



Inspection Report

ENVIGO GLOBAL SERVICES INC

310 Swamp Bridge Road
DENVER, PA 17517

Customer ID: **506556**

Certificate: **23-R-0187**

Site: 002

ENVIGO GLOBAL SERVICES INC

Type: ROUTINE INSPECTION

Date: 20-JUL-2021

2.31(c)(7)

Institutional Animal Care and Use Committee (IACUC).

Study data from Protocol 03-21 was reviewed for 2 dogs on the protocol. The protocol states "body weights will be taken on Monday, Wednesday, and Friday." This protocol involves withholding food/fasting dogs.

Neither of these dogs had body weights recorded. The attending veterinarian stated that animals had not been weighed as stated in this protocol.

Significant changes to protocols, including changes to how animals are monitored, must be approved in order to assure IACUC oversight of animal activities and procedures.

Correct by ensuring that the IACUC requires modifications be made to protocols in writing when there are proposed significant changes to on-going activities involving animals. And further by ensuring that such modifications are evaluated by the IACUC and approved or approval is withheld in accordance with the Animal Welfare Act regulations. Any protocols for which significant modifications to ongoing activities are occurring without such approval at this time, must be resubmitted to the IACUC for review no later than 8/30/2021.

Prepared By: DIANA CARE

USDA, APHIS, Animal Care

Date:

18-OCT-2021

Title: VETERINARY MEDICAL
OFFICER

Received by Title: Facility Representative

Date:

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2.31(d)(1)(i) Critical

Institutional Animal Care and Use Committee (IACUC).

Protocol 003-21 describes a study in which lactating female dogs and their puppies undergo different manipulations of their diet to determine the effects on prevention of mastitis post-weaning. One experimental group in this study is subjected to a 48-hour fast (abrupt removal of food completely from an ad libitum feeding schedule) and the second experimental group has their total daily food ration severely decreased. The abrupt nature of this transition is expected to cause more than momentary or slight distress not only to the nursing dam, but also to the puppies as their food supply will also decline during that period (female's negative energy balance from lack of food is intended to decrease her milk supply). The principal investigator did not address this as a source of distress for the female dogs or the puppies in the approved written protocol; as such, the protocol neither describes any means to alleviate this distress, nor scientifically justifies in writing the withholding of any such means.

The lack of this required information in the written protocol (reviewed and approved by the IACUC) prevents the IACUC from ensuring that the proposed activities related to the care and use of the animals will avoid or minimize discomfort and distress to the dogs and puppies.

Correct by ensuring that the IACUC, for all future proposals, is able to determine that all proposed activities will avoid or minimize discomfort, pain, and distress when conducting a review of the activities related to the care and use of animals in order to approve the proposed activities. To be corrected by 08/03/21.

2.31(d)(2)

Institutional Animal Care and Use Committee (IACUC)

One protocol had a conflict of interest during its review and approval processes:

Protocol 003-21: lists the attending veterinarian as a co-principal investigator. The same attending veterinarian conducted

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the veterinary consultation as required by section 2.31(d)(1)(iv)(B) of this subpart. However, since the attending veterinarian is also the co-PI, she should not have participated in the review or approval process for this protocol, as she has a conflict of interest.

Allowing individuals with a conflict of interest to participate in the review and approval process interferes with the integrity and neutrality of that process aimed to ensure optimal animal welfare and the judicious use of animals in study activities. Correct by ensuring that no member contributes to a quorum nor participates in an IACUC review or approval of an activity in which that member has a conflicting interest (e.g., is personally involved in the activity), except to provide information requested by the IACUC. Correct by 08/03/21.

2.31(d)(4)

Institutional Animal Care and Use Committee (IACUC).

The IACUC has not notified the principal investigators (PI) and the research facility in writing of its decision to approve the submitted protocols. According to the attending veterinarian, once the protocols are approved by DMR the principal investigator signs the official protocol. The IACUC did not notify the PI in writing, by its process of adding the date of IACUC approval on the several protocols reviewed at the time of inspection.

Written notification of IACUC approval for proposed activities involving animals is important to maintain records regarding which protocols and their amendments have been approved and the date of their approval. IACUC functions as an oversight committee to help monitor animal welfare in research and written records confirm the IACUC is functioning as required by the Animal Welfare Act.

