

Annual Report to OLAW

Institution: **Cummings School of Veterinary Medicine Tufts University– Grafton campus**

Assurance Number: **#D16-00572 (A4059-01)**

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.](#)).
See Appendix II
- The individual designated by this institution as the Institutional Official has changed.
[See Item V.]
- The membership of this institution's IACUC has changed. *[See 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.]

See Appendix I

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.]

See Appendix I

III. Minority Views [Select A or B]

- 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: Philip Hinds, PhD	Name: Heather Gipson-Cosier, JD, MA
Signature: (b) (6)	Signature: (b) (6)
Date: January 2, 2019	Date: January 3, 2019

V. Change in Institutional Official

Name:	
Title:	Degree/Credential:
Name of Institution:	
Address:	
E-mail:	
Phone:	Fax:

VI. Change in IACUC Membership [Current roster]

Institution: Cummings School of Veterinary Medicine-Tufts University (Grafton campus)			
IACUC Contact Information			
Address: (b) (6)			
E-mail: (b) (6)			
Phone: (b) (6)		Fax:	
IACUC Chairperson			
Name: Philip Hinds, PhD			
Title: Professor and Chair, Department of Development, Molecular and Chemical Biology, Tufts University School of Medicine; Associate Director, Molecular Oncology Research Institute, Professor, Radiation Oncology, Tufts Medical Center; Deputy Director, Tufts Cancer Center			Degree/Credentials: PhD
PHS Policy Membership Requirements***: Scientist			
IACUC Roster			
Name of Member/ Code*	Degree/Credential	Position Title/ Occupational Background**	PHS Policy Membership Requirements***
(b) (6)			Scientist
			Vice Chair, Veterinarian

(b) (6)			Veterinarian
			Nonaffiliated/ Nonscientist
			Scientist
			Vice Chair, Scientist
			Nonaffiliated/ Nonscientist
			Scientist
			Scientist
			Scientist
			Veterinarian
			Scientist
Scott E. Perkins	VMD, MPH, DACLAM	Senior Director, Division of Laboratory Animal Medicine, Attending Veterinarian at Tufts University and Tufts Medical Center, and Clinical Professor, Environmental & Population Health	Veterinarian
(b) (6)			Scientist
			Scientist
			Scientist
			Vice Chair, Scientist
			Scientist



(b) (6)

Alternate for
(b) (6)
[Redacted]
[Redacted]
[Redacted]

Alternate for
(b) (6)
[Redacted]
[Redacted]

Scientist

Alternate for
(b) (6)
[Redacted]
[Redacted]

Appendix I
Tufts University-Tufts Medical Center
IACUC Animal Care and Use Program and Facility Review Schedule (2018)

January	February	March
<p><u>Program Review:</u> Semiannual Report to Institutional Official signed by Committee and sent to Institutional Officials (01/03/18).</p>	<p><u>Program Review:</u> Review and discussion of OLAW checklist “Institutional Policies and Responsibilities” Sections 1-4 as referenced by the Guide (8th ed.) (02/07/18).</p>	<p><u>Program Review:</u> Review and discussion of OLAW checklist “Institutional Policies and Responsibilities” Sections 5-7 as referenced by the Guide (8th ed.) (03/16/18).</p>
April	May	June
<p><u>Program Review:</u> Review and discussion of OLAW Checklist Institutional Policies and Responsibilities Sections 9-12 as referenced by the Guide (8th ed.) (04/04/18).</p>	<p><u>Program Review:</u> Review and discussion of “Institutional Policies and Responsibilities Section 8 and Veterinary Care Sections 1-6 as referenced by the Guide (8th ed.) (05/02/18).</p> <p><u>IACUC Inspections:</u> 05/22/2018 05/24/2018</p>	<p><u>IACUC Inspections:</u> 06/13/2018 06/15/2018 06/25/2018</p>
July	August	September
<p><u>Program Review:</u> Semiannual Report to Institutional Official signed by Committee and sent to Institutional Officials (07/11/18).</p> <p><u>IACUC Inspections:</u> 07/17/2018</p>	<p><u>Program Review:</u> Review and discussion of OLAW Checklist Institutional Policies and Responsibilities Sections 1-4 as referenced by the <i>Guide (8th ed.)</i> (08/01/18).</p>	<p><u>Program Review:</u> Review and discussion of OLAW Checklist Institutional Policies and Responsibilities Sections 5-7 as referenced by the <i>Guide (8th ed.)</i> (09/05/18).</p>
October	November	December
<p><u>Program Review:</u> Review and discussion of OLAW Checklist Institutional Policies and Responsibilities Sections 9-12 as referenced by the <i>Guide (8th ed.)</i> (10/03/18).</p> <p><u>IACUC Inspections:</u> 10/03/2018 10/24/2018</p>	<p><u>Program Review:</u> Review and discussion of “Institutional Policies and Responsibilities Section 8 and Veterinary Care Sections 1-6 as referenced by the Guide (8th ed.) (11/07/18).</p> <p><u>IACUC Inspections:</u> 11/01/2018 11/15/2018 11/19/2018</p>	<p><u>IACUC Inspections:</u> 12/03/2018 12/05/2018</p>

Appendix II

Program Changes: ([PHS Policy IV.A.1.a-i](#)):

The IACUC Policy on IACUC Review Procedures & Voting Categories and the IACUC Policy on Review of Amendments to Approved Protocols were changed to allow either method of IACUC review (1) Full Committee Review (FCR) by a convened quorum of the members of the IACUC or (2) Expedited Review (ER) by a subcommittee of the IACUC employed only after all voting members have been provided an opportunity to call for Full Committee Review. Previously there were restrictions placed on the type of protocol/amendment that could be reviewed by DMR.

Additionally, the IACUC Policy on Requirements for Personnel Working with IACUC-Covered Animals was changed to require renewal of Rodent Survival Surgical (RSS) Training every three years to align with the requirements for Mandatory Animal Care and Use training. Previously RSS training only needed to be completed one time prior to working with animals.

Annual Report to OLAW

Institution: Cummings School of Veterinary Medicine Tufts University– Grafton campus
Assurance Number: #D16-00572 (A4059-01)
Reporting Period: January 1, 2019 – December 31, 2019

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.](#)).
- The individual designated by this institution as the Institutional Official has changed.
[See Item V.]
- The membership of this institution's IACUC has changed. [See 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.]

See Appendix I

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.]

See Appendix I

III. Minority Views [Select A or B]

- 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: Philip Hinds, PhD	Name: Heather Gipson-Cosier, JD, MA
Signature: (b) (6)	Signature: (b) (6)
Date: January 22, 2020	Date: January 22, 2020

V. Change in Institutional Official

Name: N/A	
Title:	Degree/Credential:
Name of Institution:	
Address:	
E-mail:	
Phone:	Fax:

VI. Change in IACUC Membership [Current roster]

Institution: Cummings School of Veterinary Medicine-Tufts University (Grafton campus)			
IACUC Contact Information			
Address: (b) (6)			
E-mail: (b) (6)			
Phone: (b) (6)		Fax:	
IACUC Chairperson			
Name: Philip Hinds, PhD			
Title: Professor and Chair, Department of Development, Molecular and Chemical Biology, Tufts University School of Medicine; Associate Director, Molecular Oncology Research Institute, Professor, Radiation Oncology, Tufts Medical Center; Deputy Director, Tufts Cancer Center			Degree/Credentials: PhD
PHS Policy Membership Requirements***: Scientist			
IACUC Roster			
Name of Member/ Code*	Degree/Credential	Position Title/ Occupational Background**	PHS Policy Membership Requirements***
(b) (6)			Scientist
(b) (6)			Vice Chair, Veterinarian

(b) (6)			Veterinarian
			Nonaffiliated/ Nonscientist
			Scientist
			Vice Chair, Scientist
			Nonaffiliated/ Nonscientist
			Scientist
			Scientist
			Scientist
			Veterinarian
Scott E. Perkins	VMD, MPH, DACLAM	Senior Director, Division of Laboratory Animal Medicine, Attending Veterinarian at Tufts University and Tufts Medical Center, and Clinical Professor, Environmental & Population Health	Veterinarian
(b) (6)			Scientist
			Scientist
			Scientist
			Scientist
			Vice Chair, Scientist
			Scientist



(b) (6)

Alternate for
[redacted] (b) (6)
[redacted]
[redacted]
[redacted]

Alternate for
[redacted] (b) (6)
[redacted]
[redacted]

Scientist

Appendix I
Tufts University-Tufts Medical Center
IACUC Animal Care and Use Program and Facility Review Schedule (2019)

January	February	March
<p><u>Program Review:</u> Semiannual Report to Institutional Official signed by Committee and sent to Institutional Officials (01/09/19).</p>	<p><u>Program Review:</u> Review and discussion of OLAW checklist “Institutional Policies and Responsibilities” Sections 1-4 as referenced by the Guide (8th ed.) (02/06/19).</p>	<p><u>Program Review:</u> Review and discussion of OLAW checklist “Institutional Policies and Responsibilities” Sections 5-7 as referenced by the Guide (8th ed.) (03/06/19).</p>
April	May	June
<p><u>Program Review:</u> Review and discussion of OLAW Checklist Institutional Policies and Responsibilities Sections 9-12 as referenced by the Guide (8th ed.) (04/03/19).</p>	<p><u>Program Review:</u> Review and discussion of “Institutional Policies and Responsibilities Section 8 and Veterinary Care Sections 1-6 as referenced by the Guide (8th ed.) (05/01/19).</p> <p><u>IACUC Inspections:</u> 05/13/2019 05/15/2019 05/20/2019 05/23/2019</p>	<p><u>IACUC Inspections:</u> 06/18/2019 06/26/2019</p>
July	August	September
<p><u>Program Review:</u> Semiannual Report to Institutional Official signed by Committee and sent to Institutional Officials (07/10/19).</p>	<p><u>Program Review:</u> Review and discussion of OLAW Checklist Institutional Policies and Responsibilities Sections 1-4 as referenced by the <i>Guide (8th ed.)</i> (08/07/19).</p>	<p><u>Program Review:</u> Review and discussion of OLAW Checklist Institutional Policies and Responsibilities Sections 5-7 as referenced by the <i>Guide (8th ed.)</i> (09/11/19).</p> <p><u>IACUC Inspections:</u> 09/25/2019</p>
October	November	December
<p><u>Program Review:</u> Review and discussion of OLAW Checklist Institutional Policies and Responsibilities Sections 9-12 as referenced by the <i>Guide (8th ed.)</i> (10/02/19).</p> <p><u>IACUC Inspections:</u> 11/22/2019 11/24/2019</p>	<p><u>Program Review:</u> Review and discussion of “Institutional Policies and Responsibilities Section 8 and Veterinary Care Sections 1-6 as referenced by the Guide (8th ed.) (11/06/19).</p> <p><u>IACUC Inspections:</u> 11/08/2019</p>	

Annual Report to OLAW

Institution: Cummings School of Veterinary Medicine Tufts University-Grafton Campus
Assurance Number: #D16-00572 (A4059-01)
Reporting Period: January 1, 2020-September 30, 2020

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.

