

Annual Report to OLAW

Institution: U.S. Army Institute of Surgical Research
Assurance Number: D16-00869 (A4669-01)
Reporting Period: January 1, 2018 – December 31, 2018

This institution's Institutional Animal Care and Use Committee (IACUC), through the Institutional Official, provides this annual report to the Office of Laboratory Animal Welfare (OLAW).

I. Program Changes *[Select A or B]*

- ☐ A. There have been **no changes** in this institution's program for animal care and use as described in the Assurance. *[Skip to Item II.]*
- ☒ B. Change(s) in this institution's program for animal care and use as described in the Assurance have occurred during this reporting period. *(FAQ 6)*

Select all that apply:

- ☐ This institution's AAALAC accreditation status has changed *(PHS Policy IV.A.2.)*.
- ☐ AAALAC Accredited – Category 1
- ☐ Non-Accredited – Category 2
- ☐ This institution's program for animal care and use has changed *(PHS Policy IV.A.1.a-i.)*.
[Attach a full description of the changes.]
- ☒ The individual designated by this institution as the Institutional Official has changed.
[Provide name, title(s), address, e-mail, phone, and fax numbers in Item V.]
- ☒ The membership of this institution's IACUC has changed. *[Provide current roster of members in Item VI.]*

II. Semiannual Evaluations

This IACUC has conducted semiannual evaluations of the institution's program and inspections of the institution's facilities (including satellite facilities) on the dates below. Reports of the evaluations and inspections have been submitted to the Institutional Official. The reports include any IACUC-approved departures from the *Guide* with a reason for each departure, any deficiencies (significant or minor) that were identified, and a plan and schedule for correction of each deficiency. *[Do not provide semiannual reports unless they include a minority view.]*

A. Program Evaluations

[Two dates (month/day/year) must be provided to satisfy the PHS Policy requirement that evaluations be done at 6 month intervals. If the IACUC conducted more than 2 evaluations of the program during the reporting period, please attach a list showing the dates.]

Date 1: 5/10/18	Date 2: 11/8/18
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B. Facility Inspections

[Two dates (month/day/year) must be provided to satisfy the PHS Policy requirement that facility inspections be done at 6 month intervals. If the IACUC conducted more than 2 inspections of each site during the reporting period, please attach a list showing the dates.]

Date 1: 5/11/18

Date 2: 11/15/18

III. Minority Views [Select A or B]

- [X] A. There were **no minority** views during this reporting cycle.
- [] B. Any minority views submitted by members of the IACUC regarding reports filed under PHS Policy IV.F. for this reporting cycle are attached.

IV. Signatures

IACUC Chairperson	Institutional Official
Name: (b) (6) PhD	Name: (b) (6) MD
Signature: (b) (6)	Signature: (b) (6)
Date: 22 Jan 19	Date: (b) (6) JAN 23 2019

V. Change in Institutional Official

Name: (b) (6) MD	
Title: Commander	Degree/Credential: MD, MBA, MS, FACOG, FACHE
Name of Institution: U.S. Army Institute of Surgical Research	
Address: [street, city, state, zip code]	
3698 Chambers Pass JBSA Fort Sam Houston, TX 78234-6315	
E-mail: (b) (6) @mail.mil	
Phone: (b) (6)	Fax: (b) (6)

VI. Change in IACUC Membership [*Current roster*]

Institution: U.S. Army Institute of Surgical Research			
IACUC Contact Information			
Address: [street, city, state, zip code] (b) (6) (b) (6) 3698 Chambers Pass JBSA Fort Sam Houston, TX 78234-6315			
E-mail: (b) (6) @mail.mil			
Phone: (b) (6)		Fax: (b) (6)	
IACUC Chairperson			
Name: (b) (6)			
Title: Research Physiologist		Degree/Credentials: PhD	
PHS Policy Membership Requirements***: Scientist			
IACUC Roster [<i>Provide below or attach</i>]			
Name of Member/ Code*	Degree/ Credential	Position Title/ Occupational Background**	PHS Policy Membership Requirements***
(b) (6)	VMD, DACLAM	Deputy Chief, Research Support Division	Veterinarian (AV)
PM2	PhD	Research Physiologist	Scientist
PM3	PhD	Research Biologist	Scientist
PM4	PhD	Research Physiologist	Scientist
PM5	MD, MS	Biomedical Research Physiologist	Scientist
PM6	PhD	Research Biologist	Scientist
NSPM1	MBA, MS	Contract Specialist	Nonscientist
NAPM1	BS, AAS, ATA	Electronics Engineer	Nonaffiliated
AVM1	DVM, DACVECC	Chief, Research Support Division	Alternate – Veterinarian (AV)
AM1	MD	Research Scientist	Alternate – Scientist
AM2	PhD	Research Physiologist	Alternate – Scientist
AM3	MD, PhD	Research Physiologist	Alternate – Scientist

* Names of members, other than the chairperson and veterinarian, may be represented by a number or symbol in this report to OLAW. Sufficient information to determine that all appointees are appropriately qualified must be provided and the identity of each member must be readily ascertainable by the institution and available to authorized OLAW or other PHS representatives upon request.

** List specific position titles for all members, including nonaffiliated (e.g., banker, teacher, volunteer fireman; not "community member" or "retired").

*** PHS Policy Membership Requirements:

<i>Veterinarian</i>	veterinarian with training or experience in laboratory animal science and medicine or in the use of the species at the institution, who has direct or delegated program authority and responsibility for activities involving animals at the institution.
<i>Scientist</i>	practicing scientist experienced in research involving animals.
<i>Nonscientist</i>	member whose primary concerns are in a nonscientific area (for example, ethicist, lawyer, member of the clergy).
<i>Nonaffiliated</i>	individual who is not affiliated with the institution in any way other than as a member of the IACUC, and is not a member of the immediate family of a person who is affiliated with the institution. This member is expected to represent general community interests in the proper care and use of animals and should not be a laboratory animal user. A consulting veterinarian may not be considered nonaffiliated.

