

A3012-1J

**Morse, Brent (NIH/OD) [E]**

**From:** Morse, Brent (NIH/OD) [E]  
**Sent:** Thursday, February 24, 2022 2:08 PM  
**To:** Clarke, Carol L - MRP-APHIS; Tubbs, Jai (NIH/OD) [E]  
**Cc:** Bassage, Lance H - MRP-APHIS; Maginnis, Gwendalyn M - MRP-APHIS; Miller, Dana - MRP-APHIS; PerezBaum, Rachel - MRP-APHIS  
**Subject:** RE: Concerns about an assured institution

Thank you for providing this information , Dr. Clarke. We will review the documents and investigate any potential violation of the PHS Policy which, as you know, requires compliance with applicable USDA regulations. We will keep the USDA informed of the progress of OLAW's investigation.

Best regards, Brent Morse

Brent C. Morse, DVM, DACLAM  
Director, Division of Compliance Oversight  
Office of Laboratory Animal Welfare  
National Institutes of Health

**From:** Clarke, Carol L - MRP-APHIS <carol.l.clarke@usda.gov>  
**Sent:** Thursday, February 24, 2022 1:47 PM  
**To:** Morse, Brent (NIH/OD) [E] <morseb@mail.nih.gov>; Tubbs, Jai (NIH/OD) [E] <jacquelyn.tubbs@nih.gov>  
**Cc:** Bassage, Lance H - MRP-APHIS <lance.h.bassage@usda.gov>; Maginnis, Gwendalyn M - MRP-APHIS <gwendalyn.m.maginnis@usda.gov>; Miller, Dana - MRP-APHIS <dana.miller2@usda.gov>; PerezBaum, Rachel - MRP-APHIS <Rachel.PerezBaum2@usda.gov>  
**Subject:** [EXTERNAL] Concerns about an assured institution

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Dear Dr. Morse and Dr. Tubbs:

My purpose in contacting you is to inform you of a noncompliance at Eastern Virginia Medical School D-16-00007, and A-3022-01 that OLAW may wish to look into. The study in question raises concerns about animal health and well-being.

In September 2021, our inspector found evidence that multiple major operative procedures were occurring on transferred animals without obtaining approval from the DA of Animal Care to conduct this work. [See enclosed inspection report].

The school responded on 12/21/21, by submitting an exception request for approval. They want to perform up to 6 successive C-sections on 5 baboons to study estradiol events on fetus and the dam. The exception is only needed for 3 animals that were transferred from other studies. Of those 3, two already had 3 C-sections.

Despite responses to our questions, we are still unclear why 6 C-sections are necessary and how an animal that undergoes C-sections annually can serve as its 'own control' as they state. The study design and scientific justification are hard to follow. We are very concerned about pain/distress and whether 6 C-sections on one animals are adequately scientifically justified.

I was reminded during our deliberations that the work is PHS funded, hence I am bringing OLAW into the loop before going any further.

The rest of the attachments are pdfs of the request (12.21.21) and responses to my questions. I am on leave March 3-9<sup>th</sup> and my last official day is March 10<sup>th</sup>. Let me know whether OLAW will pursue any actions. Best regards.

**Carol Clarke, DVM, DACLAM**  
**Senior Staff Officer (Laboratory Animals)**  
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