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: see Appendix I	Date 2:
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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: Waiver received from OLAW due to COVID 19	Date 2: 09/23/2020
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III. Minority Views [*Select A or B*]

- 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: Philip Hinds, PhD	Name: Heather Gipson-Cosier, JD, MA
Signature:  (b) (6)	Signature:  (b) (6)
Date: 10/27/20	Date: 10/28/20

V. Change in Institutional Official

Name: N/A	
Title:	Degree/Credentials:
Name of Institution:	
Address: [<i>street, city, state, zip code</i>]	
Phone:	Fax:
E-mail:	

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

Institution: Cummings School of Veterinary Medicine-Tufts University Grafton Campus			
IACUC Contact Information			
Address:  (b) (6)			
E-mail:  (b) (6)			
Phone:  (b) (6)		Fax:	
IACUC Chairperson			
Name: Philip Hinds, PhD			
Title: Professor and Chair, Department of Development, Molecular and Chemical Biology, Tufts University School of Medicine; Associate Director, Molecular Oncology Research Institute, Professor, Radiation Oncology, Tufts Medical Center; Deputy Director, Tufts Cancer Center			Degree/Credentials: PhD
PHS Policy Membership Requirements***: Scientist			
IACUC Roster [<i>Provided below</i>]			
Name of Member/ Code*	Degree/ Credentials	Position Title/ Occupational Background**	PHS Policy Membership Requirements***
 (b) (6)			Scientist
			Vice Chair, Veterinarian
			Veterinarian
			Nonaffiliated/ Nonscientist
			Scientist

			(b) (6)
			Vice Chair, Scientist
			Scientist
			Scientist
			Scientist
			Veterinarian
Scott E. Perkins	VMD, MPH, DACLAM	Senior Director, Division of Laboratory Animal Medicine, Attending Veterinarian at Tufts University and Tufts Medical Center, and Clinical Professor, Environmental & Population Health	Veterinarian
			(b) (6)
			Scientist
			Scientist

(b) (6)	
	Nonaffiliated/ Nonscientist
	Nonaffiliated/ Nonscientist
	Scientist
	Vice Chair, Scientist
	Scientist
	Alternate for (b) (6)
	Alternate for (b) (6)
	Alternate for (b) (6)
	Nonaffiliated/ Nonscientist

* 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 (e.g., 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 or former user. A consulting veterinarian may not be considered nonaffiliated.

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

Statement of Burden

Public reporting burden for this collection of information is estimated to average 90 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0765). Do not return the completed form to this address.

Tufts University-Tufts Medical Center

Appendix I

January	February	March
<p><u>Program Review:</u> Semiannual Report to Institutional Official signed by Committee and sent to Institutional Officials (01/08/20).</p>	<p><u>Program Review:</u> Review and discussion of OLAW checklist “Institutional Policies and Responsibilities” Sections 1-4 as referenced by the Guide (8th ed.) (02/05/20).</p>	<p><u>Program Review:</u> Review and discussion of OLAW checklist “Institutional Policies and Responsibilities” Sections 5-7 as referenced by the Guide (8th ed.) (03/04/20). <u>IACUC Inspections:</u> Waiver from OLAW received 03/25/20 OLAW expects the Tufts University’s IACUC to complete inspections of its animal facilities that were postponed and schedule the next inspections within 6 months.</p>
April	May	June
<p><u>Program Review:</u> Review and discussion of OLAW Checklist Institutional Policies and Responsibilities Sections 9-12 as referenced by the Guide (8th ed.) (04/01/20).</p>	<p><u>Program Review:</u> Review and discussion of “Institutional Policies and Responsibilities Section 8 and Veterinary Care Sections 1-6 as referenced by the Guide (8th ed.) (05/06/20).</p>	
July	August	September
<p><u>Program Review:</u> Semiannual Report to Institutional Official signed by Committee and sent to Institutional Officials (07/01/20).</p>	<p><u>Program Review:</u> Review and discussion of OLAW Checklist Institutional Policies and Responsibilities Sections 1-4 as referenced by the Guide (8th ed.) (08/05/20).</p>	<p><u>Program Review:</u> Review and discussion of OLAW Checklist Institutional Policies and Responsibilities Sections 5-7 as referenced by the Guide (8th ed.) (09/09/20). <u>IACUC Inspections: 09/23/20-Swine Unit II</u></p>
October	November	December



FOR US POSTAL SERVICE DELIVERY:

Office of Laboratory Animal Welfare
Division of Assurances
6705 Rockledge Drive
RKL 1, Suite 360, MSC 7982
Bethesda, Maryland 20892-7982
Home Page: <http://grants.nih.gov/grants/olaw/olaw.htm>

FOR EXPRESS MAIL:

Office of Laboratory Animal Welfare
Division of Assurances
6705 Rockledge Drive, Suite 360
Bethesda, Maryland 20817
Telephone: (301) 496-7133

March 26, 2018

Re: Assurance D16-00572 (A4059-01)
Report to OLAW for CY 2017

Heather Gipson-Cosier, JD, MA
Associate Vice Provost for Research Compliance
Tufts University - Cummings School of Veterinary Medicine
136 Harrison Avenue
Medford, MA 02111

Dear Heather Gipson-Cosier,

This notice is to acknowledge that the Division of Assurances, Office of Laboratory Animal Welfare (OLAW) received and reviewed your institution's Annual Report that was submitted in accordance with Part IV.F. of the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals, revised 2015.

The Annual Report to OLAW is a key document in a continuing relationship with the PHS. It contains pertinent information regarding the policies and procedures in place to provide for the appropriate care and use of laboratory animals.

We look forward to receiving your next report for the period January 1, 2018 through December 31, 2018 within 30 days (January 31, 2019) of the end of the reporting period. Please include your Assurance number on your Annual Report and in all correspondence to OLAW.

Thank you for your attention to these matters.

Sincerely,

 Expired certificate

 Tiffani T. Soto

Signed by: Tiffani T. Soto -S (Affiliate)
Program Assistant
Division of Assurances
Office of Laboratory Animal Welfare

cc:
IACUC Contact



FOR US POSTAL SERVICE DELIVERY:

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

FOR EXPRESS MAIL:

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

January 09, 2019

Re: Assurance D16-00572 (A4059-01)
Report to OLAW for CY 2018

Heather Gipson-Cosier, JD, MA
Associate Vice Provost for Research Compliance
Tufts University - Cummings School of Veterinary Medicine
136 Harrison Avenue
Medford, MA 02111

Dear Ms. Gipson-Cosier,

This notice is to acknowledge that the Division of Assurances, Office of Laboratory Animal Welfare (OLAW) received and reviewed your institution's Annual Report that was submitted in accordance with Part IV.F. of the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals, revised 2015.

The Annual Report to OLAW is a key document in a continuing relationship with the PHS. It contains pertinent information regarding the policies and procedures in place to provide for the appropriate care and use of laboratory animals.

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Thank you for your attention to these matters.

Sincerely,

 Expired certificate

 Tiffani T. Soto

Signed by: Tiffani T. Soto -A (Affiliate)
Program Assistant
Division of Assurances
Office of Laboratory Animal Welfare

cc:
IACUC Contact



FOR US POSTAL SERVICE DELIVERY:

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

FOR EXPRESS MAIL:

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

January 30, 2020

Re: Assurance D16-00572 (A4059-01)
Report to OLAW for CY 2019

Heather Gipson-Cosier, JD, MA
Associate Vice Provost for Research Compliance
Tufts University - Cummings School of Veterinary Medicine
136 Harrison Avenue
Medford, MA 02111

Dear Ms. Gipson-Cosier,

This notice is to acknowledge that the Division of Assurances, Office of Laboratory Animal Welfare (OLAW) received and reviewed your institution's Annual Report that was submitted in accordance with Part IV.F. of the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals, revised 2015.

The Annual Report to OLAW is a key document in a continuing relationship with the PHS. It contains pertinent information regarding the policies and procedures in place to provide for the appropriate care and use of laboratory animals.

The Annual Report to OLAW for the year 2020 will harmonize with the USDA Reporting Period which is October 1 through September 30th, due to OLAW by December 1st. Therefore, the Annual Report to OLAW for Fiscal Year 2020, will cover the reporting period of January 1, 2020 to September 30, 2020 (a partial year) and will be due to OLAW by December 1, 2020. In the subsequent year the Annual Report will cover the period, October 1, 2020 to September 30, 2021 due to OLAW by December 1, 2021. Please include your Assurance number on your Annual Report and in all correspondence to OLAW.

Thank you for your attention to these matters.

Sincerely,

 Expired certificate

 Tiffani T. Mills

Signed by: Tiffani T. Mills -S (Affiliate)
Program Assistant
Division of Assurances
Office of Laboratory Animal Welfare

cc:
IACUC Contact



FOR US POSTAL SERVICE DELIVERY:

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

FOR EXPRESS MAIL:

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

October 29, 2020

Re: Assurance D16-00572 (A4059-01)
2020 Annual Report to OLAW

Health Gipson-Cosier, JD, MA
Associate Vice Provost for Research Compliance
Tufts University – Cummings School of
Veterinary Medicine
136 Harrison Avenue
Medford, MA 02111

Dear Ms. Gipson-Cosier,

This notice is to acknowledge that the Division of Assurances, Office of Laboratory Animal Welfare (OLAW) received and reviewed your institution's Annual Report that was submitted in accordance with Part IV.F. of the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals, revised 2015.