[Note: all members must be appointed by the CEO (or individual with specific written delegation to appoint members) and must be voting members. Non-voting members and alternate members must be so identified.]

VIII. Membership of the IACUC

Date: February 2016			
Name of Institution: US Army Institute of Surgical Research			
Assurance Number: A4669-01			
IACUC Chairperson			
Name*: (b) (6)			
Title*: Research Physiologist			Degree/Credentials*: PhD
Address*: (street, city, state, zip code)			
3611 Chambers Pass Fort Sam Houston, TX 78234-6315			
E-mail*: (b) (6) @mail.mil			
Phone*: (b) (6)		Fax*: (b) (6)	
IACUC Roster			
Name of Member/ Code**	Degree/ Credentials	Position Title***	PHS Policy Membership Requirements****
(b) (6)	DVM, MPH	Chief, Research Support Division / Attending Veterinarian	Veterinarian
PM2	PhD	Research Physiologist	Scientist
PM3	PhD	Biochemist	Scientist
PM4	PhD	Research Physiologist	Scientist
PM5	PhD	Research Physiologist	Scientist
PM6	PhD	Senior Research Physicist	Scientist
NSPM1	MBA, MS	Contract Specialist	Nonscientist
NAPM1	BS, AAS, ATA	Electronics Engineer	Nonaffiliated
PM: Primary Member NSPM: Nonscientific Member NAPM: Nonaffiliated Member			
Alternate Members:			
AVM1	VMD	Chief, Veterinary Support Branch / Alternate for Attending Veterinarian	Veterinarian
AM1	BS, LATG	Biomedical Science Research Technician	Scientist
AM2	PhD	Senior Research Biologist	Scientist
AM3	PhD	Biochemist	Scientist

AM4	PhD, M.Sci	Research Microbiologist	Scientist
AM5	PhD	Research Physiologist	Scientist
AM6	PhD	Research Physiologist	Scientist
NSAM	MPA	Chief, Operations, Security and Training	Nonscientist
NAAM1	MSEE	Integration Manager	Nonaffiliated
NAAM2	MD	OTBS Consultant for Internal Medicine	Nonaffiliated
AVM: Alternate Veterinary Member AM: Alternate Member NSAM: Nonscientific Alternate Member NAAM: Nonaffiliated Alternate Member			

* This information is mandatory.

** Names of members, other than the chairperson and veterinarian, may be represented by a number or symbol in this submission to OLAW. Sufficient information to determine that all appointees are appropriately qualified must be provided and the identity of each member must be readily ascertainable by the institution and available to authorized OLAW or other PHS representatives upon request.

*** List specific position titles for all members, including nonaffiliated (e.g., banker, teacher, volunteer fireman; not "community member" or "retired").

**** PHS Policy Membership Requirements:

Veterinarian veterinarian with training or experience in laboratory animal science and medicine or in the use of the species at the institution, who has direct or delegated program authority and responsibility for activities involving animals at the institution.

Scientist practicing scientist experienced in research involving animals.

Nonscientist member whose primary concerns are in a nonscientific area (e.g., ethicist, lawyer, member of the clergy).

Nonaffiliated individual who is not affiliated with the institution in any way other than as a member of the IACUC, and is not a member of the immediate family of a person who is affiliated with the institution. This member is expected to represent general community interests in the proper care and use of animals and should not be a laboratory animal user. A consulting veterinarian may not be considered nonaffiliated.

[Note: all members must be appointed by the CEO (or individual with specific written delegation to appoint members) and must be voting members. Non-voting members and alternate members must be so identified.]

X. Facility and Species Inventory

[illegible]

*Institutions may identify animal areas (buildings/rooms) by a number or symbol in this submission to OLAW. However, the name and location must be provided to OLAW upon request.



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTHFOR US POSTAL SERVICE DELIVERY:

Office of Laboratory Animal Welfare
Rockledge One, Suite 360
6705 Rockledge Drive - MSC 7982
Bethesda, Maryland 20892-7982
Home Page: <http://grants.nih.gov/grants/olaw/olaw.htm>

FOR EXPRESS MAIL:

Office of Laboratory Animal Welfare
Rockledge One, Suite 360
6705 Rockledge Drive
Bethesda, Maryland 20817
Telephone: (301) 496-7163
Facsimile: (301) 402-7065

June 8, 2017

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

Colonel (b) (6)
Commander
US Army Institute of Surgical Research
3698 Chambers Pass
JBSA Fort Sam Houston, Texas 78234-6315

Dear Colonel (b) (6)

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your June 7, 2017 letter 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 (USAISR). According to the information provided, OLAW understands that on a pain study involving rats, study records were extremely disorganized, information was incomplete, data sheets were misfiled, some records were missing, signatures and dates were missing, and animal records did not include full information on pain assessment, drug administration, and behavioral testing. Some animals were euthanized before undergoing experimental procedures while others were used for behavior testing which had not been approved by the Institutional Animal Care and Use Committee (IACUC).

The corrective actions consisted of the IACUC terminating some of the protocols, requiring the laboratory staff to undertake retraining on records management and regulatory compliance, revoking the Principal Investigator's animal use privileges for six months, and prohibiting the PI from serving as PI or associate investigator for an additional six months (although the PI may assist in animal studies). Upon full resumption of animal activities, the PI will be subject to enhanced oversight by Quality Assurance Management. The data acquired from the studies in question was determined not to be publishable because it was inaccurate.

