm more than willing to further clarify this as necessary, however I will have limited access to email until Monday of next week when I return. I have to leave for a Dr. Appt. now, but will try to respond as promptly as I can while being in the field this week.

John S Humphrey
Wildlife Biologist
USDA/APHIS/WS

National Wildlife Research Center
FL Field Station
2820 East University Ave.
Gainesville, FL 32641
Phone: 352-375-2229 ext. 3
Cell: (b) (6), (b) (7)(C)
Fax: 352-378-4925

John.S.Humphrey@aphis.usda.gov

From: Chandler, Jeffrey C - APHIS

Sent: Tuesday, May 28, 2019 2:40 PM

To: Humphrey, John S - APHIS <john.s.humphrey@usda.gov>

Cc: Kluever, Bryan M - APHIS <bryan.kluever@usda.gov>

Subject: RE: Potential IACUC Protocol Non-Compliance, QA-2840

Hi John,

That's fine regarding the write-up. But regarding the current status of the study, I need to know the status of this right away. Please let me know today if this study is still on going.

Thanks,

jeff

From: Humphrey, John S - APHIS

Sent: Tuesday, May 28, 2019 10:12 AM

To: Chandler, Jeffrey C - APHIS <jeffrey.c.chandler@usda.gov>

Cc: Kluever, Bryan M - APHIS <bryan.kluever@usda.gov>

Subject: RE: Potential IACUC Protocol Non-Compliance, QA-2840

Hello Jeff,

I am working on your reply but have to travel this week to SC and won't be able to complete it until next week.

John S Humphrey

Wildlife Biologist

USDA/APHIS/WS

National Wildlife Research Center

FL Field Station

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John.S.Humphrey@aphis.usda.gov

From: Chandler, Jeffrey C - APHIS

Sent: Thursday, May 23, 2019 6:10 PM

To: Humphrey, John S - APHIS <john.s.humphrey@usda.gov>

Cc: Kluever, Bryan M - APHIS <bryan.kluever@usda.gov>

Subject: Potential IACUC Protocol Non-Compliance, QA-2840

John,

During IACUC review of QA-2840 Amendment 1 it came to my attention (through review of previous

documentation) that trapping occurred beyond the date of the approved Study Protocol. Performing studies beyond the study approval date is against our institutional policy (please see and review the attached policy related to Protocol Non-Compliance), and is viewed as a potentially serious IACUC infraction/concern.

Specifically, in an e-mail you sent to Laurie Baeten on March 8, 2018 at 9:46a you state that a non-target was captured (apparently) on 3/7/18. Animal use in this study appears to have only been approved through 2-28-18. I am aware that an amendment was previously drafted which would have extended the study date. However, this amendment was not approved by the IACUC or the QA Unit.

While I recognize that significant time has elapsed, upon identification of a potential IACUC non-compliance issue I am obligated to initiate an IACUC investigation into this matter. A general description of this process is included in the attached policy document.

If animal work is still being performed under this study protocol, please cease these activities immediately. Also, please let me know that status of this project immediately as it pertains to current animal use.

Additionally, please provide me with a written summary containing the following information for QA-2840 by 5-29-19 at 7:00 pm EST.

1. Provide all available information regarding the number of traps used, trapping days, and number of animals captured (targets and non-targets) after 2-28-18 .
2. Describe any other animal use that occurred under this protocol beyond 2-28-18.
3. Describe this potential protocol non-compliance issue as you see it, and how/why it occurred.

Feel free to call me with any questions you may have.

Regards,

Jeff

Jeff Chandler

BioLabs

IACUC Chair

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(b) (6), (b) (7)(C) (cell)

Jeffrey.C.Chandler@usda.gov

From: [REDACTED]@aol.com
To: Chandler, Jeffrey C - APHIS
Subject: Re: IACUC protocol noncompliance incidents / meeting
Date: Wednesday, June 26, 2019 8:06:41 AM

Jeffrey, I will be traveling and unable to attend a group meeting during the dates available. I believe that if the noncompliance was due to administrative delays, the Committee should make every effort to support completion of the research and meeting their objectives, even if the work had to extend beyond formal completion dates. I also do not have other issues to raise with the Committee. I hope the Committee can meet its quorum and have a successful meeting, and will be back and available on July 5. Best, [REDACTED]

(b) (6), (b) (7)(C)