Conducting semiannual facility inspections remains a required IACUC function, and the potential for noncompliance increases the longer inspections are delayed. Although the OLAW-approved waivers of the semiannual facility inspections do not expire, your institution is expected to conduct inspections as soon as you are safely able to do so, using the flexibilities afforded by the PHS Policy and highlighted in OLAW's Guide Notice [NOT-OD-20-088](#), [COVID FAQs](#), and [webinars](#). If not already completed, please ensure your semiannual facility inspections resume, as advised, as part of the continued oversight of your institution's animal care and use program.

We look forward to receiving your next report for the period October 1, 2020 to September 30, 2021 due to OLAW by December 1, 2021. Please include your Assurance number on your Annual Report and in all correspondence to OLAW.

Thank you for your attention to these matters.

Sincerely,

 Expired certificate

 Keri Walker

Keri Walker

Signed by: Keri L. Walker -S (Affiliate)
Program Analyst, Division of Compliance Oversight
OLAW, National Institutes of Health

cc: IACUC Contact
POC

**Cummings School of Veterinary Medicine at Tufts University (Grafton Campus)
D16-00572 (A4059-01)**

Animal Welfare Assurance for Domestic Institutions

I, *Heather Cosier*, as named Institutional Official for animal care and use at the Cummings School of Veterinary Medicine at Tufts University, provide assurance that this Institution will comply with the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (Policy).

I. Applicability of Assurance

This Assurance applies whenever this Institution conducts the following activities: all research, research training, experimentation, biological testing, and related activities involving live vertebrate animals supported by the PHS, HHS, NSF and/or NASA. This Assurance covers only those facilities and components listed below.

- A. The following are branches and components over which this Institution has legal authority, included are those that operate under a different name:

Cummings School of Veterinary Medicine at Tufts University

- B. The following are other institution(s), or branches and components of another institution:

None

II. Institutional Commitment

- A. This Institution will comply with all applicable provisions of the [Animal Welfare Act](#) and other Federal statutes and regulations relating to animals.
- B. This Institution is guided by the "[U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training](#)."
- C. This Institution acknowledges and accepts responsibility for the care and use of animals involved in activities covered by this Assurance. As partial fulfillment of this responsibility, this Institution will ensure that all individuals involved in the care and use of laboratory animals understand their individual and collective responsibilities for compliance with this Assurance, and other applicable laws and regulations pertaining to animal care and use.
- D. This Institution has established and will maintain a program for activities involving animals according to the *Guide for the Care and Use of Laboratory Animals* ([Guide](#)).
- E. This Institution agrees to ensure that all performance sites engaged in activities involving live vertebrate animals under consortium (subaward) or subcontract agreements have an Animal Welfare Assurance and that the activities have Institutional Animal Care and Use Committee (IACUC) approval.

III. Institutional Program for Animal Care and Use

- A. The lines of authority and responsibility for administering the program and ensuring compliance with the PHS Policy are as follows:

The organizational chart is attached in Appendix 1. The Institutional Official is Heather Cosier, Associate Vice Provost for Research Compliance. The Attending Veterinarian is David Lee-Parritz, DVM, DAACLAM. He has overall responsibility for all aspects of animal care and use. The organizational structure for management of the animal care and use program is designed to provide a direct line of communication between the Attending Veterinarian, the Senior Research Technician, and the Supervisor of Animal Care.

B. The qualifications, authority, and percent of time contributed by the veterinarian(s) who will participate in the program are as follows:

1) Name: Dr. David Lee-Parritz

Qualifications

- Degrees: DVM, DAACLAM
- Training or experience in laboratory animal medicine or in the use of the species at the institution: Dr. Lee-Parritz received the DVM degree in 1983 from Tufts University School of Veterinary Medicine. From 1984-1987, he received postdoctoral training as a Resident, Small Animal Internal Medicine and a Fellow, Department of Geographic Medicine at Tufts University School of Veterinary Medicine. He became a Diplomate of the American College of Laboratory Animal Medicine (ACLAM) in 1995. Dr. Lee-Parritz was named the Director of LAMS in October 2013. Previously, he was Animal Research Senior Director, Department of Comparative Medicine at Genzyme Corporation; Associate Director, Operations at the Center for Animal Resources and Comparative Medicine at Harvard Medical School; Chief, Unit of Primate Medicine and Chairman, Division of Primate Resources at the New England Regional Primate Research Center, Harvard Medical School and in private practice. Dr. Lee-Parritz has more than 30 years of full-time experience in laboratory animal medicine in association with these previous activities. He attends local, regional, national and international meetings relevant to laboratory animal medicine and clinical veterinary medicine.

Authority:

Dr. Lee-Parritz has direct program authority and responsibility for the Institution's animal care and use program including access to all animals.

Time contributed to program: Full time employee 100%



(b) (6)

C. The IACUC at this Institution is properly appointed according to PHS Policy IV.A.3.a. and is qualified through the experience and expertise of its members to oversee the Institution's animal care and use program and facilities. The IACUC consists of at least 5 members, and its membership meets the composition requirements of PHS Policy IV.A.3.b. Attached is a list of the chairperson and members of the IACUC and their names, degrees, profession, titles or specialties, and institutional affiliations.

D. The IACUC will:

- 1) Review at least once every 6 months the Institution's program for humane care and use of animals, using the *Guide* as a basis for evaluation. The IACUC procedures for conducting semiannual program reviews are as follows:

The IACUC reviews components of the program for humane care and use of animals at IACUC meetings during each 6 month cycle using the semiannual program review checklists provided by the Office of Laboratory Animal Welfare (OLAW). The program review documents are discussed as a new business item during a convened meeting. These checklists are used as a basis for discussion for each program component and how it is addressed at the Cummings School. Any deviations found in the animal care and use program from the recommendations of the *Guide* or the Animal Welfare Act Regulations are classified as either significant or minor, and schedules for their resolution are proposed. If significant, the Institutional Official is notified immediately. Minority views are solicited from Committee members. Deficiencies are monitored until correction/completion at subsequent IACUC meetings. All components of the program for humane care and use of animals are reviewed within each 6 month time period and included in the semi-annual report submitted to the Institutional Officials.

- 2) Inspect at least once every 6 months all of the Institution's animal facilities, including satellite facilities and animal surgical sites, using the *Guide* as a basis for evaluation. The IACUC procedures for conducting semiannual facility inspections are as follows:

The IACUC performs on-site evaluations of the institution's animal facilities, satellite facilities, and all other animal use areas using the inspection checklists provided by OLAW. The IACUC performs inspections at scheduled times during each 6 month cycle. All Committee members are encouraged to participate. Any deviations from the recommendations of the *Guide* or the Animal Welfare Act Regulations are given a schedule for resolution and reported on the Inspection Report. Deficiencies are voted as either significant or minor and minority views are solicited from Committee members. All deficiencies remain on the Inspection Report that is reviewed at IACUC meetings until resolved. All Semiannual IACUC inspections are completed within each 6 month time period and any deficiencies are noted on the Semiannual Report to the Institutional Officials.

- 3) Prepare reports of the IACUC evaluations according to PHS Policy IV.B.3. and submit the reports to the Institutional Official. The IACUC procedures for developing reports and submitting them to the Institutional Official are as follows:

The IACUC summarizes the evaluation of the program for humane care and use of animals and inspection of all facilities using the OLAW Program Evaluation checklists. If any deficiencies are found, they are described, identified as either minor or significant, and a reasonable and specific plan and schedule for correction of each deficiency is detailed. In any cases of significant deficiencies, the Institutional Official is alerted immediately. The report states whether the program and facilities are consistent and compliant with the *PHS Policy*, the *Guide*, and applicable Animal Welfare Regulations. Departures from the *Guide* are listed in a specific section of the protocol and must be approved by a fully convened IACUC. IACUC-approved departures and the reason for each departure are/is included in the report to the IO. Any minority views provided by the members during the semiannual period are also included in the report to the IO. Finally, the reports are signed by a majority of the IACUC members and submitted to the Institutional Official.

- 4) Review concerns involving the care and use of animals at the Institution. The IACUC procedures for reviewing concerns are as follows:

The IACUC maintains a "Whistleblower Policy" that includes procedures for individuals to use in reporting concerns to the IACUC and for the IACUC to use in evaluating those concerns and providing protection against reprisal as required by the Animal Welfare Act. These concerns are reported to the Institutional Official and also to OLAW, if voted significant. The "Whistleblower Policy" (see below) is posted in the animal facilities, available to all investigative staff on the institutional website, and included as part of the mandatory training taken by all investigators. Any reported issues will be investigated and addressed immediately, and solutions will be determined on a case-by-case basis by the IACUC. This is done by a preliminary investigation, typically in the form of a subcommittee, and presentation of the findings to the IACUC at a convened meeting with a quorum present. The IACUC discusses the findings, takes a vote on the appropriate category of non-compliance, if necessary, and determines the appropriate course of action in consultation with the Institutional Official. The IACUC's decisions and actions are reported in the minutes of its meetings.

**IACUC Policy on Reporting Deficiencies in Animal Care or Treatment
"Whistleblower Policy"**

Background

The Laboratory Animal Welfare Act is a public law administered by the U.S. Department of Agriculture that includes standards for the care and use of animals in research, testing, and teaching. The Act requires research facilities to ensure that all scientists, research technicians, animal technicians, and other personnel involved in animal care, treatment, and use are qualified to perform their duties. The training provided by the research facility must also include information on the methods personnel may use to report deficiencies in animal care or use at the institution.

Citation

“Training and instruction of personnel must include guidance in ...methods whereby deficiencies in animal care and treatment are reported, including deficiencies in animal care and treatment reported by any employee of the facility. No facility employee, Committee member, or laboratory personnel shall be discriminated against or be subject to any reprisal for reporting violations of any regulation of standards under the Act.”

Animal Welfare Act. 7 U.S.C. 2131 et seq.
Section 2.32 Personnel qualifications

Whistleblower Policy

In accordance with the regulation cited above, the person(s) reporting the violation are protected by the Institutions from reprisal. The following methods may be used to report any deficiency in animal care or treatment:

1. Call, write, e-mail, or speak to the IACUC Chair (b) (6), IACUC/IBC Regulatory Director (b) (6) (b) (6), any member of the IACUC and its staff, or the Institutional Officials (b) (6). Reported issues will be addressed immediately and appropriate solutions will be determined on a case-by-case basis.
2. If you would like to remain anonymous, you may leave a message on the University's 24-hour hotline (b) (6) (b) (6) specifically designated for reporting research misconduct. It is managed by the Office of the Vice Provost for Research. Alternatively, concerns can be registered through [EthicsPoint](#) through their website or by calling (b) (6). Indicate “Tufts University” as the organization. Anonymous reports will be handled in the same fashion as other reports, although the outcome of the IACUC’s investigation may not be reported directly to the complainant.