OLAW understands that the protocol involved was not PHS-supported, but concurs that the incidents were serious and supports the actions taken by the IACUC. The establishment and application of policies and practices that are consistent with the provisions of the PHS Policy at USAISR are commendable and avoid the perception of a double standard. Thank you for informing OLAW about this matter.

Sincerely,

(b) (6)

Director
Division of Compliance Oversight

cc: IACUC Chair



REPLY TO
ATTENTION OF

DEPARTMENT OF THE ARMY
U.S. ARMY INSTITUTE OF SURGICAL RESEARCH
3698 CHAMBERS PASS
JBSA FORT SAM HOUSTON, TEXAS 78234-6315

Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
Rockledge 1, (b) (6) MSC7982
6705 Rockledge Drive
Bethesda, MD 20892-7982

JUN 07 2017

Assurance Reference #A4669-01

Dear Director,

A report of protocol non-compliance and animal use concerns is submitted for your review. Audits of the following protocols were conducted by Quality Assurance Specialists, Quality Management Division, US Army Institute of Surgical Research:

- Type study (b) (4) "Evaluation of the Analgesic Efficacy of Novel Acetaminophen Analogs" (PI (b) (6)).
- Type study (b) (4) "Testing of More Potent and Longer-lasting APAP analogs" (PI (b) (6)).
- Protocol (b) (4) "Effects of Conotoxin Analogs on Pain in the Rat" (PI (b) (6)).

Following IACUC review of the initial audit reports, the committee requested a second audit of the studies by different auditors to ensure there was no conflict of interest. The results of the second audit of the studies were consistent with the results of the first audit.

- Study records were so disorganized that tracking animal use was very difficult or not possible in some instances. Unofficial laboratory notebooks were used with torn out pages, crossed-out information, no dates or signatures, and binders with loose miscellaneous pages.
 - Study data sheets were misfiled in other study files.
 - Pain assessment, drug administration, Veterinary Support Branch cage cards, and behavioral testing records were missing or incomplete for some study animals.
 - No records were found for 28 study animals; 24 animals were euthanized without undergoing any experimental procedures.
 - 32 animals were tested on a behavioral apparatus without IACUC approval.

The IACUC determined the following actions were required due to serious protocol non-compliance issues and the waste of research animals:

- Protocol (b) (4) and the parent protocol (b) (4) for type studies (b) (4) and (b) (4) will be terminated.
- All research team members assigned to protocol (b) (4) and (b) (4) must complete records management and regulatory compliance training. Documentation of completed training must be forwarded to the Research Regulatory Compliance Office.
- Animal research privileges for (b) (6) will be revoked for a period of six months from the date of this memorandum. For an additional six months, (b) (6) may assist with animal research studies without principal or associate investigator status on any animal protocol.
- All future research studies conducted by (b) (6) following the one-year revocation period, will be audited by Quality Assurance Management every six months until the IACUC determines after a review of the audit reports that record keeping and animal use is compliant with regulatory requirements. Any evidence of protocol non-compliance will result in permanent revocation of animal research privileges for (b) (6).

The Burn Injury Task Area Manager and the Director of Research determined the data from type studies (b) (4) and (b) (4) and protocol (b) (4) are not accurate, reliable, and publishable due to the numerous issues of protocol non-compliance.

No PHS funding was used for any of these studies.

The point of contact for this action is (b) (6) IACUC Chair,
(b) (6) (b) (6) @mail.mil.

Sincerely, (b) (6)

(b) (6)

(b) (6)

Colonel, US Army
Commanding / Institutional Official

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Thursday, June 08, 2017 11:59 AM
To: (b) (6) USARMY MEDCOM AISR (US)
Subject: RE: Report of Protocol Non-compliance #A4669-01 (UNCLASSIFIED)

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

Axel Wolff, M.S., D.V.M.
Director, Division of Compliance Oversight OLAW

-----Original Message-----

From: (b) (6) CIV USARMY MEDCOM AISR (US) [mailto:(b) (6)@mail.mil]
Sent: Thursday, June 08, 2017 10:29 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: Report of Protocol Non-compliance #A4669-01 (UNCLASSIFIED)

Classification: UNCLASSIFIED
Caveats: NONE

Director, Division of Compliance Oversight,

A report of protocol non-compliance and animal use concerns is attached for your review. We will provide any follow-up actions resulting from these findings when complete.

Assurance Reference #A4669-01

Thank you,

(b) (6) CIA
Program Manager Animal Research
US Army Institute of Surgical Research
BHT1, (b) (6)
3698 Chambers Pass
JBSA Fort Sam Houston, TX 78234-6315
Phone: (b) (6)
Fax: (b) (6)
Tube #: 78
(b) (6)@mail.mil

Classification: UNCLASSIFIED
Caveats: NONE



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTHFOR 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) 402-7065

January 29, 2019

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

Colonel (b) (6)
Commander
US Army Institute of Surgical Research
3698 Chambers Pass
JBSA Fort Sam Houston, Texas 78234-6315

Dear Colonel (b) (6)

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your January 23, 2019 letter reporting several instances of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the US Army Institute of Surgical Research (USAISR), following up on an initial report on November 13, 2018. According to the information provided, OLAW understands that on a blast injury and hemorrhage study in rats, activities were not carried out in accordance with the Institutional Animal Care and Use Committee (IACUC) approved protocol. Specifically, pain assessments were not performed per protocol, catheters were not inserted correctly, procedures not listed were performed, blast pressures varied, documentation was incorrect, dates and animal weights were incorrect, and the amount of hemorrhage was different.

