

**From:** (b) (6), (b) (7)(C)  
**To:** [APHIS-AnimalCare](#)  
**Cc:** (b) (6), (b) (7)(C); [Pannill, Elizabeth C - APHIS](#)  
**Subject:** Change in IO: University of Texas Medical Branch, Galveston 74-R0073 Customer #1469  
**Date:** Wednesday, January 6, 2021 10:49:46 AM  
**Attachments:** [Appointment Letter IO.pdf](#)

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Please see the above appointment letter naming Ms. (b) (6), (b) (7)(C) MPH as the Animal Care and Use Program, Institutional Official (IO). She is replacing Dr (b) (6), (b) (7)(C)

Please let me know if there any questions.

Sincerely;

Confidential IACUC Communication  
Texas Health & Safety Code § 161.031 et seq.  
Do Not Distribute Without Authorization

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

UTMB, Galveston

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

(b) (6), (b) (7)(C) [utmb.edu](#)

January 5, 2021

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

Research Regulations and Compliance  
Route 0133

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

This letter serves as notification of your appointment as the UTMB Institutional Official as it relates to laboratory animal research. Notification of the appointment must be made to the Office of Human Research Protection, the Office of Laboratory Animal Welfare and the United States Department of Agriculture as per their requirements.

Sincerely,



Ben G. Raimer, MD, MA, FAAP  
President, *ad interim*

**From:** [Clarke, Carol L - APHIS](#)  
**To:** [Miller, David S - APHIS](#)  
**Cc:** [APHIS-AnimalCare](#)  
**Subject:** RE: Attn: Drs. Goldentyer and Clarke  
**Date:** Tuesday, January 26, 2021 11:02:21 AM  
**Attachments:** [image001.png](#)

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Hi! Yes I handle these requests. Please let your staff know to send these. Thanks.

Carol Clarke, DVM, DACLAM  
Research Program Manager  
USDA/APHIS-Animal Care  
4700 River Rd Unit 84  
Riverdale, MD 20737  
(c) 301 887 7794

---

**From:** Miller, David S - APHIS <David.S.Miller@usda.gov>  
**Sent:** Tuesday, January 26, 2021 10:35 AM  
**To:** Clarke, Carol L - APHIS <carol.l.clarke@usda.gov>  
**Cc:** APHIS-AnimalCare <AnimalCare@usda.gov>  
**Subject:** FW: Attn: Drs. Goldentyer and Clarke

Hi Carol,  
I hope that all is well. I received the below and attached regarding multiple surgical procedures in primates. I am under the impression that this is something that you address? If not, where should this be sent? Please cc "all" so that both Program Support and myself are clear about the process.  
Thanks!  
Cheers,  
Dave

David S. Miller, DVM, PhD, DACZM, DACAW  
National Animal Welfare Specialist  
(970)825-3745

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**From:** APHIS-AnimalCare <[AnimalCare@usda.gov](mailto:AnimalCare@usda.gov)>  
**Sent:** Tuesday, January 26, 2021 6:30 AM  
**To:** Miller, David S - APHIS <[David.S.Miller@usda.gov](mailto:David.S.Miller@usda.gov)>  
**Subject:** FW: Attn: Drs. Goldentyer and Clarke

Good morning Dr. Miller,

Received this email into our main email organization box. When possible please review the attached request for procedure consideration. Please let us know if this is not in your area or if we can assist with additional information.

Sincerely,

Program Support  
USDA APHIS Animal Care  
Phone: (970) 494-7478

**Please send all paperwork to our new mailing address:**

Fort Collins: 2150 Centre Ave., **Building B, 3W11**, Fort Collins CO, 80526

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**Sent:** Monday, January 25, 2021 8:02 AM

**To:** APHIS-AnimalCare <[AnimalCare@usda.gov](mailto:AnimalCare@usda.gov)>; Clarke, Carol L - APHIS <[carol.l.clarke@usda.gov](mailto:carol.l.clarke@usda.gov)>

**Cc:** (b) (6), (b) (7)(C) @UTMB.EDU>; (b) (6), (b) (7)(C) @UTMB.EDU>; Comvalius-(b) (6), (b) (7)(C) @UTMB.EDU>

**Subject:** Attn: Drs. Goldentyer and Clarke

Good Morning,

Please find the attached modified request for your consideration. We look forward to hearing your reply.

