



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE  
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:

Office of Laboratory Animal Welfare  
6700B Rockledge Drive, Suite 2500, MSC 6910  
Bethesda, Maryland 20892-6910  
Home Page: <http://grants.nih.gov/grants/olaw/olaw.htm>

FOR EXPRESS MAIL:

Office of Laboratory Animal Welfare  
6700B Rockledge Drive, Suite 2500  
Bethesda, Maryland 20817  
Telephone: (301) 496-7163  
Facsimile: (301) 480-3387

March 30, 2022

Re: Animal Welfare Assurance  
A4669-01 [OLAW Case K]

(b) (6)

US Army Institute of Surgical Research  
3698 Chambers Pass – Suite B  
JBSA Fort Sam Houston, Texas 78234-6315

Dear (b) (6)

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your letter dated March 18, 2022 reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the U.S. Army Institute of Surgical Research. Your letter supplements the information in your November 4, 2021 initial report received in our office on November 17, 2021. According to the information provided, OLAW understands that the IACUC determined that there was a failure to correctly document appropriate animal related records on a porcine animal model protocol. Analytical tests were used that also did not adhere to the IACUC policy on the use of expired analytical materials. The associated animal activity is funded by BARDA IAA 750119PR2100075.

Corrective and preventive actions: the IACUC had suspended the protocol until corrective actions were completed, including counseling, and retraining of the principal investigator and key protocol team members. The principal investigator was to update the protocol. It is understood that all corrective actions were completed but in the interim, the principal investigator of the study left the institute. The protocol has been terminated by the IACUC. The project has been reassigned to a different principal investigator. A new protocol will be submitted to the IACUC for review and approval.

OLAW believes that the corrective and preventative measures put in place by the U.S. Army Institute of Surgical Research are consistent with the provisions of the PHS Policy on Humane Care and Use of Laboratory Animals. **OLAW notes** that this was the second report of similar noncompliance related to this study within 14 months. An increased frequency of oversight by the IACUC, or representatives, might be appropriate. We appreciate being informed of this incident and find no cause for further action by this office, at this time.

Sincerely,

(b) (6)

Digitally signed by (b) (6)

-S

Date: 2022.03.30 07:38:15 -04'00'

(b) (6)

DVM

Director

Division of Compliance Oversight

Office of Laboratory Animal Welfare

cc: IACUC contact

(b) (6)

OS/BARDA)

A4669-K



DEPARTMENT OF THE ARMY  
U.S. ARMY INSTITUTE OF SURGICAL RESEARCH  
3698 CHAMBERS PASS, SUITE B  
JBSA FORT SAM HOUSTON, TX 78234-7767

March 18, 2022

Director, Office of Compliance and Oversight  
Office of Laboratory Animal Welfare (OLAW)  
National Institutes of Health  
6700B Rockledge Drive, Suite 2500, MSC 6910  
Bethesda, MD 20892  
Attention: (b) (6)  
Reference: OLAW Case A4669-K

Dear (b) (6)

The United States Army Institute of Surgical Research, in accordance with Assurance #D16-00869 (A4669-01) provides this final report regarding animal study protocol titled "Resuscitation with Plasma in the Burned Porcine (*Sus scrofa domestica*) Model." This protocol is funded by BARDA IAA 750119PR2100075.

The principal investigator and lead research technician completed the corrective actions outlined in the memo to OLAW dated November 4, 2021. In the interim, the principal investigator of the study left the institute. The protocol has been terminated by the IACUC. The project has been reassigned to a different principal investigator. A new protocol will be submitted to the IACUC for review and approval.

The United States Army Institute of Surgical Research is committed to protecting the welfare of animals used in research. Should you have any questions regarding this report, please contact (b) (6) PhD, IACUC Chair.

Sincerely,

(b) (6) Digitally signed by  
(b) (6)  
Date: 2022.03.18 14:33:13  
-05'00'

(b) (6)  
Colonel, U.S. Army  
Commanding

(b) (6) (NIH/OD) [E]

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**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Monday, March 21, 2022 10:12 AM  
**To:** (b) (6) CIV USARMY USAISR (USA)  
**Cc:** OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** RE: Final Report to OLAW Ref. Case 4669-K

Thank you for this report, (b) (6) We will reply soon.