The corrective actions consisted of the IACUC initially suspending the protocol and subsequently terminating it. The data integrity will be assessed as it relates to the noncompliance.

OLAW understands that the protocol involved was not PHS-supported, but concurs that the incidents were serious and supports the actions taken by the IACUC. The establishment and application of policies and practices that are consistent with the provisions of the PHS Policy at USAISR are commendable and avoid the perception of a double standard. Thank you for keeping OLAW apprised on this matter.

Sincerely,

(b) (6)

Deputy Director
Office of Laboratory Animal Welfare

cc: IACUC Chair



REPLY TO
ATTENTION OF

DEPARTMENT OF THE ARMY
U.S. ARMY INSTITUTE OF SURGICAL RESEARCH
3698 CHAMBERS PASS
JBSA FORT SAM HOUSTON, TEXAS 78234-6315

JAN 23 2019

Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
Rockledge 1, (b) (6) MSC7982
6705 Rockledge Drive
Bethesda, MD 20892-7982

Assurance Reference #D16-00869 (A4669-01)

Dear Director,

A report of protocol non-compliance and animal use concerns is submitted for your review. The final summary of findings of protocol (b) (4) "A Model Development of Blast Injury and Hemorrhage in Rats" (PI (b) (6)) was presented by Quality Assurance Specialists, Quality Management Division, US Army Institute of Surgical Research at the December 13, 2018 IACUC meeting:

The results of the final summary of findings are noted below.

- Pain assessments were not done according to the IACUC approved protocol.
- Catheters were not inserted as stated in the IACUC approved protocol.
- Procedures were performed without IACUC approval.
- The animals did not receive the same blast overpressure that was stated in the IACUC approved protocol.
- There were major problems with documentation practices. Four animals in one group had two experimental records for the same animal. There was conflicting information regarding the dates and weights of the animals. Animals from the groups described as receiving a 20%, 30%, or 50% hemorrhage did not receive the correct percentage of hemorrhage.

At the December 13, 2018 IACUC meeting, the committee voted unanimously to close protocol (b) (4). In addition, the IACUC recommended that the results of this model development study be reviewed by the USAISR Department Chief, (b) (6) to determine if data integrity was compromised as a result of these non-compliance issues.

-2-

No PHS funding was used for this protocol.

The point of contact for this action is (b) (6) IACUC Chair, (b) (6)
(b) (6) (b) (6) @mail.mil.

Sincerely,

(b) (6)

(b) (6)

Colonel, U.S. Army
Commanding / Institutional Official
(b) (6)

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Monday, January 28, 2019 9:17 AM
To: (b) (6) USARMY MEDCOM AISR (US); OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Reports of Non-Compliance Assured Institution D16-00869 (A4669-01)

Thank you for providing these reports (b) (6). We will send official responses soon.

Best regards, Brent Morse

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

Please note that this message and any of its attachments are intended for the named recipient(s) only and may contain confidential, protected or privileged information that should not be distributed to unauthorized individuals. If you have received this message in error, please contact the sender.

-----Original Message-----

From: (b) (6) USARMY MEDCOM AISR (US) [mailto:(b) (6)@mail.mil]
Sent: Thursday, January 24, 2019 4:45 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: Reports of Non-Compliance Assured Institution D16-00869 (A4669-01)

Dear Director,

Three reports of non-compliance are attached for you review. Protocol (b) (4) "A Model Development of Blast Injury and Hemorrhage in Rats" and protocol (b) (4) "Efficacy of Complement Inhibitors in a Rat Model of Blast Injury and Hemorrhage" were closed by the IACUC. Protocol (b) (4) "A Rat Model of Smoke Inhalation Injury to Determine the Participation of Distal Airway Stem Cells (DASCs) in Lung Regeneration" has been suspended by the IACUC pending extensive training by the research team.

(b) (6)

(b) (6)

Research Regulatory Compliance Division
 US Army Institute of Surgical Research
 3698 Chambers Pass, Bldg 3611
 JBSA Ft. Sam Houston, TX 78234

(b) (6)

REPLY TO
ATTENTION OF

DEPARTMENT OF THE ARMY
U.S. ARMY INSTITUTE OF SURGICAL RESEARCH
3698 CHAMBERS PASS
JBSA FORT SAM HOUSTON, TEXAS 78234-6315

A4669-E

MCMR-SRA-R

13 November 2018

MEMORANDUM FOR (b) (6) USAISR

SUBJECT: Institutional Animal Care and Use Committee (IACUC) Protocol Status

1. The results of preliminary findings of protocol (b) (4) "A Model Development of Blast Injury and Hemorrhage in Rats" were reported by Quality Assurance (QA) specialists at the 8 November 2018 IACUC meeting.
2. Preliminary findings include extremely poor documentation, missing data, missing pain assessments, procedures conducted which are not included in the protocol, missing date/time on many post-procedural and post-surgical assessments and experiments, blank forms for many animals, and missing unanticipated adverse event (UAE) forms. Hemorrhage groups did not have the correct hemorrhage, and blast pressures were recorded in different measurements, but not documented as such.
3. At the 8 November 2018 IACUC meeting, the IACUC voted to suspend protocols (b) (4) "A Model Development of Blast Injury and Hemorrhage in Rats;" protocol (b) (4) "Efficacy of Complement Inhibitors in a Rat Model of Blast Injury and Hemorrhage;" protocol (b) (4) "A Rat Model of Smoke Inhalation Injury to Determine the Participation of Distal Airway Stem Cells (DASCs) in Lung Regeneration;" protocol (b) (4) "Development of a Porcine Model of Blast Injury and Hemorrhagic Shock."
4. Upon completion of the audits of these protocols, the QA specialists will submit a report of their findings to the IACUC for review. No experiments should be conducted on these protocols until further notice from the IACUC.
5. The point of contact for this action is the undersigned at (b) (6)

(b) (6)

Chair, IACUC

CF:

(b) (6) Task Area Manager

(b) (6) Institutional Official

Animal Care and Use Review Office (ACURO), MPMC
Office of Laboratory Animal Welfare (OLAW)

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Wednesday, November 14, 2018 10:15 AM
To: (b) (6) SARMY MEDCOM AISR (US)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: IACUC Status Memo - Assured Institution A4669-01

Thank you for this preliminary report, (b) (6). We will start a new case file and look forward to receiving the final report from the IO after the IACUC has completed its investigation.