Sincerely,

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

---

(b) (6), (b) (7)(C) DVM, DACLAM

Animal Resources Center

Attending Veterinarian

Assistant Professor of Microbiology and Immunology

The University of Texas Medical Branch – Galveston



Working together to work wonders™

**From:** Clarke, Carol L - APHIS <[carol.l.clarke@usda.gov](mailto:carol.l.clarke@usda.gov)>  
**Sent:** Monday, January 4, 2021 11:59 AM  
**To:** (b) (6), (b) (7)(C) @UTMB.EDU>  
**Cc:** Pannill, Elizabeth C - APHIS <[elizabeth.c.pannill@usda.gov](mailto:elizabeth.c.pannill@usda.gov)>  
**Subject:** RE: Your request to the USDA

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Dear Dr. (b) (6), (b) (7)(C)

Happy New Year! Thank you for the response letter sent December 22<sup>nd</sup> and delivered via FEDEX.

It is my understanding that UTMB requests an exemption to the regulatory requirement that limits an animal to one major operative procedure (MOP) for (b) (4) that will be transferred to a new protocol after having a MOP under protocol (b) (4).

The new study will require (b) (4) under current protocol # (b) (4). The protocol for the new study is under development and once written, will be submitted for IACUC review and approval.

Under 9 CFR § 2.31(d)(1)(x)(C), UTMB will be required to submit a request for an exemption once that new protocol has been approved by the IACUC. That request can be Emailed to [AnimalCare@USDA.Gov](mailto:AnimalCare@USDA.Gov) with ATTN to Dr. Betty Goldentyer and myself Dr. Carol Clarke. All of the instructions provided below in my 12/17/20 Email should be followed.

In the interim, continue performing work under protocol # (b) (4). In the event there is a MOP to be performed that is not specifically indicated in the protocol (e.g. (b) (4) (b) (4)); an amendment will be required because this constitutes a significant change. The amendment must be reviewed and approved by the IACUC before conducting the surgery. The outline for the amendment can be found under 9 CFR § 2.31(d)(8)(e 1-5).

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[https://www.aphis.usda.gov/animal\\_welfare/downloads/AC\\_BlueBook\\_AWA\\_508\\_comp\\_version.pdf](https://www.aphis.usda.gov/animal_welfare/downloads/AC_BlueBook_AWA_508_comp_version.pdf)

Please feel free to contact me at 301 887 7794 with any questions you may have. If you plan to send correspondence by mail, please let me know so I can go into the office to retrieve it. I am working from home due to COVID-19. Best regards.

Carol Clarke, DVM, DACLAM  
Research Program Manager  
USDA/APHIS-Animal Care  
4700 River Rd Unit 84  
Riverdale, MD 20737  
(c) 301 887 7794

---

**From:** Clarke, Carol L - APHIS  
**Sent:** Thursday, December 17, 2020 12:57 PM  
**To:** (b) (6), (b) (7)(C) [UTMB.EDU](mailto:UTMB.EDU)  
**Cc:** Pannill, Elizabeth C - APHIS <[elizabeth.c.pannill@usda.gov](mailto:elizabeth.c.pannill@usda.gov)>  
**Subject:** Your request to the USDA

Dear Dr. (b) (6), (b) (7)(C)

Hi! I just received your notice that UTMB wishes to perform another major operative procedure on nonhuman primates under a different protocol.

Enclosed is what is necessary in writing to process your request:

1. **Contacts:** Provide primary and secondary contacts complete with phone numbers and Emails.
2. **Protocol:** Provide the protocol number under which the work will be performed along with date of IACUC approval, and date of expiration.
3. **Animal:** The species, age, number of animals involved, along with ID numbers
4. **History:** A summary of previous major operative procedures (MOP) performed for research purposes only with protocol number
5. **Proposed procedures:** Summarize the proposed work along with the number of MOPs anticipated and disposition of animals at the end of the study. Is this work a collaborative surgical effort? If so, who will be responsible for the surgery and post-op care?