Correct by 08/03/21 by ensuring all IACUC decisions regarding approval of proposed activities involving animals are provided in writing to the principal investigators and the research facility. This written notification must include the approval, the decision to withhold approval, and/or the decision to require modifications of proposed animal activities.

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2.31(e)(2)

Institutional Animal Care and Use Committee (IACUC).

The following protocols, 02-19, 03-19, 002-20, 001-21, 002-21, and 003-21, simply state the number of animals to be used. No rationale for the appropriateness of the number stated is provided.

***Protocol 02-19 states that 16 dogs are to be used per year for the study but provides no explanation for why 16 dogs are needed.

***Protocol 03-19 states that 20 cats will be used per year for the study but also provides no explanation for why 20 cats are needed.

***Protocol 002-20 states that 100 female dogs will be used per year for the study and that a minimum of 50 dams and their litters must be evaluated on each of the diets. However, there is no rationale provided for the number of female dogs such as statistical calculations for statistically significant results, based on scientific literature, etc.

***Protocol 001-21 states that 4 adult dogs are needed for the training protocol. Although the protocol states that 4 animals are the minimum needed to practice on various sizes of beagles and temperaments, there is no rationale for the number of dogs based on the number of students/animal and/or the number of attempts on each animal.

***Protocol 002-21 states that 3 adult male dogs will be used per year for a study on pharmacokinetics but provides no rationale for the request of 3 dogs. The only rationale provided is that canines are the intended use for the compound being studied.

***Protocol 003-21 states that 400 adult female dogs will be used per year for the study and this is based on past production. However, in the justification for the number of animals in the study, it states that 400 dogs is the maximum number of bitches and puppies to be used in the study. The protocol has two different number requests with no rationale provided such as statistical calculations for statistically significant results, based on scientific literature or past experience, etc.

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Protocols submitted for IACUC review are required to contain a rationale for the use of live animals and for the numbers of animals to be used in the study. If no rationales are provided, the IACUC cannot complete a thorough review of the proposed activities using animals and ensure animals are not unnecessarily subjected to experimental designs.

Correct by the IACUC ensuring all new protocols submitted for review have a complete, written rationale for the use of live animals, the appropriateness of the species and the numbers of animals to be used in the study design. Correct by 09/30/2021.

2.31(e)(3)

Institutional Animal Care and Use Committee (IACUC).

Several protocols lack complete descriptions of the proposed use of the animals.

***02-19 and 03-19 are similar studies conducted in parallel on dogs and cats, respectively. The protocol states that animals will be vaccinated and blood collected. There is no mention of any other relevant details such as vaccine to be administered or the number and time points of blood draws. The approved protocol does not include any discussion of what is being studied/measured.

***004-21 is a study in which dogs have their liver perfused and subsequently harvested during a non-survival procedure. The surgical description does not include details such as the use of aseptic techniques/conditions, volume and type of perfusion fluid, and the specific steps taken to remove the liver. The anesthetic regiment does not include details such as whether inhalant anesthesia will be provided via an endotracheal tube, or if the induction agent will be given via an IV catheter (protocol states this will be given "to effect," which indicates the potential need for multiple injections if not administered through a catheter).

***002-20 is a diet trial for gestating and lactating dams with puppies. The protocol indicates two experimental diets, 1B/3B and 5L3U, which differ from the established diet of 5LL9. For the 1B/3B diet, it is not specified what the transition period will consist of or how long it will last. The stated experimental objective is to determine each diet's effects "on

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gestation, lactation, whelping/weaning, post-weaning weight gain;" however, the protocol does not mention any objective measures such as empiric body weights will be taken, only a body condition score (BCS). No details are provided on the scoring system used to assign BCS, such as the scale (1-5 vs. 1-9), or specific observations that may help the scorer to assign a numeric value (e.g., visible ribs and hip bones, protruding vertebral spinous processes, etc.).

***002-21 is a pharmacokinetic study assessing concentrations of an experimental drug in urine and blood samples taken at various times following drug administration. The protocol provides explicit detail regarding sampling of urine via ultrasound-guided cystocentesis; however, similar details regarding blood sampling procedures are missing (location of venous access, whether a venous access portal such as a catheter will be utilized or if multiple venipunctures will be performed, and volume of blood sampled).