Axel Wolff, M.S., D.V.M.
Deputy Director, OLAW

-----Original Message-----

From: (b) (6) USARMY MEDCOM AISR (US) [mailto:(b) (6)@mail.mil]
Sent: Tuesday, November 13, 2018 4:07 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: IACUC Status Memo - Assured Institution A4669-01

Dear Director,

Attached please find a memo from the U.S. Army Institute of Surgical Research, A4669-01, IACUC, regarding preliminary findings of protocol (b) (4) "A Model Development of Blast Injury and Hemorrhage in Rats" reported at the 8 Nov 18 IACUC meeting by Quality Assurance Specialists.

We will provide any follow-up actions resulting from these findings, when complete.

(b) (6)

(b) (6)

Research Regulatory Compliance Division
US Army Institute of Surgical Research
3698 Chambers Pass, Bldg 3611
JBSA Ft. Sam Houston, TX 78234

(b) (6)



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTHFOR 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) 402-7065

January 31, 2019

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

Colonel (b) (6)
Commander
US Army Institute of Surgical Research
3698 Chambers Pass
JBSA Fort Sam Houston, Texas 78234-6315

Dear Colonel (b) (6)

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your January 23, 2019 letter reporting the suspension of an animal activity at the US Army Institute of Surgical Research. According to the information provided, OLAW understands that the Institutional Animal Care and Use Committee (IACUC) took this action after determining that a rat smoke injury study was not being conducted as outlined in the approved protocol. Specifically, pain assessments were not documented, catheters were not inserted as described, additional study cohort groups were formed without approval, and there was overall poor documentation and lack of source documents. In addition, time of smoke inhalation injury differed for some rats, some rats were used to test anesthesia and then placed on study, one rat with a blocked catheter was not euthanized in time, some rats were not of the appropriate body weight, and adverse events were not reported to the IACUC.

The corrective actions consisted of suspending the protocol, requiring the Principal Investigator and staff to undertake retraining, and amending the protocol.

Based on its assessment of this explanation, OLAW understands that measures have been implemented to prevent recurrence of this problem. While OLAW concurs with the actions taken by the IACUC to comply with the PHS Policy, we also feel that it may be necessary for the IACUC to more rigorously evaluate the training and experience of investigators before allowing animal work to proceed. The serious and ongoing nature of noncompliance by this Principal Investigator (as also noted in two other noncompliance reports) points to the need for more involved post-approval monitoring, especially for high risk studies and/or investigators. Besides being an animal welfare issue, the value of the science and ability to publish are in potential jeopardy, not to mention negative public opinion. Please inform OLAW if, following extensive retraining, any additional animal related noncompliance is identified for this PI. Thank you for informing OLAW about this matter.

Sincerely,

(b) (6)

Deputy Director
Office of Laboratory Animal Welfare

cc: IACUC Chair

REPLY TO
ATTENTION OF

DEPARTMENT OF THE ARMY
U.S. ARMY INSTITUTE OF SURGICAL RESEARCH
3698 CHAMBERS PASS
JBSA FORT SAM HOUSTON, TEXAS 78234-6315

JAN 23 2019

Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
Rockledge 1, (b) (6) MSC7982
6705 Rockledge Drive
Bethesda, MD 20892-7982

Assurance Reference #D16-00869 (A4669-01)

Dear Director,

A report of protocol non-compliance and animal use concerns is submitted for your review. An audit of protocol (b) (4) "A Rat Model of Smoke Inhalation Injury to Determine the Participation of Distal Airway Stem Cells (DASCs) in Lung Regeneration" (PI (b) (6)) was presented by Quality Assurance Specialists, Quality Management Division, US Army Institute of Surgical Research at the December 13, 2018 IACUC meeting:

The results of the audit are noted below.

- Pain assessments were not documented according to the IACUC approved protocol.
- Catheters were not inserted as stated in the IACUC approved protocol.
- Poor documentation was observed regarding calculations for the doses of weight-based medications, and methods used for euthanasia.
- Additional animal groups were created without IACUC approval.
- Source documents for typewritten pages were not provided.

Additional findings include eight animals that received smoke inhalation injury at times not stated in the protocol; four animals that were used to test an anesthesia regimen and used for experimentation one week later; one animal with a blocked catheter that was not euthanized until several days after the blocked catheter was discovered; nine animals that were used outside of the protocol weight range; poor record keeping and data management. No unanticipated adverse events were submitted prior to initializing the investigation of this protocol.

The IACUC determined that these infractions on the Model Development phase of the protocol are serious and require corrective actions before studies on the Experimental Groups can be initiated. The IACUC determined that the research team must complete extensive hands-on and didactic training that will be planned and presented by the Quality Management Division.

-2-

Areas of focus will include how to prevent protocol non-compliance, how to conduct pain assessments, documentation practices, and unanticipated event recognition and reporting. In addition, amendments must be submitted to the protocol to reestablish procedures and realign the animal numbers in the protocol.