-----Original Message-----

From: Chandler, Jeffrey C - APHIS <jeffrey.c.chandler@usda.gov>
To: [REDACTED]@aol.com' <reidingerr@aol.com>; Baeten, Laurie - APHIS <laurie.baeten@usda.gov>; Bentler, Kevin T - APHIS <kevin.t.bentler@usda.gov>; Brummer, Stacey P - APHIS <stacey.p.brummer@usda.gov>; Cunningham, Frederick L - APHIS <fred.l.cunningham@usda.gov>; Davis, Amy J - APHIS <amy.j.davis@usda.gov>; Gidlewski, Thomas - APHIS <thomas.gidlewski@usda.gov>; Keacher, Kandy L - APHIS <kandy.l.keacher@usda.gov>
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Subject: IACUC protocol noncompliance incidents / meeting

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For both instances, as soon as the issue was identified, Laurie and myself intervened with the study directors and conducted a preliminary investigation. Long story short, it's our opinion that the (b) (5)

(b) (5) Nonetheless, we will convene an IACUC meeting to discuss these incidents and determine the course of action related to noncompliance. I'd like to schedule a meeting for this sometime the week of the 24th (I'll send out a doodle poll in the next couple of days). On another note, I'd like to use this IACUC meeting to discuss any issues, observations, or concerns you may have.

Best,

jeff
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Jeffrey.C.Chandler@usda.gov

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From: [Chandler, Jeffrey C - APHIS](#)
To: [Kluever, Bryan M - APHIS](#); [Humphrey, John S - APHIS](#)
Subject: QA-2840 noncompliance IACUC decision
Date: Thursday, June 27, 2019 5:03:09 PM

Hi Bryan and John,

The IACUC met today to discuss the potential noncompliance with QA-2840. The Committee unanimously voted that noncompliance occurred. As such, a subsequent discussion/vote was held regarding potential disciplinary actions. The Committee unanimously voted that no further action would be required. Thus, I consider this issue to be closed.

I also met with the QAU to develop an administrative process which will hopefully prevent this type of incident from occurring again, Center-wide. Specifically, the QAU will disseminate a monthly report to the IACUC for currently active studies with IACUC oversight. I will then review this document and send the Study Directors a warning that their IACUC approval is set to expire soon.

Please note that ensuring compliance still officially rests in the hands of the Study Director.

As for the Amendment to this study protocol which you recently submitted, it is my intention to clear that through the system tomorrow. Also note that the IACUC is not allowed to administratively extend approval if the study has expired (ie. it would have to go through this process again if animal work occurred beyond the approved study date).

Please let me know if you have any questions or concerns.

Best,

jeff

Jeff Chandler

BioLabs

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Jeffrey.C.Chandler@usda.gov

From: [Chandler, Jeffrey C - APHIS](#)
To: [Baeten, Laurie - APHIS](#)
Cc: [Vercauteren, Kurt C - APHIS](#); [Snow, Nathan P - APHIS](#)
Subject: RE: QA-3033 - Unexpected mortalities
Date: Wednesday, July 31, 2019 1:14:41 PM

Thank you everyone for reporting this issue. Please let me know the results of the chemical analysis of the placebo baits.

I concur that leaving bait stations open with corn is appropriate at this time.

Best,
jeff

From: Baeten, Laurie - APHIS
Sent: Wednesday, July 31, 2019 8:45 AM
To: Chandler, Jeffrey C - APHIS <jeffrey.c.chandler@usda.gov>
Cc: Vercauteren, Kurt C - APHIS <kurt.c.vercauteren@usda.gov>; Snow, Nathan P - APHIS <nathan.p.snow@usda.gov>
Subject: QA-3033 - Unexpected mortalities

Jeff,

I received a phone call from Nathan Snow yesterday regarding some unexpected mortalities that occurred during the bait trials under QA-3033.

NWRC's role for this project is mainly consultation and all baiting is being conducted by SREL. I believe we deferred all IACUC oversight to SREL.

Summary of discussion - Nathan please feel free to add or clarify any information to the summary:

Kaput (warfarin based toxicant) was deployed in bait stations at the South Carolina locations with poor results so the manufacturer provided some placebo baits to use in a modified pre-baiting scenario. The unexpected mortalities were noted in the areas where the placebo baits were deployed (no mortalities noted at control sites baited with corn). A total of 12 feral swine and 6 non-target mammals were found in the area. Limited sample collections for cause of death determinations were available due to scavenging and degradation.