Note: I will be out of the office 12/21/20 until 1/3/21. I can review your information after I return.  
Best regards.

Carol Clarke, DVM, DACLAM  
Research Program Manager  
USDA/APHIS-Animal Care  
4700 River Rd Unit 84  
Riverdale, MD 20737  
(c) 301 887 7794

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**From:** [Miller, David S - APHIS](#)  
**To:** [Clarke, Carol L - APHIS](#)  
**Cc:** [APHIS-AnimalCare](#)  
**Subject:** FW: Attn: Drs. Goldentyer and Clarke  
**Date:** Tuesday, January 26, 2021 10:36:07 AM  
**Attachments:** [image001.png](#)  
[USDAreqwue4st\(2\).doc](#)

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Hi Carol,

I hope that all is well. I received the below and attached regarding multiple surgical procedures in primates. I am under the impression that this is something that you address? If not, where should this be sent? Please cc "all" so that both Program Support and myself are clear about the process.

Thanks!

Cheers,

Dave

David S. Miller, DVM, PhD, DACZM, DACAW  
National Animal Welfare Specialist  
(970)825-3745

---

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**Sent:** Tuesday, January 26, 2021 6:30 AM  
**To:** Miller, David S - APHIS <David.S.Miller@usda.gov>  
**Subject:** FW: Attn: Drs. Goldentyer and Clarke

Good morning Dr. Miller,

Received this email into our main email organization box. When possible please review the attached request for procedure consideration. Please let us know if this is not in your area or if we can assist with additional information.

Sincerely,

Program Support  
USDA APHIS Animal Care  
Phone: (970) 494-7478

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**Sent:** Monday, January 25, 2021 8:02 AM  
**To:** APHIS-AnimalCare <[AnimalCare@usda.gov](mailto:AnimalCare@usda.gov)>; Clarke, Carol L - APHIS <[carol.l.clarke@usda.gov](mailto:carol.l.clarke@usda.gov)>  
**Cc:** (b) (6), (b) (7)(C) @UTMB.EDU>; (b) (6), (b) (7)(C) @UTMB.EDU>; (b) (6), (b) (7)(C) @UTMB.EDU>  
**Subject:** Attn: Drs. Goldentyer and Clarke

Good Morning,

Please find the attached modified request for your consideration. We look forward to hearing your reply.

Sincerely,

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

---

(b) (6), (b) (7)(C) DVM, DACLAM  
Animal Resources Center  
Attending Veterinarian  
Assistant Professor of Microbiology and Immunology  
The University of Texas Medical Branch – Galveston



---

**From:** Clarke, Carol L - APHIS <[carol.l.clarke@usda.gov](mailto:carol.l.clarke@usda.gov)>  
**Sent:** Monday, January 4, 2021 11:59 AM  
**T** (b) (6), (b) (7)(C) @UTMB.EDU>  
**Cc:** Pannill, Elizabeth C - APHIS <[elizabeth.c.pannill@usda.gov](mailto:elizabeth.c.pannill@usda.gov)>  
**Subject:** RE: Your request to the USDA

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Dear Dr. Brinin:

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**Sent:** Thursday, December 17, 2020 12:57 PM

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**Cc:** Pannill, Elizabeth C - APHIS <[elizabeth.c.pannill@usda.gov](mailto:elizabeth.c.pannill@usda.gov)>

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**From:** [APHIS-AnimalCare](#)  
**To:** [Miller, David S - APHIS](#)  
**Subject:** FW: Attn: Drs. Goldentyer and Clarke  
**Date:** Tuesday, January 26, 2021 8:29:00 AM  
**Attachments:** [image001.png](#)  
[USDAreqwue4st\(2\).doc](#)

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(b) (6), (b) (7)(C) DVM, DACLAM

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Attending Veterinarian  
Assistant Professor of Microbiology and Immunology  
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Working together to work wondrous™

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