This protocol has been suspended pending completion of all of the required training by the research team and IACUC approval of the amendments to the protocol. No experiments should be conducted on this protocol until further notice from the IACUC.

No PHS funding was used for this protocol.

The point of contact for this action is (b) (6) IACUC Chair, (b) (6)
(b) (6) (b) (6) @mail.mil.

Sincerely,

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

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Monday, January 28, 2019 9:17 AM
To: (b) (6) USARMY MEDCOM AISR (US); OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Reports of Non-Compliance Assured Institution D16-00869 (A4669-01)

Thank you for providing these reports (b) (6). We will send official responses soon.

Best regards, Brent Morse

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

Please note that this message and any of its attachments are intended for the named recipient(s) only and may contain confidential, protected or privileged information that should not be distributed to unauthorized individuals. If you have received this message in error, please contact the sender.

-----Original Message-----

From: (b) (6) USARMY MEDCOM AISR (US) [mailto:(b) (6)@mail.mil]
Sent: Thursday, January 24, 2019 4:45 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: Reports of Non-Compliance Assured Institution D16-00869 (A4669-01)

Dear Director,

Three reports of non-compliance are attached for you review. Protocol (b) (4) "A Model Development of Blast Injury and Hemorrhage in Rats" and protocol (b) (4) "Efficacy of Complement Inhibitors in a Rat Model of Blast Injury and Hemorrhage" were closed by the IACUC. Protocol (b) (4) "A Rat Model of Smoke Inhalation Injury to Determine the Participation of Distal Airway Stem Cells (DASCs) in Lung Regeneration" has been suspended by the IACUC pending extensive training by the research team.

(b) (6)

Research Regulatory Compliance Division
 US Army Institute of Surgical Research
 3698 Chambers Pass, Bldg 3611
 JBSA Ft. Sam Houston, TX 78234

(b) (6)



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTHFOR 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) 402-7065

January 31, 2019

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

Colonel (b) (6)
Commander
US Army Institute of Surgical Research
3698 Chambers Pass
JBSA Fort Sam Houston, Texas 78234-6315

Dear Colonel (b) (6)

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your January 23, 2019 letter reporting the termination of a research protocol at the US Army Institute of Surgical Research. According to the information provided, OLAW understands that the Institutional Animal Care and Use Committee (IACUC) took this action after determining that in a rat blast injury and hemorrhage study numerous actions were conducted that were contrary to the approved protocol. Specifically, pain assessments were not documented, two injured rats were subjected to experimental procedures, catheters were inserted without approval, blast procedures were performed on two animals simultaneously rather than one, additional unapproved blood draws were performed, hemorrhage levels were higher than approved, additional unapproved cohort trials were conducted, some rats did not receive drug treatment following shock or post-blast, some rats received unapproved control saline, some animals were not euthanized at the humane endpoint, and there was incomplete documentation. Unanticipated events were not reported promptly to the IACUC, worksheets were not prepared correctly, drug concentration was not listed, blast pressure values differed, imaging was not documented, and requests for additional animals were incorrect.

The corrective action consisted of the IACUC terminating the protocol and having the data integrity assessed by institutional leadership.

Based on the information provided, OLAW is satisfied that appropriate actions have been taken to investigate and prevent recurrence of the noncompliance. We appreciate having been informed about this matter and find no cause for further action by this Office.

Sincerely,

(b) (6)

Deputy Director
Office of Laboratory Animal Welfare

cc: IACUC Chair



REPLY TO
ATTENTION OF

DEPARTMENT OF THE ARMY
U.S. ARMY INSTITUTE OF SURGICAL RESEARCH
3698 CHAMBERS PASS
JBSA FORT SAM HOUSTON, TEXAS 78234-6315

JAN 23 2019

Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
Rockledge 1, (b) (6) MSC7982
6705 Rockledge Drive
Bethesda, MD 20892-7982

Assurance Reference #D16-00869 (A4669-01)

Dear Director,

A report of protocol non-compliance and animal use concerns is submitted for your review. An audit of protocol (b) (4) "Efficacy of Complement Inhibitors in a Rat Model of Blast Injury and Hemorrhage" (PI (b) (6)) was presented by Quality Assurance Specialists, Quality Management Division, US Army Institute of Surgical Research at the January 10, 2019 IACUC meeting:

The results of the audit are noted below.

- Pain assessments were not documented according to the IACUC approved protocol.
- Two animals were subjected to experimental procedures that should have received veterinary consultation due to their health status at the time the experimental procedures were performed.
- Catheters were inserted 1-12 days prior to blast and hemorrhage procedures; performed procedures without IACUC approval.
- Blast procedures were performed on two animals simultaneously instead of individually as illustrated in the approved protocol.
- Additional blood draws were performed without IACUC approval that were not subtracted from the total hemorrhage volume.
- Hemorrhage ranged of 40-62%, instead of 40% as indicated in the approved protocol.
- Additional animals were used in two experimental groups without IACUC approval;
- Twelve animals did not receive drug treatment after hemorrhagic shock as described in the protocol.
- Thirteen animals did not receive Coversin after hemorrhagic shock as described in the protocol.
- Ten animals received control saline that was not described in the approved protocol or addenda.
- Twelve animals did not receive drug treatment 15 minutes post-blast as stated in the approved protocol addendum #1.
- Some sham animals lacked documentation of cannulation and some cannulated animals were not euthanized until several days after the experimental endpoint.