Bait stations have been closed and the remaining bait materials were collected. Samples of the bait station contents are being sent to NWRC for chemical analysis. One squirrel liver may also be in adequate condition for testing. The chemistry unit is aware of the incoming samples and should be able to test these samples in an expedited manner.

Nathan requested the option to keep the cleaned bait stations open and baited with corn (as is being done at control locations) to maintain the acclimation of the swine in the area. I agreed that this was acceptable plan during the investigation period. We discussed whether or not an amendment would be necessary at this time. It was my suggestion that we wait to see the outcome of the testing and wait for Kurt's return (8/5) before making any written changes to the NWRC protocol.

Let me know if you have any questions regarding this unexpected mortality report.

Laurie

Laurie A. Baeten, DVM, PhD
Attending Veterinarian

laurie.baeten@usda.gov | office 970-266-6364 | cell (b) (6), (b) (7)(C)
USDA/APHIS/WS/National Wildlife Research Center
4101 LaPorte Avenue | Fort Collins, CO 80521

On 9/9/19 I asked Stacey Brummer to provide me with her impressions of QA-3122. Note the study was already complete at this point.

I note that the Committee had multiple discussions regarding the pain Category of this Study. It was Stacey's impression after the study was completed that this study should have been Column E. Stacey noted that (b) (5)

(b) (5)

Stacey also noted that although this study was not listed as Column E in the NWRC protocol, everyone involved in the work approached this as if it were a Column E study, and they were ready for intervention. Thus, on the ground, in the framework of this study nothing else could have been done for improvement of animal welfare.

In my discussion with Stacey, I indicated that the IACUC needs to reconsider (b) (5)

(b) (5)

Animal activity that occurred after proposed experiment termination date

(b)(3)(A) Federal Technology Transfer Act 15 U.S.C. 3710a, (b)(5)



Proposed experiment termination date was 12/1/18. The activity I led occurred 5/6-31/2019. There are, of course, circumstances around these 2 facts but as I think about them they are just excuses. I should have prioritized slowing down and taken the little bit of time required to check the experiment's proposed termination date. I apologize to the IACUC and AV for the lost time and headaches my oversight has caused.

Though I certainly acknowledge that Project Leaders and Study Directors are wholly responsible for lapses such as this, there are strategies that could be enlisted Team NWRC-wide that could help prevent them. For example, in recent years BioLabs has begun keeping track of recurring safety needs of NWRC folks (e.g., vaccinations, respirator fit testing) and sends individuals reminders when, for example, they are due to have their rabies titer checked. At one time the WS Training Institute at Mississippi State University was planning to do the same sort of thing to help employees know when they had to get recertified by taking various trainings (e.g., firearms, immobilization, explosives), but I don't think that ever developed. To my thought, perhaps an automated system could be put in place where Study Directors get an email every time one of their studies is a month out from the proposed experiment termination date? This would prod them to get an amendment in place if required. For a project like MUDD-FS, which has about 40 QAs in play at any given time, this would be helpful. I also appreciate that it is my responsibility to have my own system in place within my project, and I do, but it/I failed this time.

-Kurt VerCauteren, MUDD-FS Project Leader

From: [Clark, Larry - APHIS](#)
To: [Chandler, Jeffrey C - APHIS](#); [Eisemann, John D - APHIS](#); [Eckery, Douglas C - APHIS](#); [Deliberto, Thomas J - APHIS](#); [Greiner, Laura B - APHIS](#)
Subject: RE: Update on IACUC noncompliance (QA-2840) and new noncompliance (QA-2674)
Date: Thursday, June 27, 2019 4:55:57 PM

Thanks, Jeff.

I think that is something we can work toward as we integrate QA into a broader e-records management system within the Center. I believe John is having those discussions with Laura and Jenna.

Larry

Larry Clark, Ph.D.
Director
National Wildlife Research Center
USDA-APHIS-WS
4101 La Porte Ave
Fort Collins, CO 80521
Mobile: (b) (6), (b) (7)(C)
Office: 970-266-6036

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Sent: Thursday, June 27, 2019 4:51 PM
To: Clark, Larry - APHIS <larry.clark@usda.gov>; Eisemann, John D - APHIS <john.d.eisemann@usda.gov>; Eckery, Douglas C - APHIS <douglas.c.eckery@usda.gov>; Deliberto, Thomas J - APHIS <thomas.j.deliberto@usda.gov>; Greiner, Laura B - APHIS <laura.b.greiner@usda.gov>

Subject: RE: Update on IACUC noncompliance (QA-2840) and new noncompliance (QA-2674)

Hi again everyone,

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Best,
jeff

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Subject: RE: Update on IACUC noncompliance (QA-2840) and new noncompliance (QA-2674)
Ok, great. And again, thanks.