***001-21 is a teaching protocol to practice intravenous infusions via IV catheter. The protocol states 4 dogs will be used, but there is no information regarding the following: if a dog may undergo repeat iterations of such practice; if so, how many; the rest period between repeat uses; and the method and location(s) in which the IV catheter will be placed. These important details are required for the IACUC to be able to make an informed determination whether the proposed activities ensure the humane and judicious use of animals in research. Correct by ensuring proposals to conduct activities involving animals contain a complete description, in lay terms and in detail, of the proposed use of the animals. Additionally, ensure that any of the protocols listed above for which activities are still occurring or may occur in the future are amended to add a complete description of activities and resubmitted to the IACUC for review and approval. Correct by 08/30/2021.

2.35

Recordkeeping requirements.

The research facility is closely affiliated with a separate business that is licensed as an "A" dealer under the Animal Welfare Act. However, the research facility does not maintain records that disclose the acquisition or disposition of dogs

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and cats coming from and going to the Class "A" dealer. Their recordkeeping system is such that it only reflects the current use of the animals (research or breeding), but does not show the information required to be maintained of transfers between animal uses. Failure to keep and maintain records regarding transfers of animal use can lead to confusion in possession and responsibility or liability to maintain good animal health and welfare. Additionally, in the case for research animals, it may be unclear if an animal has undergone previous procedures that may compromise the integrity of ongoing research.

Correct by making and keeping records which fully and correctly disclose all pertinent information of ownership, possession, control, transport, euthanasia, sale, or other disposition, including all offspring born while in the facility's possession or under its control, as required in parts (b) and (c) of this subsection. Correct by August 30th, 2021.

2.38(a) Critical

Miscellaneous.

Medical and study data/study records for 2 animals used on each of 8 research protocols from the last year were requested from the facility on July 22nd, 2021 (records for a total of 16 animals). On July 23rd the facility provided printed medical records from their computerized system along with some handwritten surgical logs. The majority of these records do not contain any information regarding protocol-specific procedures performed on animals. On July 26th and 27th, further clarifying emails requesting study data/study records for animals were submitted to the facility. Per phone conversations, the attending veterinarian explained that notes and records generated during protocols were kept as "study data" and not included in an animal's official medical record in the electronic system. The attending veterinarian stated that according to the facility's legal department, she was not allowed to share study data with USDA personnel. These study data records were requested again, by email, on July 28th with a due date of July 29th by 9 AM. As of 9 AM on July 30th, the facility refused to provide full copies of the study records which include the procedures performed on dogs while they are on a study. At 10:30AM on July 30th, 2.5 hours before the scheduled exit briefing, USDA personnel were able to

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briefly remotely view some of the study data that had been previously requested. This review did not allow for a complete and thorough assessment of the facility's compliance with AWA regulations.

APHIS Officials must be permitted to evaluate study records that describe the procedures and exam findings from dogs participating in research studies in order to evaluate the facility's adherence to the IACUC approved protocol and to ensure compliance with the AWA regulations and standards.

Correct by furnishing any information requested by APHIS officials within a reasonable time and as may be specified in the request for such information. To be corrected: August 3rd, 2021.

This inspection was conducted with the Operations Manager and the Attending Veterinarian. The exit interview was conducted with the Operations Manager, Attending Veterinarian, Site Director, Regional Quality Assurance Manager, Director of Quality Assurance, Senior Vice President for Veterinary Services, Chief Operations Officer, and Regional Facilities Manager.

Additional Inspectors:

Rachel Perez-Baum, VETERINARY MEDICAL OFFICER

KATHRYN CAMPITELLI, VETERINARY MEDICAL OFFICER

SUSANNE BRUNKHORST, VETERINARY MEDICAL OFFICER

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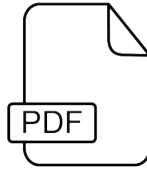
Date:
18-OCT-2021



Species Inspected

Cust No	Cert No	Site	Site Name	Inspection
506556	23-R-0187	002	ENVIGO GLOBAL SERVICES INC	20-JUL-2021

Count	Scientific Name	Common Name
000020	<i>Canis lupus familiaris</i>	DOG ADULT
000033	<i>Felis silvestris catus</i>	CAT ADULT
000053	Total	



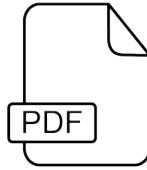
CFR:2.31(e)(2)

