



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE  
NATIONAL INSTITUTES OF HEALTH

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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

June 15, 2021

Re: Animal Welfare Assurance  
#A4555-01 (OLAW Case R)

Dr. Edward A. Jones  
President and CEO  
Houston Methodist Research Institute  
6670 Bertner Street, (b) (4)  
Houston, TX 77030

Dear Dr. Jones,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your May 19, 2021 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at The Methodist Hospital Research Institute. Your letter supplements the March 8, 2021 prompt preliminary report and the March 25<sup>th</sup> interim report. According to the information provided, OLAW understands that a possible exposure of Comparative Medicine staff to *Mycobacterium tuberculosis* (MTB) had occurred in the ABSL3 facility due to inoculation of animals with MTB on 2/10/2021 that was not communicated to the Comparative Medicine Department. There was no animal concern. The research is NIH funded.

A subcommittee of the IACUC met on March 4, 2021 and made a determination that noncompliance had occurred, including: failure to follow the direction of the AV; failure to follow the IACUC and Safety Committee Protocols; failure to post required study cage cards at the time of inoculation to notify staff that an infectious agent had been used; and failure of the PI to provide adequate oversight of the work in the ABSL3.

At a convened meeting on March 23, 2021, the IACUC voted to suspend two related Animal Use Protocols (AUP) as well as the research scientist's access to the ABSL3 facility.

A Corrective Action Plan (CAP), that assures adequate PI oversight, compliance with all policies and procedures, adherence to approved AUPs, retraining of research staff, and communication with Comparative Medicine Program (CMP) and the Biosafety Officer (BSO) was submitted, modified following subcommittee review, and then reviewed and approved by a quorum of IACUC members on April 15, 2021. Both protocols that were previously suspended were re-instated. The IACUC also approved an amendment changing the PI to enable greater oversight, and an attestation from the research staff acknowledging the authority of the AV and BSO. The IACUC required additional post approval monitoring of compliance with the CAP. This will occur at least monthly for the next 6 (six) months and a report provided to the IACUC.

Parameters have been set in place by the AV and BSO which must be completed and documented prior to re-entry into the ABSL3 facility.

The CMP staff, who were potentially exposed to MTB due to this incident, have engaged in a surveillance program with Employee Health. This involved an initial TB screening following the incident. A second screening has been completed and has shown no exposures.

The prompt consideration of this matter by The Methodist Hospital Research Institute was consistent with the philosophy of institutional self-regulation. OLAW concurs that the incident warranted reporting. Based on the information provided, OLAW is satisfied that appropriate actions have been taken to investigate this incident and prevent recurrence. We appreciate being informed of this matter and find no cause for further action by this office.

Sincerely,

**Brent C. Morse -S**

Digitally signed by Brent C.  
Morse -S  
Date: 2021.06.15 08:44:28 -04'00'

Brent C. Morse, DVM  
Director  
Division of Compliance Oversight  
Office of Laboratory Animal Welfare

cc: IACUC contact

A 4555-R



6670 Bertner Ave.  
Houston, Texas 77030  
www.houstonmethodist.org

May 19, 2021

**VIA EMAIL:** OLAW Division of Compliance Oversight (NIH/OD) [mailto:olawdco@od.nih.gov]

Director, Division of Compliance Oversight  
Office of Laboratory Animal Welfare  
National Institutes of Health  
Rockledge 1, Suite 360, MSC 7982  
6705 Rockledge Drive  
Bethesda, MD 20892-7982  
Re: Animal Welfare Assurance # A4555-01

Dear Dr. Wolff,

This is the final report for the concern initially submitted to OLAW on March 8, 2021 with an update submitted on March 26, 2021, regarding a possible personnel exposure to Mycobacterium tuberculosis (MTB) that occurred in the ABSL3 facility due to inoculation of animals with MTB without prior notice to the Attending Veterinarian (AV) and staff.

The research is NIH funded through an (b) (4) This is a multi-PI grant.

A subcommittee of the IACUC met on March 4, 2021 and made a determination that noncompliance had occurred, including: failure to follow the direction of the AV; failure to follow the IACUC and Safety Committee Protocols; failure to post required study cage cards at the time of inoculation to notify staff that an infectious agent had been used; and failure of the PI to provide adequate oversight of the work in the ABSL3. At a convened meeting on March 23, 2021, the IACUC voted to suspend two related Animal Use Protocols (AUP) pending review and approval of a Corrective Action Plan (CAP) that would assure adequate PI oversight, compliance with all policies and procedures, adherence to approved AUPs, retraining of research staff, and communication with Comparative Medicine Program (CMP) and the Biosafety Officer (BSO).

