From: (b) (b) (b) (7)(C

To: PerezBaum, Rachel - MRP-APHIS; Brunkhorst, Susanne - APHIS

Subject: [External Email]Document

Date: Thursday, July 8, 2021 10:23:15 AM

Attachments: Redacted minutes.pdf

## [External Email]

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Good morning,

Attached please find the document requested at last week's inspection.

Additionally, can you please send me the name and address of who I should send the letters with corrective actions as completed. Or an email address if appropriate.

Thanks,



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

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## Requested meeting minutes:

Adverse Events –

 20-100- (AWA)

3:21pm Member 14 arrived

PAM presented the adverse event. On February 18th, the PI submitted an adverse event report. February 4th was the first attempt to use the four of six animals died. After induce TBI. Upon the each animal, the PI team attempted to revise the lung protection as it appeared this was the cause of death. The two animals that survived did appear to have hind limb weakness and the OUV was called to check. On March 11th, PAM and IA met with the PL On the day of the procedure, the plan was to perform The animals were sedated with acepromazine at the animal facility then transported . Anesthesia was induced with isoflurane via a nose cone, and a catheter was placed in case euthanasia was necessary. They prepped the first animal with ear plugs and gauze pads to cover the eyes. The animal was moved Immediately, the PI and team opened to perform a visual inspection. The animal didn't look alive. They removed the animal from as fast as possible and tried to intubate and check for a heartrate. When they tried to intubate, they noticed blood in the tube. They couldn't recover the animal, and the PI injected beuthanasia as a precaution. The PI team tried to figure out what was going on. There had been a difference in , and in previous studies the PI had noted that if the head wasn't tilted to go up the nose and cause injury. correct this could sometime cause the They proceeded with the second animal, but added foam pads and tried to make and was "more the . The second animal also did not survive the bloody". They used more foam pads to cushion the third animal, and that animal survived. Starting with the fourth animal, they placed an old Kevlar jacket from a previous study on the animal, which seemed to help although two more animals did not survive. The PI performed necropsies on the first two pigs. She stated that the lungs were "pretty beat up". No official necropsy was performed; however, the PI does have pictures if requested. The PI stated that only the PI team performed the troubleshoots. Veterinarians were not contacted until after the six completed. The IA recommended that in the future if the lab wants to perform the necropsy themselves, to minimally include an outside set of eyes during the necropsy, such as the OUV, for a nonbiased opinion. For the two pigs that survived, they survived until the Day 7 study endpoint. The pigs were given buprenorphine after the blasts. Member 11 performed neurologic tests. Member 11's assessment stated: "The pigs are noticeably ataxic (uncoordinated) and paretic (weak) in all four limbs, worse behind. I do think this is true neurologic injury, not pain. They are also not very reactive and seem mild/moderately mentally depressed- as the PI said they are eating, drinking and mounting each other, but do not run away from me or respond much when I picked them up and even wheelbarrowed them. As a comparison, I could not catch the sham pig and barely got him cornered to be able to touch him. I think this could also be the result of to the this also could be manifestation of pain. One of the pigs was trembling which looked like possible pain. I took his temperature and it was normal and it didn't look like

fasciculation due to paresis. I think that additional buprenorphine is warranted based off of these observations, and also might help to eliminate pain behavior to better evaluate the true effects of the on mentation. If we can give the buprenorphine tomorrow morning, then I can see if there are noticeable differences on pain meds vs today when I come out tomorrow afternoon." Member 11 performed a neuro exam at 48 hours and did not think they were in pain but that the regions responsible for motion may have been damaged. The PI stated that within 2-3 days they had definitely improved. Both Member 11 and the PI think that time to recover from the pigs to regain activity. The OUV also assessed the pigs on February 8th. By day 7, the pigs' hind end weakness was very minimal. They weren't as active, but they maintained a normal appetite and were still able to perform normal behaviors.