The minutes of the IACUC meetings will reflect that the concern was investigated and detail whether non-compliance was found.

- 5) Make written recommendations to the Institutional Official regarding any aspect of the Institution's animal program, facilities, or personnel training. The procedures for making recommendations to the Institutional Official are as follows:

In most cases, the IO would be present at a convened meeting to discuss aspects of the animal care and use program and would be asked to report back to the Committee at a subsequent meeting, if any follow up was required. These discussions would be captured in the meeting minutes. Additionally, the IACUC can make written recommendations to the IO in the Semiannual Report.

- 6) Review and approve, require modifications in (to secure approval), or withhold approval of PHS-supported activities related to the care and use of animals according to PHS Policy

The investigator must submit an Animal Care and Use Protocol form to the IACUC office. Protocols are assigned a protocol number and IACUC staff work with the investigator through a pre-review process to develop a well-written and fully detailed protocol that complies with all regulatory and institutional expectations for the animal experiments and care. Each IACUC member receives all meeting materials, including copies of all protocols and protocol amendments that require Full Committee review and ongoing protocol issues approximately one week before the meeting. At the IACUC meeting, these proposed activities are reviewed for conformance with the Federal Animal Welfare Act, the *Guide*, and institutional regulations. Each protocol is discussed and the IACUC votes to determine if the protocol can be “approved”, or if there are modifications that require a “non-substantive” re-review, a “substantive” re-review, or if the protocol is “disapproved”. The result of the IACUC vote is provided to the Principal Investigator in writing, along with the list of modifications required for the protocols that received non-substantive or substantive re-review votes.

Non-substantive modifications are reviewed by a subcommittee of at least 2 IACUC members upon receipt of the response by the principal investigator. This subcommittee is appointed as Designated Reviewers by the Chair or by a Vice Chair when the Chair is absent. The approval to use this process is made unanimously by a quorum of the Full Committee. The IACUC members have voted and signed the "IACUC Policy on Review Procedures and Voting Categories" authorizing Designated Member Review to be used subsequent to a Full Committee vote of "Non-Substantive Issues". If all required modifications are made, the subcommittee can approve the protocol. Otherwise, the principal investigator is again provided, in writing, required modifications that must be made before approval can be granted. The designated member(s) cannot disapprove a protocol.

Substantive modifications are resubmitted to the Full Committee for review and are either approved or further modifications are required and provided to the principal investigator in writing, as described above.

Some protocols have the opportunity to go through Expedited Review. For this method, the protocol is provided to the Committee members for a specific duration of time to allow an adequate review. Each member then has the opportunity to call for Full Committee Review if they feel it is necessary. If any member calls for a Full Committee Review, then approval of the protocol may only be granted after review at a convened meeting of the IACUC and with the approval vote of a majority of the quorum present. If Full Committee Review is not requested, at least 2 members of the IACUC and a veterinarian designated by the Chair or Vice Chair and qualified to conduct the review shall review the protocol or amendment and will have the authority to approve, require modifications to secure approval, or request Full Committee Review. The designated member(s) cannot disapprove a protocol.

Animal work cannot be initiated until the protocol is approved by the IACUC. Final protocol and amendment documentation is maintained by the IACUC Office.

The IACUC meets regularly to conduct protocol review and other regular business. Additional meetings may be held upon the request of the Chair. A quorum consisting of >50% of the voting members is required to conduct official IACUC business. Efforts are made to ensure as many IACUC members as possible are able to attend meetings. No member of the IACUC may participate in the review or approval of a research project in which the member has a conflict of interest except to provide information to the IACUC. This member is recused from the vote and it is recorded in the meeting minutes. If a member has a minority view, they are asked to submit a minority report. The minority report is submitted in the semi-annual report to the Institutional Official and in the annual report submitted to OLAW.

IACUC Policy on Review Procedures and Voting Categories

The Institutional Animal Care and Use Committee (IACUC) must conduct a review of the components related to the care and use of animals and determine if they are in accordance with Public Health Service (PHS) Policy, the Animal Welfare Act/Regulations, and other local, state, and federal laws or regulations relating to animals.

Policy

There are two valid methods of IACUC review (1) Full Committee Review (FCR) by a convened quorum of the members of the IACUC, or (2) Expedited Review (ER) by a subcommittee of the IACUC. ER is employed only after all voting members have been provided an opportunity to call for Full Committee Review.

Full Committee Review

Documents submitted for Full Committee Review are distributed to the members well enough in advance of the meeting to allow for an adequate review. Full Committee Review must occur during a convened meeting with a quorum of the IACUC members present. No member may participate in the IACUC review or approval if they have a conflict of interest, except to provide information requested by the IACUC; nor may a member who has a conflicting interest contribute to the

constitution of a quorum. Abstentions from voting (for reasons *other* than conflict of interest) do not alter the quorum and do not change the number of votes required for approval.

FCR requires a majority vote of the quorum present to approve, require modifications to secure approval, or withhold approval. These specific categories are explained below. If additional modifications are requested, the list is agreed upon by the Full Committee and a vote for either substantive or non-substantive is taken to determine the next review designation.

- If non-substantive modifications are required to secure approval, a revision can be submitted for Designated Member Review (DMR) as described below.
- If substantive modifications are required, the revision must be submitted back to Full Committee Review.

Expedited Review

Documents submitted for Expedited Review are sent electronically to all members for a specific duration that enables enough time to perform an adequate review. The members are instructed to review the submissions and are given a deadline by which to respond. Members may vote for either a Full Committee Review (FCR) or Designated Member Review (DMR). Calls for FCR are kept as part of the review documentation.

- If anyone calls for Full Committee Review during this timeframe, the document must then be submitted to a convened IACUC meeting for FCR, as described above.
- If no member calls for FCR, the submission continues to DMR as described below.

Designated Member Review

A subcommittee of the IACUC is designated by the Chair or Vice-Chair (in the Chair's absence) to act as the Designated Member Reviewers (DMR's) either after Full Committee Review or after receiving no vote for FCR through the Expedited Review process.

- For use of DMR after a Full Committee Review, the Designated Member subcommittee is made up of at least **two** IACUC members. Additional members may be selected, if deemed appropriate.
- For use of DMR after Expedited Review, the Designated Member subcommittee is made up of at least **two** IACUC members, one of which must be a veterinarian. Again, additional members may be selected if deemed appropriate.

The Designated Member Reviewers (DMR's) must be unanimous in any decision. They must all review identical versions of the submission. If modifications are requested by any one of the reviewers, the other reviewers must be aware of and agree to the modifications. DMRs have the authority to approve, require modifications to secure approval, or request Full Committee Review. If a Designated Member calls for a Full Committee Review, then approval may be granted only after review at a convened meeting of a quorum of the IACUC and with the approval vote of a majority of the quorum present. The Designated Member(s) cannot disapprove a submission.

Notification of the Investigators

Regardless of the method of review, the IACUC will notify investigators and the institution in writing of its decision to approve or withhold approval of those activities related to the care and use of animals, or of any modifications required to secure IACUC approval. If the IACUC decides to withhold approval of an activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond.

Voting Categories

- APPROVAL – no additional changes are required, and approval can be granted.
- DISAPPROVAL – the research cannot be conducted at this time.
- MODIFICATIONS TO SECURE APPROVAL:
 - NON-SUBSTANTIVE ISSUES– non-substantive modifications are required to secure approval. The revision is submitted to Designated Member Review*. If all required modifications are made, the subcommittee can approve or require additional modifications to secure approval by selecting either Designated Member or Full Committee Review of the required modifications. The designated reviewers cannot disapprove.

SUBSTANTIVE ISSUES- If a protocol requires substantive modifications, the revised protocol or amendment must be submitted back to a Full Committee Review. The revision can either be approved or the committee can require further modifications to secure approval by selecting either Designated Member* or Full Committee Review of the required modifications.

*Signature page included on the original

- 7) Review and approve, require modifications in (to secure approval), or withhold approval of proposed significant changes regarding the use of animals in ongoing activities according to PHS Policy IV.C. The IACUC procedures for reviewing proposed significant changes in ongoing research projects are as follows:

The principal investigator completes a protocol amendment form and submits it to the IACUC. If the amendment contains significant changes regarding the use of animals in ongoing activities, procedures follow the "IACUC Policy on Review Procedures and Voting Categories" (as above) and the amendment is reviewed by one of the valid methods of IACUC review (Full Committee Review or Designated Member Review). The amendment is voted upon in the same manner as a full protocol. Documents submitted for Expedited Review are sent electronically to all members for a specific duration that enables enough time to perform an adequate review. The members are instructed to review the submissions and are given a deadline by which to respond. Members may vote for either a Full Committee Review (FCR) or Designated Member Review (DMR). If anyone calls for Full Committee Review during this timeframe, the document must then be submitted to a convened IACUC meeting for FCR, as described above. If no member calls for FCR, the submission continues to DMR.

The following are considered Significant Changes:

- from non-survival to survival surgery;
- resulting in greater pain, distress, or degree of invasiveness;
- in housing and/or use of animals in a location that is not part of the animal program overseen by the IACUC;
- in species;
- in study objectives;
- in Principal Investigator (PI);
- that impact personnel safety;
- increase in animals > 50% the number originally approved

The **Policy on Review of Amendments to Approved Protocols** states:

The IACUC may administratively handle the following, less substantial, changes that do not fall under the above categories:

1. Increase in animals \leq 50% the number approved in the original protocol, given:
 - The original rationale for the number of animals supports the requested increase.
 - Additional animal numbers will be added via the Amendment Form and the PI will be notified that the increase has been added to the approved protocol.
 - If the conditions are not met or are ambiguous, IACUC staff have the authority to refer the amendment to the IACUC for FCR or DMR.