(b) (6) M.S., D.V.M.  
Deputy Director, OLAW

**From:** (b) (6) CIV USARMY USAISR (USA) <(b) (6) civ@mail.mil>  
**Sent:** Monday, March 21, 2022 9:52 AM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Subject:** [EXTERNAL] Final Report to OLAW Ref. Case 4669-K

**CAUTION:** This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and are confident the content is safe.

Dear (b) (6)

Attached is a final report concerning protocol non-compliance for your review. Reference case 4669-K.

Respectfully,

(b) (6)

(b) (6)

Research Regulatory Compliance Division  
US Army Institute of Surgical Research  
3698 Chambers Pass, Ste. B  
JBSA Ft. Sam Houston, TX 78234-7767  
(b) (6)



## OLAW Division of Compliance Oversight (NIH/OD)

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**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Monday, November 22, 2021 4:15 PM  
**To:** (b) (6)  
**Subject:** RE: Report of Protocol Non-compliance

Hello (b) (6)

Thank you for providing this report to OLAW. OLAW will accept the report as a preliminary report of noncompliance. Once the corrective measures are completed, or scheduled for completion, please have the final report signed by the Institutional Official and send to OLAW. Please send it to my attention and reference OLAW Case A4669-K. Thank you.

Best regards, (b) (6)

(b) (6) DVM, DACLAM  
Director, Division of Compliance Oversight  
Office of Laboratory Animal Welfare  
National Institutes of Health

**From:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Sent:** Friday, November 19, 2021 6:59 AM  
**To:** (b) (6)  
**Cc:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Subject:** RE: Report of Protocol Non-compliance

Thank you for this report. We will send a response soon.

(b) (6)  
Deputy Director, OLAW

**From:** (b) (6)  
**Sent:** Wednesday, November 17, 2021 1:07 PM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Subject:** Report of Protocol Non-compliance

Dear Director,  
Attached is a report of protocol non-compliance for your review.

Respectfully,

(b) (6)  
Research Regulatory Compliance Division  
US Army Institute of Surgical Research  
3698 Chambers Pass, Ste. B  
JBSA Ft. Sam Houston, TX 78234-7767

(b) (6)



DEPARTMENT OF THE ARMY  
U.S. ARMY INSTITUTE OF SURGICAL RESEARCH  
3698 CHAMBERS PASS, SUITE B  
JBSA FORT SAM HOUSTON, TX 78234-7767

A4669-K

November 4, 2021

Director, Office of Compliance and Oversight  
Office of Laboratory Animal Welfare (OLAW)  
National Institutes of Health  
6700B Rockledge Drive, Suite 2500, MSC 6910  
Bethesda, MD 20892

Dear Director,

The United States Army Institute of Surgical Research, in accordance with Assurance #D16-00869 (A4669-01) provides this report of noncompliance regarding animal study protocol titled "Resuscitation with Plasma in the Burned Porcine (*Sus scrofa domestica*) Model." This protocol is funded by BARDA IAA 750119PR2100075.

Quality Management Division staff received information that the protocol was not being conducted in accordance with the approved protocol. As a result, the Chief, Quality Management Division requested a directed review of the protocol.

At a recently convened meeting of the IACUC, the committee determined that the IACUC approved protocol is not being adhered to as written. There was a failure to correctly document appropriate animal related records. Analytical tests were used that did not adhere to the IACUC policy on the use of expired analytical materials.

The IACUC has suspended the protocol until corrective actions are completed. The principal investigator and key protocol team members are to schedule counseling with their leadership. The principal investigator is to update the protocol to incorporate all IACUC approved addenda, minor changes and significant changes handled administratively by the attending veterinarian. The principal investigator and key study personnel are to receive additional regulatory compliance training. The principal investigator and key study personnel are to receive animal procedure training. Further, the principal investigator and key study personnel are to receive additional training on protocol adherence, good documentation practices, and data management. The protocol will remain suspended until the revised protocol is reviewed and the changes are approved at a convened meeting of the IACUC and all corrective actions are completed.

The United States Army Institute of Surgical Research is committed to protecting the welfare of animals used in research. Should you have any questions regarding this report, please contact (b) (6) IACUC Chair.

Sincerely,

(b) (6)



(b) (6) (NIH/OD) [E]

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(b) (6)  
Deputy Director, OLAW

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Respectfully,

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Research Regulatory Compliance Division  
US Army Institute of Surgical Research  
3698 Chambers Pass, Ste. B  
JBSA Ft. Sam Houston, TX 78234-7767

(b) (6)