Photographer: Rachel Perez-Baum **Certificate:** 23-R-0187

Date and Time: 7/23/2021 11:00 AM **Legal Name:** ENVIGO GLOBAL SERVICES INC

Inspection No: 2016090000739002 **Facility Name:** ENVIGO GLOBAL SERVICES INC

Description: Protocol 01-21 **FOIA**



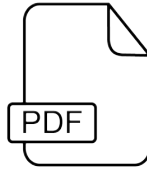
CFR:2.31(e)(2)

Photographer: Rachel Perez-Baum **Certificate:** 23-R-0187

Date and Time: 7/23/2021 11:00 AM **Legal Name:** ENVIGO GLOBAL SERVICES INC

Inspection No: 2016090000739002 **Facility Name:** ENVIGO GLOBAL SERVICES INC

Description: Protocol 2-20



CFR:2.31(c)(7);2.31(d)(1)(i);2.31(d)(2);2.31(d)(4);2.31(e)(2)

Photographer: Diana Care

Certificate: 23-R-0187

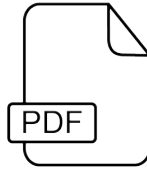
Date and Time: 7/23/2021 11:00 AM

Legal Name: ENVIGO GLOBAL SERVICES INC

Inspection No: 2016090000739002

Facility Name: ENVIGO GLOBAL SERVICES INC

Description: Protocol 03-21 fasting and mastitis prevention. **FOIA** contains proprietary info.



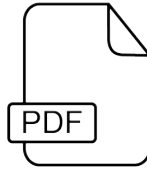
CFR:2.31(e)(2);2.31(e)(3)

Photographer: Rachel Perez-Baum **Certificate:** 23-R-0187

Date and Time: 7/23/2021 11:00 AM **Legal Name:** ENVIGO GLOBAL SERVICES INC

Inspection No: 2016090000739002 **Facility Name:** ENVIGO GLOBAL SERVICES INC

Description: Protocol 03-19



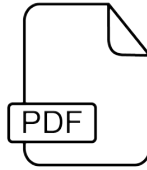
CFR:2.31(e)(2)

Photographer: Rachel Perez-Baum **Certificate:** 23-R-0187

Date and Time: 7/23/2021 11:00 AM **Legal Name:** ENVIGO GLOBAL SERVICES INC

Inspection No: 2016090000739002 **Facility Name:** ENVIGO GLOBAL SERVICES INC

Description: Protocol 02-21 **FOIA**



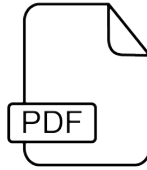
CFR:2.31(e)(3)

Photographer: Rachel Perez-Baum **Certificate:** 23-R-0187

Date and Time: 7/23/2021 11:00 AM **Legal Name:** ENVIGO GLOBAL SERVICES INC

Inspection No: 2016090000739002 **Facility Name:** ENVIGO GLOBAL SERVICES INC

Description: Protocol 04-21



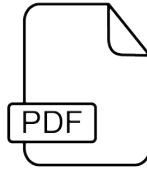
CFR:2.38(a)

Photographer: Rachel Perez-Baum **Certificate:** 23-R-0187

Date and Time: 7/30/2021 9:00 AM **Legal Name:** ENVIGO GLOBAL SERVICES INC

Inspection No: 2016090000739002 **Facility Name:** ENVIGO GLOBAL SERVICES INC

Description: Email requesting medical records.



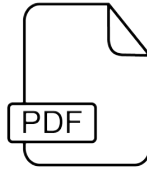
CFR:2.38(a)

Photographer: Rachel Perez-Baum **Certificate:** 23-R-0187

Date and Time: 7/30/2021 9:00 AM **Legal Name:** ENVIGO GLOBAL SERVICES INC

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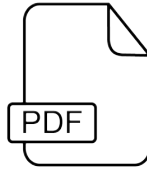
CFR:2.38(a)

Photographer: Rachel Perez-Baum **Certificate:** 23-R-0187

Date and Time: 7/30/2021 9:00 AM **Legal Name:** ENVIGO GLOBAL SERVICES INC

Inspection No: 2016090000739002 **Facility Name:** ENVIGO GLOBAL SERVICES INC

Description: Email requesting medical records.