- 8) Notify investigators and the Institution in writing of its decision to approve or withhold approval of those activities related to the care and use of animals, or of modifications required to secure IACUC approval according to PHS Policy IV.C.4. The IACUC procedures to notify investigators and the Institution of its decisions regarding protocol review are as follows:

The IACUC notifies the investigator and the institution in writing with the outcome of the review. This includes approval of the protocol or amendment or if modifications are required before a revision of the document can be resubmitted for review. These communications are sent to the Principal Investigator and are authorized by the IACUC Chair or a Vice-Chair in the absence of the Chair. All modifications to the protocols/amendments must be documented in writing prior to approval. The IACUC deliberations for category of vote and the required revisions (if any) are included in the Minutes for each meeting. The Subsequent Actions Report provides a listing of the protocols and amendments that were re-reviewed subsequent to the IACUC meeting and that were reviewed by Expedited Review/Designated Member Review between IACUC meetings. This list also includes the approval date for all protocols/amendments. These requirements are the same for all protocols that require modifications regardless of the type of re-review required (FCR or DMR). All review documents are kept in the final protocol file. The Institutional Official is notified of IACUC decisions through the text of the Minutes and the Subsequent Actions Report. If protocol approval is withheld, the investigator has the opportunity to respond in person or in writing.

- 9) Conduct continuing review of each previously approved, ongoing activity covered by PHS Policy at appropriate intervals as determined by the IACUC, including a complete review at least once every 3 years according to PHS Policy IV.C.1.-5. The IACUC procedures for conducting continuing reviews are as follows:

The IACUC mandates annual renewal of all protocols. The Principal Investigator must confirm to the IACUC that no changes have been made since the most recent review and if he/she wishes to keep the protocol active or if the protocol is to be terminated. Any changes in the protocol would be reviewed as described above in #7. In addition, a complete review of each protocol is required every 3 years by a new (de novo submission) protocol by the principal investigator. This review is performed the same as for new protocol submissions, as described above in #6. Thus, all protocols are reviewed de novo at least once every three years. See "IACUC Policy and Procedures for Continuing Review of Animal Research Protocols" below.

IACUC Policy for Continuing Review of Animal Protocols

Regulations

Public Health Service (PHS) Policy/National Institutes of Health (NIH)

In accordance with PHS Policy at IV.C.5, protocol approvals cannot be granted for more than 3 years. The Office of Laboratory Animal Welfare (OLAW) views this as a serious violation of the PHS Policy and this would be reportable to OLAW under the [prompt reporting requirement](#).

Animal Welfare Act (AWA)/United States Department of Agriculture (USDA)

In accordance with AWA regulations at 9 CFR 2.31(a), continuing review must be performed not less than annually.

Institutional Policy

Protocols are approved for a three year period. During the protocol's lifespan, the IACUC conducts continuing review of all active protocols annually for the first two years and then a complete *de novo* review on the third year.

Annual Renewals

The IACUC requires that all protocols be renewed during the first and second year of the protocol's lifespan for all species in order to remain active. If the Annual Renewal form is not completed by the submission deadline, the IACUC may terminate the protocol.

Three-Year *De Novo* Review

In compliance with PHS Policy, the IACUC requires that all protocols are re-submitted as new protocols every 3 years. This review is referred to as a "*de novo*" review because the protocol receives the same scrutiny by the Committee as if it were a brand-new submission.

A notification is sent by the IACUC Office well in advance of the expiration date to the Principal Investigator (PI) stating that the approved protocol is subject to the *de novo* review. If the PI intends on renewing the protocol, the new protocol should be submitted early enough to avoid delays that could lead to a lapse in approval.

Terminations/Expirations of Protocols

If the PI is allowing the protocol to expire or is terminating the project before its expiration date, the IACUC Office must obtain written confirmation from the PI that no work will continue and no animals will be housed under the protocol. If the PI is allowing the protocol to expire, the PI must confirm that all work under the protocol will cease **prior** to the expiration date. Any animals currently on the protocol may be transferred onto another active protocol using an [Animal Protocol Transfer Form](#).

IACUC monitors ongoing activities (post-approval monitoring) using a multi-disciplinary team approach for continuing IACUC oversight of animal activities. Ongoing monitoring of animal care and use includes program oversight, through program evaluations, congruency reviews, review of protocols, and ensuring individuals who work with animals are appropriately trained by observation of LAMS staff and the AV; and also, during laboratory inspections and protocol preparation. Trained animal care personnel and veterinary technicians perform daily observation of animals, assist researchers with animal procedures, and provide post-operative care to the animals in our facility. Any irregularities may be reported to the IACUC through the AV. During the IACUC inspections, animal procedures, anesthetics, analgesics, applicable IACUC policies, etc. are discussed with the lab members and compared to the IACUC protocols. Laboratory equipment is examined, and proper use and upkeep may be discussed. Animal records are also reviewed. IACUC staff review with PI's and/or lab members applicable IACUC policies, regulations, etc. during the preparation of the protocols/amendments to serve as a training opportunity and to aid in compliance. During continuing protocol review/annual renewal, the PI updates the IACUC on any adverse or unexpected experimental outcomes. Any concerns are reported to the IACUC for review/discussion at an IACUC meeting.

- 10) Be authorized to suspend an activity involving animals according to PHS Policy IV.C.6. The IACUC procedures for suspending an ongoing activity are as follows:

The Institutional Official, in consultation with the IACUC, reviews the activity and reason for suspension at a convened meeting of a quorum of the IACUC. If the Institutional Official is not present at the IACUC meeting during the suspension vote, he/she would be provided the reasoning prior to the Principal Investigator being notified. The IO needs to be involved in the notification of the suspension to the PI as well as in determining the correction of the issue. A vote for suspension must be made at a convened meeting of a quorum of the members and by majority of that quorum present. After suspension of an activity, the Principal Investigator is informed, in writing, of the IACUC vote, the details of the suspension, and the requirements that must be met in order to request an IACUC re-review. If there is a vote for suspension, the Institutional Official provides OLAW with a full explanation.

- E. The risk-based occupational health and safety program for personnel working in laboratory animal facilities and personnel who have frequent contact with animals is as follows:

The occupational health and safety program for personnel who work in laboratory animal facilities or have any contact with animals is provided by the Occupational & Environmental Health Network (OEHN) (b) (6) oversees the program and serves as an advisor to the occupational health program for persons with animal contact. All personnel who work with animals in research must participate in the occupational health program. The program includes a tetanus vaccine or prophylaxis (unless an informed decision to decline immunizations is made), health exams, other medical procedures based on risk assessment, education, and use of protective gear. This plan is based on the *Guide for the Care and Use of Laboratory Animals* and the ILAR Occupational Health Guidelines. Completion of the OHS assessment is required of all personnel listed on a protocol, all personnel with regular animal contact, or personnel entering the facilities, regardless of the level of their interaction with animals. Exceptions may be made for visitors (inspectors, visitors, etc.) that need to enter the animal facilities on a case by case basis, in which case they are escorted by LAMS or IACUC Staff. All individuals with animal contact must participate in the Occupational Health and Safety program, which requires yearly evaluation and clearance.

Personnel are trained to promptly report all suspected work-related injuries and illness to their supervisor and the LAMS supervisor. They are informed if they are bitten or scratched by an animals, have been cut or scratched by an instrument or piece of equipment that has been exposed to an animal or its bodily fluids, to follow the basic first aid precautions immediately. This includes scrubbing the wound with antiseptic soap and flushing the injured area with water. They are then guided to contact the Occupational Health and Safety Office, describe the incident, and follow their instructions regarding treatment. The emergency contact numbers are placed throughout the laboratories and animal facilities. Additionally, the direct line for the Tufts Police is posted and they are trained first responders. All medical emergencies can be directed to the University of Massachusetts Medical Center. In addition, employees are educated during the IACUC's Mandatory Animal Care and Use training about what to do in the event of bites, scratches or injury as well being provided education on an annual basis via the annual Occupational Health and Safety Clearance requirement.

Animal care personnel, veterinary, and laboratory staff are provided all the necessary equipment and work clothing. Disposable gloves and isolation gowns or personalized laboratory coats are available outside animal housing rooms and must be donned before entrance. Tyvek jumpsuits, face shields, or safety goggles, and fit-tested respirators are also available for the veterinary or animal care staff when needed. A commercial laundering service is used that exchanges used with clean laboratory coats once per week.

Sinks are located at several sites within the animal facilities, in the cage wash areas, and in most procedure rooms. Sinks are equipped with anti-bacterial soap and disposable towels. Personnel are required to wash hands and change protective gear between animal holding rooms and/or procedure room of different health status.

All personnel are trained in the proper way of handling animals and follow specific procedural techniques when working with the animals. They are also made aware of safe conduct within the facilities through personal instruction and posted signs. Topics covered include: protective clothing requirements, use of hazardous agents, sharps disposal. Other methods used to reduce physical injury are: provision of wheeled carts for material handling, placement of sharps containers in all sites where sharps may be used.

Eating and drinking are only allowed in designated areas, all of which are outside of the animal facilities. Smoking is prohibited in all areas of the university, except designated outside areas.

All scientific and LAMS personnel receive training in biosafety, chemical hygiene, and hazard communication. Animal studies that involve the use of hazardous substances must be reviewed and approved by the appropriate institutional safety committee(s). An Institutional Biosafety Committee (IBC) reviews and approves projects involving infectious agents, recombinant DNA,

biological toxins and select agents. The Chemical Hygiene Officer reviews and approves work performed with chemical hazards. Exposure control plans are in place. All scientific and LAMS personnel receive training in biosafety, chemical hygiene, and hazard communication. Animal studies that involve the use of hazardous substances must be reviewed and approved by the appropriate institutional safety committee(s).

Risk assessment and hazard identification is an ongoing process that involves the Environmental Health and Safety (EHS). EHS identifies potential hazards in the work environment and conducts assessment of the associated risks. Individuals with relevant education, training and experience assess workplace risks and hazards and implement safeguards for potential hazards such as chemical cleaning agents, wet floors, ladder use, etc.

Specific training in the areas of zoonoses, allergies, precautions taken during pregnancy, illness or immune suppression is addressed during the animal user's Occupational Health and Safety Clearance requirement, which is updated annually. Anyone that is planning to work with live animals must complete an Animal Use Assessment Form and submit it directly to the Occupational Health and Safety (OHS) office prior to animal use and facility entrance. The user is required to answer specific questions regarding his/her medical history and current issues on the form, so that a risk assessment can be performed by the nurse on a case-by-case basis. Additional follow up may be required depending upon the risks identified on this form. Clearance by the OHS nurse is required prior to working with live animals.