Larry Clark, Ph.D.
Director
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USDA-APHIS-WS
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Subject: RE: Update on IACUC noncompliance (QA-2840) and new noncompliance (QA-2674)
Sorry, but I was not clear in my email. I meant Laura could arrange a meeting with me and Jeff, not the entire management team.

John D. Eisemann
Technology Transfer Program Manager
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4101 Laporte Avenue
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T: 970-266-6158
F: 970-266-6157
C: 970-672-6207
E: john.d.eisemann@usda.gov

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I am not sure a meeting with the MT is necessary at this point. I would like you guys to proceed with a plan on how to make this happen and then come back to the MT with that draft implementation plan.
The objective is to make sure our study directors are notified of important dates for QAs and what actions need to be taken. The relevant MT member should be cc'd as well.

Thanks

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Subject: RE: Update on IACUC noncompliance (QA-2840) and new noncompliance (QA-2674)
Jeff,

QA does not have an automated process for notifying Study Directors about the status of their protocols. It is something we could discuss with Laura. Would you like Laura to arrange a meeting?

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Cc: Eisemann, John D - APHIS <john.d.eisemann@usda.gov>
Subject: RE: Update on IACUC noncompliance (QA-2840) and new noncompliance (QA-2674)
Thanks Jeff.

This question may be more for John and the QA group. Do we have an auto-generated notification system that would indicate to the study director the pending lapse in approval date for a QA? If not, that is something we should look into developing. Maybe notifications of 1 month, 1 week, study is lapsed.

Thanks,

Larry

Larry Clark, Ph.D.
Director
National Wildlife Research Center
USDA-APHIS-WS
4101 La Porte Ave
Fort Collins, CO 80521
Mobile: 970-219-2619
Office: 970-266-6036

From: Chandler, Jeffrey C - APHIS

Sent: Wednesday, June 12, 2019 6:12 PM

To: Clark, Larry - APHIS <larry.clark@usda.gov>; Eckery, Douglas C - APHIS <douglas.c.eckery@usda.gov>; Deliberto, Thomas J - APHIS <thomas.j.deliberto@usda.gov>

Subject: Update on IACUC noncompliance (QA-2840) and new noncompliance (QA-2674)

Hi everyone,

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The preliminary investigation was performed for each of these studies per our policy, and both protocols by definition are noncompliant. The results will be shared with the IACUC tomorrow. The causation of both of these incidents was an administrative lapse by the study director, but it's our

(b) (5) Laurie and myself are both in agreement that further punitive action is not needed for either of these studies, and we will approach the Committee from that perspective.

Best,

jeff

Jeff Chandler

BioLabs

IACUC Chair

USDA/APHIS/WS National Wildlife Research Center

4101 Laporte Avenue

Fort Collins, Colorado 80521-2154

970-266-6090 (phone)

(b) (6), (b) (7)(C) (cell)

Jeffrey.C.Chandler@usda.gov

From: [Chandler, Jeffrey C - APHIS](#)
To: [Clark, Larry - APHIS](#); [Eckery, Douglas C - APHIS](#); [Deliberto, Thomas J - APHIS](#)
Subject: RE: Potential IACUC Non-Compliance, QA-2840
Date: Thursday, May 23, 2019 3:59:12 PM

Will do. I will also forward that letter along to all of you.

jeff

From: Clark, Larry - APHIS
Sent: Thursday, May 23, 2019 3:58 PM
To: Chandler, Jeffrey C - APHIS <jeffrey.c.chandler@usda.gov>; Eckery, Douglas C - APHIS <douglas.c.eckery@usda.gov>; Deliberto, Thomas J - APHIS <thomas.j.deliberto@usda.gov>
Subject: Re: Potential IACUC Non-Compliance, QA-2840
Please add Bryan Kluever to the cc when issuing the letter
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From: Chandler, Jeffrey C - APHIS <jeffrey.c.chandler@usda.gov>
Sent: Thursday, May 23, 2019 2:59 PM
To: Clark, Larry - APHIS; Eckery, Douglas C - APHIS; Deliberto, Thomas J - APHIS
Subject: Potential IACUC Non-Compliance, QA-2840

Hi everyone,

I just wanted to make you aware of a potential IACUC non-compliance issue with QA-2840. John Humphrey is the Study Director.