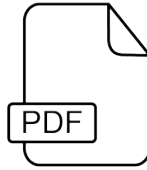
CFR:2.31(e)(2);2.31(e)(3)

Photographer: Rachel Perez-Baum **Certificate:** 23-R-0187

Date and Time: 7/23/2021 11:00 AM **Legal Name:** ENVIGO GLOBAL SERVICES INC

Inspection No: 2016090000739002 **Facility Name:** ENVIGO GLOBAL SERVICES INC

Description: Protocol 2-19



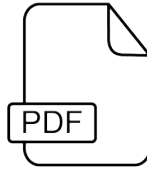
CFR:2.38(a)

Photographer: Rachel Perez-Baum **Certificate:** 23-R-0187

Date and Time: 7/30/2021 9:00 AM **Legal Name:** ENVIGO GLOBAL SERVICES INC

Inspection No: 2016090000739002 **Facility Name:** ENVIGO GLOBAL SERVICES INC

Description: Email requesting medical records.



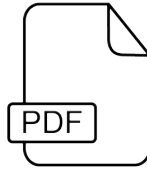
CFR:2.38(a)

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Description: Email requesting medical records.



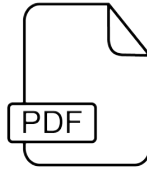
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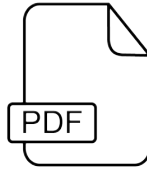
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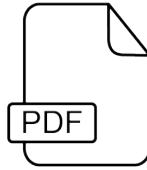
CFR:2.38(a)

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Date and Time: 7/30/2021 9:00 AM **Legal Name:** ENVIGO GLOBAL SERVICES INC

Inspection No: 2016090000739002 **Facility Name:** ENVIGO GLOBAL SERVICES INC

Description: Email requesting medical records.



CFR:2.38(a)

Photographer: Rachel Perez-Baum

Certificate: 23-R-0187

Date and Time: 7/29/2021 4:30 PM

Legal Name: ENVIGO GLOBAL SERVICES INC

Inspection No: 2016090000739002

Facility Name: ENVIGO GLOBAL SERVICES INC

Description: Memo regarding attempts to access all records pertaining to animals on study protocols. This memo includes attempts up until 5:30 PM on July 29, 2021. Further attempts were made July 30, 2021.

***** FOIA WARNING May contain Personally Identifiable Information or Proprietary Information*****



Animal and Plant
Health Inspection
Service

Memorandum

Animal Care

To: Dana Miller
From: Rachel Perez-Baum
CC:
Date: 7/29/2021
Subject: 32-A-0774 Site 005

The following memo includes additional information regarding the request for individual animal medical records in coordination with all study protocols from the last year including active and inactive protocols.

On Friday, July 23, 2021 around 7:50 am I sent another email out to the manager of operations (MO) and the attending veterinarian (AV) clarifying that we would be finishing a routine research inspection and would require all protocols from this past calendar year including protocols that are inactive, not currently active, and active. Additionally, we requested copies of all medical records from at least 2 animals from each protocol.

When picking up the records Friday afternoon, the MO explained that a few of the research protocols don't have any medical records from the dogs since they were just "observation" studies. She also explained that one of the protocols is approved but hasn't started yet or been scheduled yet.

On Monday, July 26th, we began going through the records and looking at the research documents. For one study (003-20) we were provided a print out of the basic computer medical history which includes routine weights, vaccinations, dental care, ear cleaning, etc. but does not contain any history related to research procedures. We were also provided hand-written surgical/treatment forms for two dogs which had the research records from muscle biopsy procedures. However, the included records had no mention of the treadmill stress test the dogs underwent or the injection of a compound, heart rate measurements, etc. For Protocols 03-19 and 02-19 we received some handwritten treatment forms for 2 dogs and 2 cats. The 2 dog medical files and one cat medical file were records of their routine neuters and the last cat medical file was records of treating a bite wound from a fight. None of the records included administration of the test vaccine or the subsequent blood draws as stated in the protocol. Protocols 002-21 and 003-21 only have the basic medical records from the system which do not indicate any procedures that were performed based on the protocols nor that the animals participated in a research study. Finally, Protocols 001-21 and 002-20 were sent with no corresponding records. An email was sent out by Dr. Diana Care to the MO and AV requesting additional information regarding Protocol 003-21 and indicating that the protocol stated weights would be recorded three times (Monday, Wednesday, and Friday) and the animals would be examined for mastitis daily for 10 days post-weaning. Since the medical records provided do not have these weights recorded, do not specify which branch of the study the animal was assigned to, and don't have any results from the daily physical exams for mastitis, the email asked if there were any additional medical records which contained this information.