- F. The total gross number of square feet in each animal facility (including each satellite facility), the species of animals housed there and the average daily inventory of animals, by species, in each facility is provided in the attached Facility and Species Inventory table. (see Section X)
- G. The training or instruction available to scientists, animal technicians, and other personnel involved in animal care, treatment, or use is as follows:

Training is mandated to all people who have contact with live animals or are responsible for animal protocols, including scientists, laboratory staff, animal technicians, and other personnel involved in animal care, treatment, or use. The mandatory training covers Federal, State, and Institutional regulations and/or policies that govern research animal use, including methods that minimize the number of animals required to obtain valid results and limit animal pain and distress, proper veterinary care and monitoring, requirements for husbandry, biological and chemical hazards use, occupational health and safety, and personnel training with species and techniques. The list below describes in further detail the kind of training required per category of personnel involved in the animal program. See "*IACUC Policy on Mandatory IACUC Training*" below.

1. All personnel: All personnel including scientists, animal technicians, research staff listed on an approved protocol, members and staff of the IACUC, and all other personnel involved in animal care, treatment, or use must complete an IACUC Mandatory Animal Care and Use Training at least once every 3 years. The training sessions are administered by the IACUC via an online format and each participant must obtain an 80% score on a quiz to be considered trained. If the quiz cannot be passed, an individual training session with an IACUC staff member is organized. Access to the animal facilities is provided only if the individual has successfully completed this training. Failure to complete this training requirement results in the loss of access to the animal facilities and removal from the protocol.
2. LAMS staff: The department currently has five full time laboratory animal technicians, one research technician and a working supervisor who provides husbandry and technical support. All of the animal care staff have appropriate pre-employment experience in animal care and husbandry or have received appropriate on-site specialized training and have from 3 to 33 years of experience working with rodents and small research animals. Staff meetings for all LAMS employees are held on a routine basis. IACUC policies and animal care guidelines are introduced and regularly reviewed at staff meetings. As appropriate, Institutional safety officers are invited to present safety seminars to the

- LAMS staff during these meetings. On-the-job training includes working with experienced animal care technicians and attending other relevant in-house training courses (e.g., chemical safety, blood borne pathogens). All animal care staff have received and utilizes instruction regarding minimizing the number of animals required to obtain valid results and training has emphasized the limitation of pain and distress to animals used in research. All LAMS staff complete the IACUC Mandatory Animal Care and Use Training at least once every 3 years. Continuing education includes attending local NEBAALAS meetings; local meetings and webinars by groups such as the Massachusetts Society of Medical Research (MSMR) and National Association for Biomedical Research (NABR); and lecture-based training sessions that includes training in laboratory animal care, humane treatment and facility maintenance. The animal technicians are strongly encouraged to attend AALAS certification-training sessions held by the New England Branch of AALAS. All technicians are members of local and National AALAS branches with one technician preparing for ALAT, two certified at ALAT level, three at LAT and one LATG level.
3. IACUC members: New IACUC members are given an individual orientation when they are appointed to the IACUC. Our institution has an IACUC website where Federal regulations, their accompanying websites (USDA/APHIS and OLAW), and IACUC policies are provided. During orientation, the new member is provided their own copies or links to relevant documents, which may include: Animal Welfare Act, PHS Policy, the *Guide for the Care and Use of Laboratory Animals*, the most recent PHS Assurance document, information about AAALAC and relevant parts of the AAALAC Program Description, Institutional IACUC policies, and animal care and use guidelines. For ongoing training of the IACUC members, informational items (new OLAW notices, etc.) are sent via email and/or included for discussion in the IACUC meeting agenda. Topics such as research or testing methods that minimize the number of animals required to obtain valid results as well as the minimization of distress are include in these emails and as meeting agenda items. Additionally, IACUC members also receive regular informational emails from biomedical research groups, such as National Association for Biomedical Research (NABR) and Massachusetts Society of Medical Research (MSMR), the IACUC column from Lab Animal, standards or policies from agencies or other institutions, information on new animal models, and relevant information on animal care and use.
 4. Scientific and technical staff: The interaction of the veterinary and regulatory staff with investigators through the IACUC protocol review process is an important means of detecting the need for additional training germane to particular projects. Hands-on training in animal handling and procedures for staff members is offered routinely. Videotape and reference book libraries are maintained in the LAMS office. New lab technicians are encouraged to view these materials as prelude to animal studies. Training in many rodent and large animal experimental, medical and surgical procedures is provided. Criteria essential to an acceptable protocol application include demonstration that the minimum number of animals will be used to obtain valid results, use of appropriate anesthetic and analgesic agents, procedural refinements to eliminate or reduce animal pain and distress, adequate post-procedural animal monitoring and care, and rational expectations in selecting the animal model. The veterinarian(s) and veterinary technician, also provide hands-on training in animal handling and procedures for staff members. The Cummings School is fortunate to have many faculty members in the Clinical Sciences, the Biomedical Sciences and the Infectious Disease and Global Health departments who have extensive experience in highly technical rodent and large animal experimentation. These scientists have provided assistance to others when needed. Our institution is fortunate to have a relatively low turnover among Principal Investigators and many of whom are also veterinarians that are actively involved in animal care and use.
 5. Personnel that perform rodent survival surgery: The IACUC mandates an additional training for all personnel who perform survival rodent surgeries (see "*IACUC Policy for Mandatory Rodent Surgical Training*" below). All personnel listed on animal care and use protocols that perform survival surgery and PI's of protocols that include survival surgery must complete an online training followed by a quiz in order to attain approval to perform surgery. Identification of personnel that plan on performing survival surgery is required. Hands-on training in surgery is offered by the veterinary staff upon request.

Policy on Requirements for Personnel Working with IACUC-Covered Animals

I. Purpose of Policy

Regulatory agencies, accrediting bodies, and funding entities have requirements for personnel who use or are exposed to animals in research, teaching, and/or training. Each institution is charged with devising programs that address these requirements through the Institutional Animal Care and Use Committee (IACUC). The purpose of this policy is as follows:

- 1) List the requirements that personnel must complete to work on IACUC protocols.
- 2) Provide authority to determine exceptions or modifications to these requirements, as necessary.
- 3) Summarize how compliance will be ensured.

II. IACUC Clearance for Personnel

At Tufts University/Tufts Medical Center, all training and health requirements must be complete before an individual may work with animals or be a Principal Investigator (PI) on an IACUC-covered activity. When the necessary requirements for each person are complete, the IACUC office will notify the individual and PI in writing.

There are many different types of animal use and levels of risk; therefore, it is necessary to ensure that these requirements are completed, standardized, and documented. This policy provides general parameters for each requirement, and acceptable alternative methods and criteria to allow exemptions. The IACUC office is charged with interpreting this policy for each person and will keep documentation regarding IACUC Clearance.

No work with animals may occur prior to IACUC Clearance.

III. Personnel Requirements

Below are the requirements to obtain IACUC Clearance (see above). Our institutions provide forms and presentations that can be used to complete the requirements. Access to the forms, trainings, and further guidance is provided on the [IACUC Personnel Page](#).

1. Request to add Personnel to an Animal Protocol (Supplement P)
2. IACUC Training(s)
 - a. Mandatory Animal Care and Use Training
 - b. Rodent Survival Surgery Training, *as applicable*
3. Occupational Health and Safety (OHS) Authorization

1. Personnel Added onto an Animal Protocol

To work with live animals each person must be added to each active IACUC protocol on which he or she will work. All listed personnel must review and understand the approved IACUC protocol/amendments. The Principal Investigator is responsible for ensuring that all protocol personnel are familiar with the study and are adequately trained (see [IACUC Policy on Definition and Responsibilities of an IACUC Principal Investigator](#)). Personnel additions on a protocol are handled administratively via [Supplement P](#) and do not need to be reviewed by the IACUC.¹

Exemptions

By way of this policy, the IACUC exempts the following groups from being listed as protocol personnel. However, training and occupational health and safety requirements must still be met.

- Veterinary and husbandry staff of the Laboratory Animal Medicine Service (LAMS), the Farm, Foster Hospital for Small Animals (FHSA), Hospital for Large Animals (HLA), Tufts Comparative Medicine Services (Tufts CMS), and Comparative Biology Unit (CBU) performing routine clinical duties.
- Students in a classroom or veterinary clinical setting involved in training activities with animals, who are monitored by the Principal Investigator or designee. Designated instructors may NOT be student instructors.

- Clients on studies that are overseen by a Tufts CMS or LAMS veterinary staff member as the Principal Investigator, conducted only in the Tufts CMS/LAMS/CBU facilities, FHSA, or HLA **and** are always supervised by Tufts CMS/LAMS/CBU staff.

2. IACUC Trainings

Mandatory Animal Care and Use (MACU) Training - the Institution provides an online Mandatory Animal Care and Use presentation and quiz. This module provides training on how to comply with animal regulations, institutional policies, and the guidelines and procedures within Tufts CMS/LAMS/CBU. All personnel listed on an animal protocol, including Principal Investigators, must complete this basic training at least once every three years.

Rodent Survival Surgery (RSS) Training - all personnel who will participate in rodent survival surgery must complete this training prior to performance of surgery and renew at least once every three years. Principal Investigators of protocols that include rodent survival surgery must also complete and renew this training even if they do not perform the surgery(ies).

Alternatives/Exemptions

The IACUC understands that alternative training may be better suited to a project (or person's) situation. In these cases, there may be other forms of training that are acceptable to the IACUC. These situations can be justified and determined as compliant with this policy by the IACUC office with IACUC Chair/Vice-Chair consultation, if necessary.

3. Occupational Health and Safety (OHS) Authorization

The OHS authorization is a required risk management assessment that is used to establish a high level of safety for all individuals who 1) work with animals in research, teaching/training, 2) are involved in the care and use of research/teaching animals, and/or 3) may have significant exposure to animal housing areas. The purpose of the form is to identify relevant individual health concerns which may affect a person's ability to safely conduct the proposed activity.

To allow accurate assessment of individual risk, each person must submit a confidential form directly to the OHS service provider for their campus. Once the medical professional has completed the review of the form, the IACUC office will receive a date of medical authorization for that person to be exposed to animals. This authorization must be updated on an annual basis.