The CAP was submitted, modified following subcommittee review, and then reviewed and approved by a quorum of IACUC members on April 15, 2021. Both protocols that were previously suspended were re-instated. The IACUC also approved an amendment changing the PI to enable greater oversight, and an attestation from the research staff acknowledging the authority of the AV and BSO. The IACUC required additional post approval monitoring of compliance with the CAP. This will occur at least monthly for the next 6 (six) months and a report provided to the IACUC.

Parameters have been set in place by the AV and BSO which must be completed and documented prior to re-entry into the ABSL3 facility.

The CMP staff, who were potentially exposed to MTB due to this incident, have engaged in a surveillance program with Employee Health. This involved an initial TB screening following the incident. A second screening has been completed and has shown no exposures.

If you have any questions, please do not hesitate to contact me at 713-441-1261.

Sincerely,

DocuSigned by:  
(b) (6)

B75B08EA6519405...  
Edward A. Jones  
Institutional Official  
The Methodist Hospital Research Institute

## Wolff, Axel (NIH/OD) [E]

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**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Friday, May 28, 2021 7:04 AM  
**To:** (b) (6)  
**Cc:** OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** RE: OLAW Final Report of Animal Concern A4555

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

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

**From:** (b) (6)  
**Sent:** Wednesday, May 26, 2021 1:01 PM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Cc:** Jones, Edward A. <EAJones@houstonmethodist.org>; (b) (6)  
**Subject:** OLAW Final Report of Animal Concern A4555

Dr. Wolff,

Please find attached the final report from the HMRI IO regarding this investigation. Please let me know if you need anything further.

Thank you,

(b) (6)

Houston Methodist. Leading Medicine.

Houston Methodist is ranked by *U.S. News & World Report* as the No. 1 hospital in Texas for patient care and safety and one of the top 20 hospitals in the nation. In addition, we are nationally ranked in 11 specialties, the most in the state, and have been national leaders throughout the COVID-19 pandemic in research, offering innovative treatments and surpassing CDC safety standards. For more than 100 years, Houston Methodist has provided the best — and safest — clinical care, advanced technology and patient experience. That is our promise of leading medicine.

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R

March 25, 2021

VIA EMAIL: OLAW Division of Compliance Oversight (NIH/OD) [mailto:olawdco@od.nih.gov]

Director, Division of Compliance Oversight  
Office of Laboratory Animal Welfare  
National Institutes of Health  
Rockledge 1, Suite 360, MSC 7982  
6705 Rockledge Drive  
Bethesda, MD 20892-7982

Re: Animal Welfare Assurance # A4555-01

Dear Dr. Wolff,

This letter is written to follow up on the initial report of a concern submitted to OLAW on March 8, 2021 regarding a report to the Chair of Houston Methodist Research Institute's (HMRI) IACUC, David R. Beers, Ph.D. from the Attending Veterinarian, Tanya Herzog, DVM DACLAM (AV) that a possible personnel exposure to Mycobacterium tuberculosis (MTB) occurred in the ABSL3 facility due to inoculation of animals with MTB.

The research is NIH funded through an (b) (4) This is a multi-PI grant.

This incident continues to be investigated by the IACUC subcommittee. The preliminary findings and responses from the PI were reviewed at the March 23, 2021 IACUC meeting. The Committee found that this constituted noncompliance including: failure to follow the direction of the AV; failure to follow the IACUC and Safety Committee Protocols; failure to post required study cards at the time of inoculation to notify staff that an infectious agent had been used; and failure of the PI to provide adequate oversight of the work in the ABSL3.

The PIs reported that the work was conducted under two approved IACUC protocols but due to cage card notations, it is unclear under which protocol this work was being conducted. Due to these findings, the IACUC voted to suspend both approved protocols as well as the research scientist's access to the ABSL3 facility until the corrective action plan is reviewed and approved. We expect this to occur at the April 27, 2021 meeting and will provide another update at that time.