The MO and AV called me the evening of 7/26 to discuss the email and the answers via phone. According to the MO and AV, the medical records for the dogs in the system do not contain any of the study information, procedures, results, etc. Those are all listed in the "study data" instead. I mentioned that we would likely need all of that and we continued with the questions in the email.

On July 27th, at about 3:30 PM I sent another email to the MO and AV with additional questions we had regarding protocols and another request for the records from animals on protocols. In this email I used

the term “study data” since that was used to reference the additional records we were seeking the previous evening on the phone. Although the email states “We will need copies of the study data for the animals pulled from protocols” which could be misinterpreted as records only for animals that didn’t complete a protocol, the facility should have understood based on previous conversations that this was referencing the 2 animals they had already chosen from each study to provide us records of.

On the afternoon of July 28th, the AV called, and I added Dr. Care into the phone call so all three of us could discuss the answers to the previous email. Unfortunately, Dr. Care had to step out of the phone call towards the end, but we finally reached the request #7 for the “study data.” The AV stated over the phone that the lawyers had told her to not provide any study data to APHIS and she inquired as to the regulation that required them to provide that information. Additionally, she stated that the study data is owned by the company who hired them to perform the research and not Envigo. I admitted that I would have to look as I did not know it off the top of my head. After looking, I mentioned for the AV to look at page 65 of the blue book (Regulation 2.38 Miscellaneous) as I believed that would be it, but I understood nothing explicitly states the study data or medical records so I would check with my supervisor and we would get back to them.

After discussing the end of the phone call with Dr. Care and she discussed it with Dr. Miller, the two of them drafted an email and sent to the MO and AV with a third request for all study records to be provided by 9 AM on 7/29 with a warning that if the records were not furnished in time, the facility would be cited for 2.38 as a critical citation. Another email was sent by Dr. Care the evening of 7/28 requesting the acquisition and disposition records for dogs that moved from Envigo RMS’s Class A License to the Envigo Global Sciences’ R – Research registration. Additionally, records were requested for any dogs who upon return to the Class A inventory were then sold or adopted.

At 6:30 AM on 7/29, another email was sent to the Envigo MO and AV from Dr. Care requesting copies of all active protocols from which animals were reported on the FY2020 Annual report. If we already have copies of those protocols, we asked for them to clarify which they were.

At 8:57 AM on 7/29, we received a response from the MO which stated they were confused as to which records had been requested and that they have tried to provide the records requested based on the email correspondence they have received.

Finally, at about 3 PM on 7/29 an email was sent from Dr. Care to the Envigo MO and AV explaining in more detail that we are asking for all study data, all medical records, and all other records for the specific animals already identified for each protocol on 7/23. The facility was asked to furnish this information by 4 PM. As of 5 PM, no further communication has been received by USDA APHIS Animal Care from the facility.

From: [PerezBaum, Rachel - MRP-APHIS](#)
To: (b) (6), (b) (7)(C)
Cc: [Care, Diana M - APHIS](#)
Subject: Additional Questions/Clarifications
Date: Tuesday, July 27, 2021 3:28:00 PM

Good afternoon,

We have some more questions for you:

1. We are interested in how you document dogs that belong to your dealer's license versus the research registration? Is there an easy way in the system to track who they belong to, or is it all one big population shared?
2. Do you track puppies born to a dam that is on a research protocol? If the puppies are transferred back to the dealer's inventory, is that documented in their records?
3. When we were there, about 20 dogs were on a current protocol. Do you have records for their acquisition (when they transferred from the dealer's license to the registration)? As we were looking through the numerous medical records, we didn't see any indication of whether the dog had participated in a protocol. Similarly, while looking at the puppy records- how do you identify those that were on/born into protocol?
4. Can you provide a variance approval letter from USDA for the use of tattoo's as primary identification on your "A" license?
5. Are there any additional medical records that would include more information past the basic print out we received? E.g. If additional tests, specific PE results, necropsy results, treatments, etc. were documented, where are those located? (For tattooed and serial number dogs)
6. Can you provide us additional information on what the medical code "Missing" means?
7. We will need copies of the study data for the animals pulled from protocols.

Thank you for your time. If virtual records are easier, please let me know and you can set up a shared file drive. Also, if you prefer to call and discuss the answers, please feel free.