Alternatives/Exemptions

The IACUC understands that there may be alternative ways to achieve OHS training, risk assessment, and medical treatment that are better suited to a project or person's situation. These situations can be justified and determined as compliant with this policy by the IACUC office with IACUC Chair/Vice-Chair consultation, if necessary.

IV. Failure to Complete or Renew Personnel Requirements

A database of all completion dates per individual is managed by the IACUC office. Personnel will be assisted with reminders, but it is the Principal Investigator's responsibility to ensure that his/her personnel have completed and renew all IACUC personnel requirements.

If an individual fails to complete or renew any personnel requirement it may become an issue of non-compliance for the Principal Investigator. Please refer to the [IACUC Policy on Protocol Non-Compliance and/or Animal Mistreatment](#) for how the IACUC handles non-compliance.

References

¹Office of Laboratory Animal Welfare (2017). "Significant Changes to Animal Activities" [Online]. Available: https://grants.nih.gov/grants/olaw/significant_changes.htm

United States Department of Agriculture. (2017). *Animal Welfare Act and Animal Welfare Regulations*. Retrieved from https://www.aphis.usda.gov/animal_welfare/downloads/AC_BlueBook_AWA_FINAL_2017_508comp.pdf

Policy for Conducting Survival Surgical Procedures in Rodents

Background

Institutional and Federal guidelines and regulations require all rodent survival surgical procedures to be performed utilizing aseptic technique. The IACUC considers a survival surgical procedure to be one in which the animal awakes from the anesthetic, even if for a short period of time. Note: This does not include [murine tail biopsies](#).

Policy

The IACUC must approve any changes in the surgical technique via an amendment PRIOR to implementing the change. Protocol personnel performing rodent survival surgery must adhere to the following:

Training

- Prior to conducting any rodent survival surgery, all personnel must complete the Rodent Survival Surgery (RSS) Training as per the [IACUC Policy on Requirements for Personnel Working with IACUC-Covered Animals](#).
- Additional supervised hands-on training is strongly recommended to assure the surgeon has mastered good surgical technique including asepsis, thermoregulation, gentle tissue handling, minimal dissection of tissue, appropriate use of instruments, effective hemostasis, post-operative monitoring, administration of analgesics, and correct use of suture materials and patterns.

Pre-Surgical Preparation

- Although specialized surgical facilities are not required for rodent surgery, a clean, dedicated space that provides separation from other activities is required.
- The surgical area must be cleaned with disinfectant prior to and after all surgical procedures.
- The surgeon and assistant(s) must wear sterile surgical gloves, a surgical mask, and either a clean lab coat (for work performed in an investigator laboratory only), scrub top, or disposable gown. A hair bonnet is strongly recommended to further reduce surgical site contamination.
- The animal must be prepared appropriately for surgery, which includes:
 - Provision of eye lubricant
 - Removal of the fur/hair
 - Disinfectant/ethanol wipe of the skin (3x for each scrub). Alcohol alone is not acceptable for surgical skin preparation.
 - Administration of analgesic as outlined in the IACUC approved protocol. This is usually done prior to making the incision.

Surgery:

- All surgical instruments must be sterilized before each procedure and in between animals.
- Animals must be provided with supplemental heat while under anesthesia and during recovery.
- Animals must be monitored continuously while under anesthesia.
- Incisions must be closed with appropriate suture material or clips.
 - Silk sutures and braided sutures are not permitted when closing a skin incision.

Post-Operative Care:

- Animals must be monitored and provided with supplemental heat at least until they have regained sternal recumbency.
- Nutritional and hydration support should be given as required/needed.
- Analgesics must be administered as approved in the IACUC protocol/amendment.
- A Rodent Surgery Report card must be completed and placed on all cages housing post-surgical rodents. Cards may be customized with Tufts CMS/LAMS/CBU Veterinarian approval. See the IACUC

[Policy on Maintaining Proper Animal Health Records of Research Animals](#) for more information on requirements.

- Non-absorbable suture or wound clips **must be removed 7-14 days** postoperatively as appropriate after healing has occurred.

IV. Institutional Program Evaluation and Accreditation

All of this Institution's programs and facilities (including satellite facilities) for activities involving animals have been evaluated by the IACUC within the past 6 months and will be reevaluated by the IACUC at least once every 6 months according to PHS Policy IV.B.1.-2. Reports have been and will continue to be prepared according to PHS Policy IV.B.3. All IACUC semiannual reports will include a description of the nature and extent of this Institution's adherence to the PHS Policy and the *Guide*. Any departures from the *Guide* will be identified specifically and reasons for each departure will be stated. Reports will distinguish significant deficiencies from minor deficiencies. Where program or facility deficiencies are noted, reports will contain a reasonable and specific plan and schedule for correcting each deficiency. Semiannual reports of the IACUC's evaluations will be submitted to the Institutional Official. Semiannual reports of IACUC evaluations will be maintained by this Institution and made available to the OLAW upon request.

This Institution is Category 1 — accredited by the [Association for Assessment and Accreditation of Laboratory Animal Care International \(AAALAC\)](#). As noted above, reports of the IACUC's semiannual evaluations (program reviews and facility inspections) will be made available upon request.

V. Recordkeeping Requirements

- A. This Institution will maintain for at least 3 years:
 1. A copy of this Assurance and any modifications made to it, as approved by the PHS
 2. Minutes of IACUC meetings, including records of attendance, activities of the committee, and committee deliberations
 3. Records of applications, proposals, and proposed significant changes in the care and use of animals and whether IACUC approval was granted or withheld
 4. Records of semiannual IACUC reports and recommendations (including minority views) as forwarded to the Institutional Official, Heather Cosier, JD, Associate Vice Provost for Research Compliance.
 5. Records of accrediting body determinations
- B. This Institution will maintain records that relate directly to applications, proposals, and proposed changes in ongoing activities reviewed and approved by the IACUC for the duration of the activity and for an additional 3 years after completion of the activity.
- C. All records shall be accessible for inspection and copying by authorized OLAW or other PHS representatives at reasonable times and in a reasonable manner.

VI. Reporting Requirements

- A. The institutional reporting period is the federal fiscal year (October 1 – September 30). The IACUC, through the Institutional Official, will submit an annual report to OLAW after September 30, but on or before December 1 of each year. The annual report will include:
 1. Any change in the accreditation status of the Institution (e.g., if the Institution obtains accreditation by AAALAC or AAALAC accreditation is revoked)
 2. Any change in the description of the Institution's program for animal care and use as described in this Assurance

3. Any change in the IACUC membership
 4. Notification of the dates that the IACUC conducted its semiannual evaluations of the Institution's program and facilities (including satellite facilities) and submitted the evaluations to the Institutional Official, Heather Cosier, JD, Associate Vice Provost for Research Compliance.
 5. Any minority views filed by members of the IACUC
- B. The IACUC, through the Institutional Official, will promptly provide OLAW with a full explanation of the circumstances and actions taken with respect to:
1. Any serious or continuing noncompliance with the PHS Policy
 2. Any serious deviations from the provisions of the *Guide*
 3. Any suspension of an activity by the IACUC
- C. Reports filed under VI.A. and VI.B. above should include any minority views filed by members of the IACUC.

VII. Institutional Endorsement and PHS Approval

A. Authorized Institutional Official	
Name: Heather Cosier, JD,	
Title: Associate Vice Provost for Research Compliance.	
Name of Institution: The Cummings School of Veterinary Medicine, Tufts University	
Address: <i>(street, city, state, country, postal code)</i> Office of the Vice Provost for Research Tufts University 136 Harrison Ave Boston, MA 02111	
Phone: (b) (6)	Fax: (b) (6)
E-mail: heather.cosier@tufts.edu	
Acting officially in an authorized capacity on behalf of this Institution and with an understanding of the Institution's responsibilities under this Assurance, I assure the humane care and use of animals as specified above.	
Signature: (b) (6)	Date: 02-03-2021

B. PHS Approving Official <i>(to be completed by OLAW)</i>	
<p>Doreen H. Bartlett, BS, AA, RVT, LATG Senior Assurance Officer, Division of Assurances Office of Laboratory Animal Welfare (OLAW) National Institutes of Health 6700B Rockledge Drive Suite 2500 MSC 6910 Bethesda, MD 20892 bartletd@od.nih.gov 301-496-7163</p>	
Signature: Doreen H. Bartlett -S <small>Digitally signed by Doreen H. Bartlett -S Date: 2021.02.03 10:39:38 -05'00'</small>	Date: February 3, 2021
Assurance Number: D16-00572 (A4059-01)	
Effective Date: February 1, 2021	Expiration Date: January 31, 2025

VIII. Membership of the IACUC

Date: November 1, 2020			
Name of Institution: The Cummings School of Veterinary Medicine, Tufts University			
Assurance Number: D16-00572 (A4059-01)			
IACUC Chairperson			
Name*: Dr. Phil Hinds			
Title*: Professor and Chair, Department of Developmental, Molecular and Chemical Biology, Tufts University School of Medicine; Associate Director, Molecular Oncology Research Institute; Professor, Radiation Oncology, Tufts Medical Center; Deputy Director, Tufts Cancer Center			Degree/Credentials*: PhD
Address*: (street, city, state, zip code) 136 Harrison Ave. OVPR/IACUC Boston, MA 02111			
E-mail*: phil.hinds@tufts.edu			
Phone*: (b) (6)		Fax*: (b) (6)	
IACUC Roster			
Name of Member/ Code**	Degree/ Credentials	Position Title***	PHS Policy Membership Requirements****
(b) (6)			Scientist
			Vice Chair, Veterinarian
			Veterinarian
			Nonaffiliated/ Nonscientist
			Scientist

(b) (6)			
			Vice Chair, Scientist
			Scientist
			Scientist
			Scientist
			Scientist
David Lee-Parritz	DVM, DACLAM	Director, Laboratory Animal Medicine Service, and Clinical Professor & Chair, Environmental & Population Health, Cummings School of Veterinary Medicine at Tufts University	Veterinarian
(b) (6)			Veterinarian
			Scientist
			Scientist

(b) (6)	
	Scientist
	Nonaffiliated/ Nonscientist
	Scientist
	Vice Chair, Scientist
	Scientist
	Alternate for Scott Perkins or Michael Esmail (Veterinarian)
Alternate for Scott Perkins & Michael Esmail (Veterinarian)	

* 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.]