Additional findings include extremely poor documentation practices; unanticipated event reports not reported to the IACUC within 48 hours as required in IACUC (b) (4) "Reporting Unanticipated Events;" individual worksheets were not signed or initialed; worksheets had scratch outs instead of a

-2-

single line being drawn through an item; incorrect worksheets from another protocol were used, or had the incorrect title on the worksheet; the volumes of Ketamine/Xylazine administered to the animals were documented, but the concentrations of the drugs were not documented; blast overpressures were mostly expressed as psi, but occasionally expressed as kPa; computed tomography scans were never documented; the reasons for requesting replacement animals in the periodic review report submitted to the IACUC differed from what was documented on the protocol worksheets.

Due to the seriousness and numerous infractions that have occurred on this protocol, the IACUC voted to close protocol (b) (4) at the 10 January 2019 IACUC meeting. No additional animal use may be conducted on this protocol.

The IACUC recommended that the results of this protocol be reviewed by the USAISR Department Chief, (b) (6) to determine if data integrity was compromised as a result of these problems and protocol deviations.

No PHS funding was used for this protocol.

The point of contact for this action is (b) (6) IACUC Chair, (b) (6) @mail.mil.

Sincerely,

(b) (6)

(b) (6)

Colonel, U.S. Army
Commanding / Institutional Official

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Monday, January 28, 2019 9:17 AM
To: (b) (6) USARMY MEDCOM AISR (US); OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Reports of Non-Compliance Assured Institution D16-00869 (A4669-01)

Thank you for providing these reports (b) (6). We will send official responses soon.

Best regards, Brent Morse

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

Please note that this message and any of its attachments are intended for the named recipient(s) only and may contain confidential, protected or privileged information that should not be distributed to unauthorized individuals. If you have received this message in error, please contact the sender.

-----Original Message-----

From: (b) (6) USARMY MEDCOM AISR (US) [mailto:(b) (6)@mail.mil]
Sent: Thursday, January 24, 2019 4:45 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: Reports of Non-Compliance Assured Institution D16-00869 (A4669-01)

Dear Director,

Three reports of non-compliance are attached for you review. Protocol (b) (4) "A Model Development of Blast Injury and Hemorrhage in Rats" and protocol (b) (4) "Efficacy of Complement Inhibitors in a Rat Model of Blast Injury and Hemorrhage" were closed by the IACUC. Protocol (b) (4) "A Rat Model of Smoke Inhalation Injury to Determine the Participation of Distal Airway Stem Cells (DASCs) in Lung Regeneration" has been suspended by the IACUC pending extensive training by the research team.

(b) (6)

(b) (6)

Research Regulatory Compliance Division
 US Army Institute of Surgical Research
 3698 Chambers Pass, Bldg 3611
 JBSA Ft. Sam Houston, TX 78234

(b) (6)



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTHFOR 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) 402-7065

April 15, 2019

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

Colonel (b) (6)
Commander
US Army Institute of Surgical Research
3698 Chambers Pass
JBSA Fort Sam Houston, Texas 78234-6315

Dear Colonel (b) (6)

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your April 5, 2019 letter reporting the termination of an animal activity at the U.S. Army Institute of Surgical Research.

According to the information provided, OLAW understands that the activity was an experimental study in swine to evaluate a test article. The Institutional Animal Care and Use Committee (IACUC) took this action after receiving a report on March 25, 2019 that compression to stem bleeding was being applied longer than in the IACUC approved protocol. Because of two prior non-compliance concerns associated with this activity, an investigation of the concerns was conducted by an IACUC subcommittee and the IACUC voted unanimously to terminate the protocol during a meeting held March 27, 2019. No PHS funding was used for this activity. Based on its assessment of this explanation, OLAW concurs with the actions taken by the IACUC to comply with the PHS Policy. Thank you for keeping OLAW apprised on this matter.

Sincerely,

(b) (6)

(b) (6)

VMD, DCAW
Veterinary Medical Officer
Office of Laboratory Animal Welfare

cc: IACUC Contact

New case
A4669-H



REPLY TO
ATTENTION OF

DEPARTMENT OF THE ARMY
U.S. ARMY INSTITUTE OF SURGICAL RESEARCH
3698 CHAMBERS PASS, BLDG 3611
JBSA FORT SAM HOUSTON, TEXAS 78234-7767

APR 05 2019

Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
Rockledge 1, (b) (6), MSC7982
6705 Rockledge Drive
Bethesda, MD 20892-7982

Assurance Reference #D16-00869 (A4669-01)

Dear Director,

A report of protocol non-compliance is submitted for your review. On 25 March 2019, the IACUC received a report of non-compliance on protocol (b) (4) "Hemorrhage Control Management of Compressible Wounds during Prolonged Field Care (PFC) using a Swine Model." The protocol non-compliance occurred when Combat Gauze® was being tested. After the third application of Combat Gauze®, there was still slight bleeding which stopped after 3 minutes of additional compression. The 3 minutes of additional compression is not in compliance with the approved version of protocol (b) (4).

Two previous protocol non-compliance concerns have occurred on this protocol, January 30, 2019 and February 20, 2019. Due to the two previous non-compliance concerns plus the non-compliance concern noted above, the IACUC Alternate Chair, who was acting in the absence of the IACUC Chair, and a scientific voting member of the IACUC acted upon a recommendation of the attending veterinarian, and commenced an investigation of the non-compliance concern.

Several U.S. Army Institute of Surgical Research personnel involved with the protocol were interviewed during the course of the investigation, including the principal investigator. All interviewee versions of the non-compliance report were very similar. Ultimately, the USAISR Commander (Institutional Official) was consulted. The Commander advised that the experiment as it stood was in non-compliance of the protocol and that the animal was to be euthanized. The attending veterinarian euthanized the animal at ~1600 on 25 March 2019.