In review of previous documentation for an amendment to this study protocol, the IACUC identified documentation that indicated that animals were being used beyond the approved study date. Our policy identifies this as non-compliance. I will notify the Study Director shortly that the IACUC will investigate this per our policy.

Currently, I do not have additional details regarding this issue.

Let me know if there are questions/concerns.

Tkz,

jeff

Jeff Chandler

BioLabs

IACUC Chair

USDA/APHIS/WS National Wildlife Research Center

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Larry

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(b) (5)
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(b) (5)

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Larry

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Best,

jeff

Jeff Chandler
BioLabs
IACUC Chair
USDA/APHIS/WS National Wildlife Research Center
4101 Laporte Avenue
Fort Collins, Colorado 80521-2154
970-266-6090 (phone)
970-988-0321 (cell)
Jeffrey.C.Chandler@usda.gov

From: [Vercauteren, Kurt C - APHIS](#)
To: [Chandler, Jeffrey C - APHIS](#)
Subject: FW: CSU analysis
Date: Friday, December 20, 2019 2:00:33 PM

From: Vercauteren, Kurt C - APHIS
Sent: Monday, September 30, 2019 12:48 PM
To: (b) (6), (b) (7)(C) @genesislabs.com>
Cc: (b) (6), (b) (7)(C) @kaputproducts.com>
Subject: RE: CSU analysis

Hi (b) (6), (b) (7)(C)

Great, glad to hear Dr. (b) (6), (b) (7)(C) analyses is complete. NWRC should be about done, too. Dead animals found included 17 feral swine, seven raccoons, two opossums, one squirrel, and one dove. Jim had the dove analyzed by UC-Davis, and it did not die of from the lure.

How do you think the bromadiolone got in the lure?

Kurt

From: (b) (6), (b) (7)(C) [mailto:(b) (6), (b) (7)(C) @genesislabs.com]
Sent: Monday, September 30, 2019 10:28 AM
To: Vercauteren, Kurt C - APHIS <kurt.c.vercauteren@usda.gov>
Cc: (b) (6), (b) (7)(C) @kaputproducts.com>
Subject: CSU analysis

Kurt,

We heard from (b) (6), (b) (7)(C) that his results were in line with those of NWRC for bromadiolone in the Feral Hog Lure. We are awaiting his final report. I've advised (b) (6), (b) (7)(C) to prepare an EPA Section 6(a)(2) report and submit it to the EPA. This is an unfortunate setback. Please provide details on the non-targets and numbers.

Thanks,

(b) (6), (b) (7)(C)

(b) (6), (b) (7)(C)

Genesis Labs
Celebrating 30 years of Service
Tel: 970-568-7059
Fax: 950-568-3293
www.genesislabs.com

From: [Vercauteren, Kurt C - APHIS](#)
To: [Snow, Nathan P - APHIS](#); [Goldade, David A - APHIS](#); [Volker, Steven F - APHIS](#)
Subject: Fwd: Bromadiolone
Date: Wednesday, October 2, 2019 4:26:20 PM
Attachments: [image001.png](#)

FYI, (b) (5)

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From: (b) (6), (b) (7)(C)@kaputproducts.com>
Sent: Tuesday, October 1, 2019 11:47:02 AM
To: Vercauteren, Kurt C - APHIS <kurt.c.vercauteren@usda.gov>
Cc: (b) (6), (b) (7)(C)@genesislabs.com>; (b) (6), (b) (7)(C)@scimetricsltd.com>
Subject: Bromadiolone

Hi Kurt,

Richard asked me to send you an explanation as to the possible contamination cause of Bromadiolone in Feral Hog Lure.

To introduce the oils to the feral hog lure we utilize a pneumatic pressure pot that introduces it through sprayer heads into the mixer. We use the same mixer and the same pressure pot in the production of our bromadiolone bait. We suspect that though the mixer was cleaned out we failed to drain and clean the pressure pot and hoses to remove any residual bromadiolone from a previous batch of bait. Thus, when we added the oils to the lure it flushed the residual bromadiolone into the lure

We have implemented changes in our SOP's to eliminate this happening in the future.

Regards,

(b) (6), (b) (7)(C)

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