Rachel Pérez-Baum, DVM, MPH

Veterinary Medical Officer

USDA, APHIS, Animal Care

Cell: (b) (6), (b) (7)(C)

rachel.perezbaum2@usda.gov

From: [Care, Diana M - APHIS](#)
To: (b) (6), (b) (7)(C)
Cc: [PerezBaum, Rachel - MRP-APHIS](#)
Subject: Additional records request
Date: Wednesday, July 28, 2021 5:52:32 PM

Good evening,

I am requesting the following records:

Records of acquisition and disposition showing movement of dogs from the Class A license to Research registration and back to Class A license. In other words, records of dogs on protocols who are returned to the main inventory after the study is concluded. I would also like records for any dogs who, upon return to the inventory, were then sold or adopted.

Thank you,

Diana Care, DVM, MPH, DACVPM

Veterinary Medical Officer

Mississippi/Tennessee/Alabama

USDA APHIS Animal Care

Phone: (662) 707-0131

From: [PerezBaum, Rachel - MRP-APHIS](#)
To: (b) (6), (b) (7)(C)
Cc: [Care, Diana M - APHIS](#)
Subject: Records Requested
Date: Friday, July 23, 2021 7:48:05 AM
Attachments: [image001.png](#)

Good morning (b) (6), (b) (7)(C),

Diana and I discussed the records we need today one more time last night and I wanted to put it in writing for you. We do need a few more documents than I believe were in that stack. We are going to finish the inspection on the research registration as well so there are some of those documents included below:

Facility inspection report from Jan 2021

All protocols from the last 12 months (current or inactive)

A complete set of medical records from at least two animals from each protocol

A cat protocol or holding SOP

The owners of the cats and the MOU decision/agreement between your companies as to who is responsible for reporting them on the annual report. (This can be just written down for us)

The mortality log with Diana's notes please

A copy of the medical code list definitions

The medical records marked with a blue star on the mortality log

SOPs for general sanitation and whelping sanitation

Thank you for your help in acquiring these documents.

-Rachel

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From: (b) (6), (b) (7)(C)
Sent: Tuesday, July 20, 2021 4:33:22 PM
To: PerezBaum, Rachel - MRP-APHIS <Rachel.PerezBaum2@usda.gov>; Care, Diana M - APHIS <diana.care@usda.gov>
Cc: (b) (6), (b) (7)(C)
Subject: [External Email]Contact Information

[External Email]

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Hello,

I thought this might be a better means of making sure we don't misplace each other's contact information. I'm certainly looking forward to forging a strong relationship and welcome feedback on our facility. My cell number is listed below and (b) (6), (b) (7)(C) can be reached at (b) (6), (b) (7)(C).

Unfortunately, I'm too new to have business cards just yet so this communication will need to serve

the purpose for now.

Thanks,

(b) (6), (b) (7)(C)
(b) (6), (b) (7)(C) - Cumberland
Mobile (b) (6), (b) (7)(C)

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From: (b) (6), (b) (7)(C)
To: Care, Diana M - APHIS
Cc: PerezBaum, Rachel - MRP-APHIS; Miller, Dana - APHIS
Subject: [External Email]Records request re: 2020 Annual report
Date: Thursday, July 29, 2021 8:57:14 AM
Attachments: image003.png

[External Email]

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Good Morning Dr Care and Dr Perez-Baum,

There has been some confusion regarding exactly which records you have requested. The request sent to us on Tuesday, July 27th, (pictured below), line 7 asked for copies of study data not specifically medical records. Line 5 asked if additional medical records exist and to that question I can say it depends on the individual animal.

We have some more questions for you:

- 1) We are interested in how you document dogs that belong to your dealer's license versus the research registration? Is there an easy way in the system to track who they belong to, or is it all one big population shared?
- 2) Do you track puppies born to a dam that is on a research protocol? If the puppies are transferred back to the dealer's inventory, is that documented in their records?
- 3) When we were there, about 30 dogs were on a current protocol. Do you have records for their acquisition (when they transferred from the dealer's license to the registration)? As we were looking through the numerous medical records, we didn't see any indication of whether the dog had participated in a protocol. Similarly, while looking at the puppy records- how do you identify those that were on/born into protocol?
- 4) Can you provide a variance approval letter from USDA for the use of tattoo's as primary identification on your "A" license?
- 5) Are there any additional medical records that would include more information past the basic print out we received? E.g. If additional tests, specific PE results, necropsy results, treatments, etc. were documented, where are those located? (For tattooed and serial number dogs)
- 6) Can you provide us additional information on what the medical code: "Missing" means?
- 7) We will need copies of the study data for the animals pulled from protocols.