An ad hoc meeting of the IACUC occurred on 27 March 2019, to discuss the non-compliance concerns that have occurred on protocol (b) (4). After review of the non-compliance concerns, the IACUC voted unanimously to terminate the protocol effective immediately.

No PHS funding was used for this protocol.

The point of contact for this action is (b) (6) Alternate IACUC Chair, (b) (6) @mail.mil.

Sincerely,
(b) (6)
(b) (6)
(b) (6)
Colonel, U.S. Army
Commanding / Institutional Official

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Thursday, April 11, 2019 8:12 AM
To: (b) (6) USARMY MEDCOM AISR (US); OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Report of Non-Compliance and Subsequent IACUC Investigation D16-00869 (A4669-01)

Thank you for providing this report. We will send an official response soon.

Best regards, Brent Morse

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

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-----Original Message-----

From: (b) (6) USARMY MEDCOM AISR (US) [mailto:(b) (6)@mail.mil]
Sent: Monday, April 08, 2019 10:29 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: Report of Non-Compliance and Subsequent IACUC Investigation D16-00869 (A4669-01)

Dear Director,

A report of protocol non-compliance and subsequent IACUC investigation is submitted for review.

Respectfully,

(b) (6)

Research Regulatory Compliance Division
US Army Institute of Surgical Research
3698 Chambers Pass, Bldg 3611
JBSA Ft. Sam Houston, TX 78234

(b) (6)

Jeopern



Initial Report of Noncompliance

By: awDate: 6/12/19Time: 1:30Name of Person reporting: (b) (6)Telephone #: [REDACTED]Fax #: [REDACTED]Email: [REDACTED]Name of Institution: US Army Inst of Surgical ResearchAssurance number: A4669Did incident involve PHS funded activity? No

Funding component: _____

Was funding component contacted (if necessary): _____

What happened?

3 noncompliances previously reported, internal audits done + animal privileges suspended.

Species involved: Swine

Personnel involved: _____

Dates and times: _____

Animal deaths: _____

Projected plan and schedule for correction/prevention (if known): _____

Protocol terminated

Projected submission to OLAW of final report from Institutional Official: _____

OFFICE USE ONLY

Case # _____



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
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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) 402-7065

July 8, 2019

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

Colonel (b) (6)
Commander
US Army Institute of Surgical Research
3698 Chambers Pass
JBSA Fort Sam Houston, Texas 78234-6315

Dear Colonel (b) (6)

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your June 28, 2019 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the US Army Institute of Surgical Research. According to the information provided, OLAW understands that a rat study was found to have poor recordkeeping, an inaccurate number of animals used, missing or adjusted source data, undocumented drug dose calculations, and incomplete testing regimens.

The corrective actions consisted of the Institutional Animal Care and Use Committee (IACUC) terminating the protocol and having the data reviewed for integrity. The Principal Investigator subsequently left the institution.

Based on its assessment of this explanation, OLAW understands that measures have been implemented to correct and prevent recurrence of this problem. OLAW concurs with the actions taken by the IACUC to comply with the PHS Policy.

Sincerely,

(b) (6)

Deputy Director
Office of Laboratory Animal Welfare

cc: IACUC Chair

A4669-I



DEPARTMENT OF THE ARMY
U.S. ARMY INSTITUTE OF SURGICAL RESEARCH
3698 CHAMBERS PASS
JBSA FORT SAM HOUSTON, TEXAS 78234-6315

REPLY TO
ATTENTION OF

JUN 28 2019

Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
Rockledge 1, (b) (6) MSC7982
6705 Rockledge Drive
Bethesda, MD 20892-7982

Assurance Reference #D16-00869 (A4669-01)

Dear Director,

The final audit report of protocol (b) (4) "The Effect of Selective Retinoic Acid Receptor- γ Agonist R667 With and Without an Androgen Receptor Response Element Agonist on Skeletal Muscle Function Following Volumetric Muscle Loss in the Rat (*Rattus norvegicus*)" was presented by Quality Assurance Specialists, Quality Management Division, US Army Institute of Surgical Research (USAISR) at the June 13, 2019 IACUC meeting.

The results of the report indicate failure to follow good documentation practices; an inaccurate accounting of the number of animals used on the protocol; missing or adjustment of source data; undocumented drug dose calculations; incomplete testing regimens.

The IACUC voted to terminate protocol (b) (4) at the June 13, 2019 IACUC meeting. No additional animal use may be conducted on this protocol.

The IACUC recommended that the results of this protocol be reviewed by the USAISR Director of Research and the Department Chief, to determine if data integrity was compromised as a result of these problems. The IACUC did not recommend a plan to proceed with re-training, as the principal investigator left the USAISR.

No PHS funding was used for this protocol.

The point of contact for this action is (b) (6) IACUC Chair, (b) (6) (b) (6) @mail.mil.

Sincerely,

(b) (6)

(b) (6) MD
Colonel, U.S. Army
Commanding / Institutional Official

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Wednesday, July 03, 2019 8:23 AM
To: (b) (6) USARMY MEDCOM AISR (USA); OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Final Audit Report D16-00869 (A4669-01)

Thank you for providing this report. We will send an official response soon.

Best regards, Brent Morse

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

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-----Original Message-----

From: (b) (6) USARMY MEDCOM AISR (USA) [mailto:(b) (6)@mail.mil]
Sent: Tuesday, July 02, 2019 4:57 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: Final Audit Report D16-00869 (A4669-01)

Dear Director,

A final audit report is submitted for review.

Respectfully,

(b) (6)

Research Regulatory Compliance Division
US Army Institute of Surgical Research
3698 Chambers Pass, Bldg 3611
JBSA Ft. Sam Houston, TX 78234

(b) (6)