If you have any questions, please do not hesitate to contact me at (b) (6)

Sincerely,

(b) (6)  
Edward A. Jones  
Institutional Official  
President & CEO  
The Methodist Hospital Research Institute

**Wolff, Axel (NIH/OD) [E]**

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**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Friday, March 26, 2021 11:18 AM  
**To:** (b) (6)  
**Cc:** OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** RE: OLAW Updated Report of Animal Concern A4555

Thank you. We will send a response soon.  
Axel Wolff

---

**From:** (b) (6)  
**Sent:** Friday, March 26, 2021 11:16 AM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Subject:** OLAW Updated Report of Animal Concern A4555

Dr. Wolff,

Please find attached an updated report from the HMRI IO regarding this investigation. Please let me know if you need anything further at this time.

Thank you,

(b) (6)

As of 1/31/2020, ORP has moved to the Josie Roberts Building at 7550 Greenbriar, 4<sup>th</sup> Floor.

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**From:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Sent:** Friday, March 12, 2021 6:10 AM  
**To:** (b) (6)  
**Cc:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Subject:** [EXTERNAL] RE: OLAW Initial Report of Animal Concern A4555.docx

Thank you for this preliminary report, (b) (6) We will open 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

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**From:** (b) (6)  
**Sent:** Thursday, March 11, 2021 12:38 PM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Subject:** OLAW Initial Report of Animal Concern A4555.docx

Attached please find the initial report from the Institutional Official at HMRI. Please let me know if you need anything further at this time.

Thank you,

(b) (6)

As of 1/31/2020, ORP has moved to the Josie Roberts Building at 7550 Greenbriar, 4<sup>th</sup> Floor.

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6670 Bertner Ave.  
Houston, Texas 77030  
www.houstonmethodist.org

March 8, 2021

VIA EMAIL: OLAW Division of Compliance Oversight (NIH/OD) [mailto:olawdco@od.nih.gov]

Director, Division of Compliance Oversight  
Office of Laboratory Animal Welfare  
National Institutes of Health  
Rockledge 1, Suite 360, MSC 7982  
6705 Rockledge Drive  
Bethesda, MD 20892-7982

Re: Animal Welfare Assurance # A4555-01: Initial Report of Noncompliance

Dear Director,

This letter is written to report a concern received by the Chair of Houston Methodist Research Institute's (HMRI) IACUC, David R. Beers, Ph.D. from the Attending Veterinarian (AV), Tanya Herzog, DVM DACLAM.

The research is NIH-funded through an (b) (4) This is a multi-PI grant.

On 3/2/21, Dr. Herzog reported to the IACUC Chair that a possible exposure of the Comparative Medicine staff to Mycobacterium tuberculosis (MTB) had occurred in the ABSL3 facility due to inoculation of animals with MTB on 2/10/2021 that was not communicated to the Comparative Medicine Department.

There was no animal concern. The immediate safety of animal care staff is the IACUC chief concern.

A subcommittee of the IACUC was convened and has begun investigating the incident. Preliminary findings are that noncompliance occurred which led to the potential harm of animal facility staff and that this event is reportable to the IACUC, OLAW, and the Funding agency. All work in the ABSL3 under this protocol has been stopped pending IACUC review of the incident.

The IACUC subcommittee continues to investigate this incident as well as perform a root cause analysis (RCA) and will provide a full report of the incident, the proposed actions, and any additional finding to the IACUC at the next scheduled meeting on March 23, 2021.

The Institution takes the welfare of animals and staff very seriously and has instituted a root cause analysis (RCA). The status of the employee surveillance program, investigation and IACUC review will be reported within the next month.

If you have any questions, please do not hesitate to contact me at (b) (6)

Sincerely,

DocuSigned by:

(b) (6)

Edward A. Jones  
Institutional Official  
President & CEO  
The Methodist Hospital Research Institute

CC:

(b) (6)

## Wolff, Axel (NIH/OD) [E]

---

**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Friday, March 12, 2021 7:10 AM  
**To:** (b) (6)  
**Cc:** OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** RE: OLAW Initial Report of Animal Concern A4555.docx

Thank you for this preliminary report, (b) (6) We will open 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

**From:** (b) (6)  
**Sent:** Thursday, March 11, 2021 12:38 PM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Subject:** OLAW Initial Report of Animal Concern A4555.docx

Attached please find the initial report from the Institutional Official at HMRI. Please let me know if you need anything further at this time.

Thank you,

(b) (6)

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