In the packet of documents submitted to Dr Perez-Baum on Friday, July 23rd in response to the initial request received Friday, July 23rd we sent the requested 2 record per protocol active or inactive in the past 12 months.

<u>Protocol</u>	<u>Animals Submitted</u>
003-21	CKHCNH and CIECAL
002-21	CIHCPR and CJICKD
003-20	CEJCIE and CEJCFX
003-19	6587798 and 6587950
002-19	M191076 and M190258

Protocols 001-21 and 002-20 did not have any associated medical records. This information was shared with Dr. Perez-Baum on Friday, July 23rd.

We have done our best to provide records as requested based on the email correspondence received from your agency. If you could please provide additional clarification as to your request we will work to provide such documents but we will need additional time once we understand exactly which documents need to be pulled.

Thanks,

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

(b) (6), (b) (7)(C) - Cumberland
Mobile (b) (6), (b) (7)(C)

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From: [Care, Diana M - APHIS](#)
To: (b) (6), (b) (7)(C)
Cc: [PerezBaum, Rachel - MRP-APHIS](#)
Subject: Re: Records Requested
Date: Monday, July 26, 2021 12:29:52 PM
Attachments: [image001.png](#)

Good morning,

Thank you for the records. I have a few follow up questions:

1) The SOP for "Sanitation of Cat Rooms" states that litter boxes and cages are sanitized every 14 days by using an appropriate detergent solution and water rinse. Is this correct? What detergent solution is used- Is it the GP-100?

2) Protocol 003-21:

- When was this protocol approved by the IACUC? Is there any documentation of approval by the IACUC to the PI?
- When was this protocol active? Records show it was approved in spring of 2021, so can I assume it was active for spring and early summer 2021?
- The protocol says that dogs will be fasted and their weights recorded on Mon/Weds/Friday. Weights such as this are not recorded in the dog's individual medical records which were provided, and it not clear from the medical records when the dog whelped and which arm of the protocol she was on. Are there any additional medical records from this study where the thrice weekly weights are recorded, as well as the mastitis exams which occurred daily for 10 days?
- The box is not checked for "veterinary review" for this Cat D protocol. Was a veterinary review conducted? If so, was it conducted by the PI or did you use any other veterinarian?

If you would prefer to discuss these questions via phone, I am available today, Wednesday, and Friday. You are also welcome to reach out to Dr. Perez-Baum in lieu of myself to discuss your responses with her.

Respectfully,

Diana Care, DVM, MPH, DACVPM

Veterinary Medical Officer

Mississippi/Tennessee/Alabama

USDA APHIS Animal Care

Phone: (662) 707-0131

From: PerezBaum, Rachel - MRP-APHIS <Rachel.PerezBaum2@usda.gov>

Sent: Friday, July 23, 2021 6:48 AM

To: (b) (6), (b) (7)(C)

Cc: Care, Diana M - APHIS <diana.care@usda.gov>

Subject: Records Requested

Good morning (b) (6), (b) (7)(C),

Diana and I discussed the records we need today one more time last night and I wanted to put it in writing for you. We do need a few more documents than I believe were in that stack. We are going to finish the inspection on the research registration as well so there are some of those documents included below:

Facility inspection report from Jan 2021

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A cat protocol or holding SOP

The owners of the cats and the MOU decision/agreement between your companies as to who is responsible for reporting them on the annual report. (This can be just written down for us)

The mortality log with Diana's notes please

A copy of the medical code list definitions

The medical records marked with a blue star on the mortality log

SOPs for general sanitation and whelping sanitation

Thank you for your help in acquiring these documents.

-Rachel

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From: (b) (6), (b) (7)(C)

Sent: Tuesday, July 20, 2021 4:33:22 PM

To: PerezBaum, Rachel - MRP-APHIS <Rachel.PerezBaum2@usda.gov>; Care, Diana M - APHIS <diana.care@usda.gov>

Cc: (b) (6), (b) (7)(C)

Subject: [External Email]Contact Information

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Unfortunately, I'm too new to have business cards just yet so this communication will need to serve the purpose for now.

Thanks,

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

(b) (6), (b) (7)(C) - Cumberland

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