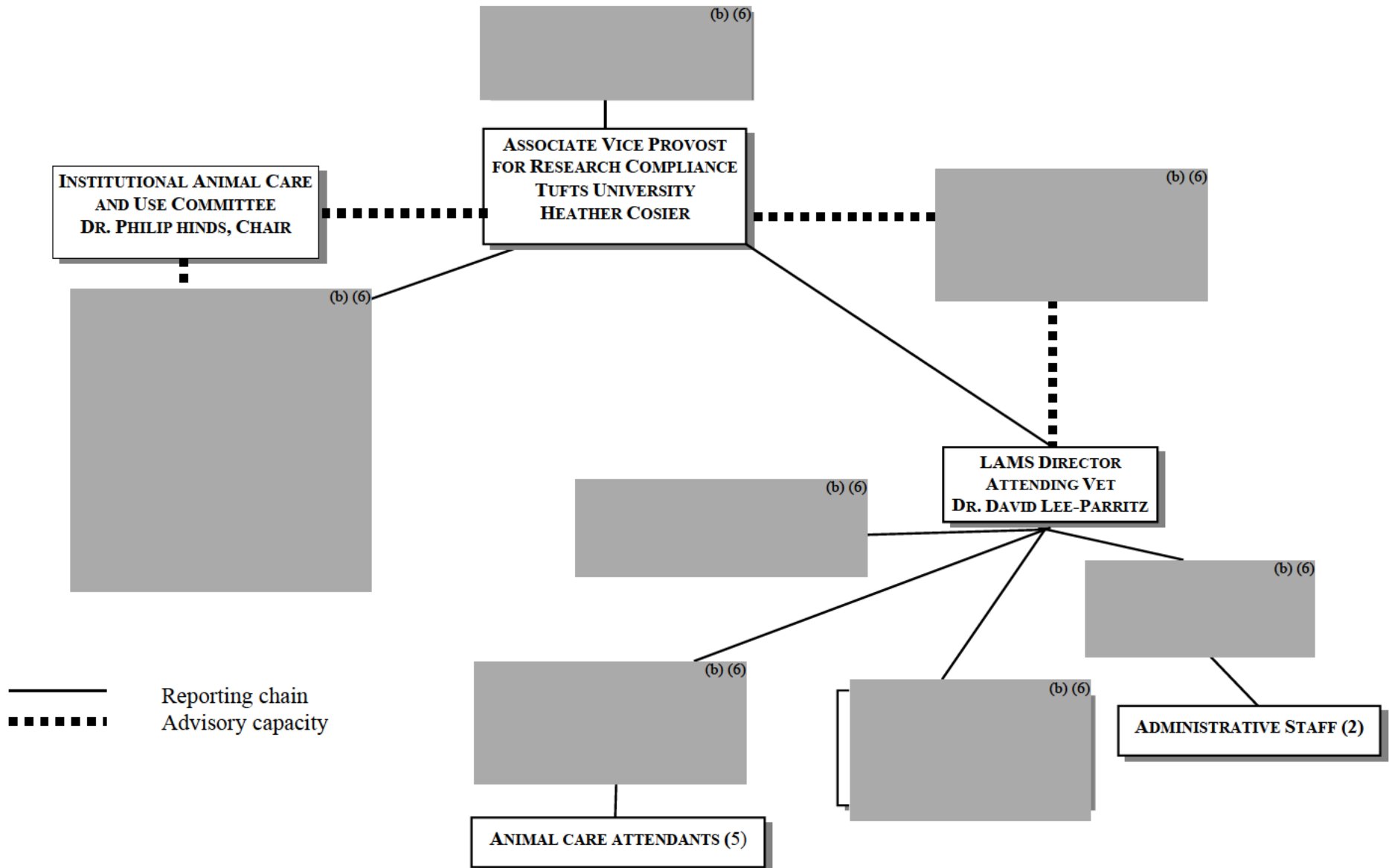
(b) (6)

X. Facility and Species Inventory

Date: November, 2020			
Name of Institution: The Cummings School of Veterinary Medicine, Tufts University			
Assurance Number: D16-00572 (A4059-01)			
Laboratory, Unit, or Building*	Gross Square Feet [include service areas]	Species Housed [<i>use common names, e.g., mouse, rat, rhesus, baboon, zebrafish, African clawed frog</i>]	Approximate Average Daily Inventory
(b) (4)	8570	Swine	436
	4286	Chickens Horses	100 6
	4833	Goats	0
	4887	Cattle	27
	2540 -	Sheep	43
	2898	Chickens	100
	7656	Swine Alpaca	2 2
	6875	Dogs	20
	5930	Mice Rats Hamster	940 300 6
	7000	Mice Hamster	21 40
	8570	Swine	436

*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.

**TUFTS UNIVERSITY CUMMINGS SCHOOL OF VETERINARY MEDICINE
LABORATORY ANIMAL MEDICINE SERVICE (LAMS)**





DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:

Office of Laboratory Animal Welfare
Division of Assurances
6705 Rockledge Drive
RKL 1, Suite 360, MSC 7982
Bethesda, Maryland 20892-7982
Home Page: <http://grants.nih.gov/grants/olaw/olaw.htm>

FOR EXPRESS MAIL:

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

March 08, 2017

Re: Assurance Approval for **D16-00572**
(A4059-01)

Simin Meydani, MS, DVM, PhD
Vice Provost for Research, Tufts University
Cummings School of Veterinary Medicine at Tufts University
136 Harrison Avenue
Medford, MA 02111

Dear Dr. Meydani,

I am pleased to inform you that the Office of Laboratory Animal Welfare (OLAW) reviewed and approved your institution's Animal Welfare Assurance (Assurance) that was submitted in accordance with the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (Policy), revised 2015.

Your Assurance, identification number **D16-00572 (A4059-01)**, became effective on **February 28, 2017** and will expire on **January 31, 2021**. Please include the Assurance number on all correspondence to OLAW. A copy of the signed Assurance document is enclosed. The signature page provides verification of approval by OLAW and specifies the period during which your institution's Assurance is effective.

The Assurance is a key document in defining the relationship of your Institution with the PHS. It sets forth the responsibilities and procedures of your Institution regarding the care and use of laboratory animals. Among the important elements of the Assurance, I would especially call your attention to the reporting requirements that are essential for continued compliance with the PHS Policy. Please note that an Annual Report to OLAW is required at least once every 12 months. Annual Reports for the previous calendar year are due by January 31st.

If I may be of any further assistance, please do not hesitate to contact me.

Sincerely,

 Expired certificate

 Doreen H. Bartlett

Signed by: Doreen H. Bartlett -S

Senior Assurance Officer
Office of Laboratory Animal Welfare

Encl: As stated

cc: IACUC Chair
IACUC/IBC Regulatory Director
IACUC Coordinator



FOR US POSTAL SERVICE DELIVERY:
Office of Laboratory Animal Welfare
Division of Assurances
6700B Rockledge Drive
Suite 2500, MSC 6910
Bethesda, Maryland 20892-6910
Home Page: <https://olaw.nih.gov>

FOR EXPRESS MAIL:
Office of Laboratory Animal Welfare
Division of Assurances
6700B Rockledge Drive, Suite 2500
Bethesda, Maryland 20817
Telephone: (301) 496-7163

February 3, 2021

Re: Assurance Approval for D16-00572 (A4059-01)

Heather Cosier, JD
Associate Vice Provost for Research Compliance
Tufts University - Cummings School of Veterinary Medicine
136 Harrison Avenue
Medford, MA 02111

Dear Ms. Cosier:

I am pleased to inform you that the Office of Laboratory Animal Welfare (OLAW) reviewed and approved your institution's Animal Welfare Assurance (Assurance) that was submitted in accordance with the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (Policy), revised 2015.

Your Assurance, identification number **D16-00572 (A4059-01)**, became effective on **February 1, 2021** and will expire on **January 31, 2025**. Please include the Assurance number on all correspondence to OLAW. You will receive a copy of the signed Assurance document by email. The signature page provides verification of approval by OLAW and specifies the period during which your institution's Assurance is effective.

The Assurance is a key document that sets forth the responsibilities and procedures of your Institution regarding the care and use of laboratory animals according to the PHS Policy. The practices described in the Assurance document must be followed by all individuals in the animal care and use program.

If I may be of any further assistance, please do not hesitate to contact me.

Sincerely,

 Expired certificate

 Doreen H. Bartlett

Signed by: Doreen H. Bartlett -S
Doreen H. Bartlett, BS, AA, RVT, LATG
Senior Assurance Officer, Division of Assurances, OLAW
National Institutes of Health

cc: IACUC Contact(s)



Office of the Vice Provost for Research
Institutional Animal Care and Use Committee

Division of Assurances
Office of Laboratory Animal Welfare
National Institutes of Health
6700B Rockledge Drive, Suite 2500
Bethesda, MD 20892-6910
Phone: 301-496-7163
E-mail: olawdoa@mail.nih.gov
Fax: 301-451-5672

Re: Changes to be reported to the Office of Laboratory Animal Welfare (OLAW) for Tufts University & Tufts Medical Center

To Whom It May Concern,

Please find a list of changes to be reported to OLAW effective **April 1, 2021**.

These changes apply to the following Assurances:

- Tufts University-Tufts Medical Center, Boston: D16-00459 (A3775-01)
- Tufts University, Medford campus: D16-00073 (A3115-01)
- Cummings School of Veterinary Medicine at Tufts University: D16-00572 (A4059-01)

Sincerely,

 (b) (6)



Changes to be reported to OLAW for Tufts

PHS Assurance #D16-00459 (A3775-01)
PHS Assurance #D16-00073 (A3115-01)
PHS Assurance #D16-00572 (A4059-01)

1. A new IACUC Chair to be appointed as of April 1, 2021

Name: Gillian Beamer, VMD, PhD, DACVP
Title: Assistant Professor, Department of Infectious Disease and Global Health
Office: Tufts University
Phone: (b) (6)
Fax: (b) (6)
Email Address: gillian.beamer@tufts.edu

2. IACUC roster as of April 1, 2021

Chair

Gillian Beamer, VMD, PhD, DACVP *Assistant Professor, Department of Infectious Disease and Global Health, Cummings School of Veterinary Medicine at Tufts University*



(b) (6)

David Lee-Parritz, DVM, DAACLAM *Director, Laboratory Animal Medicine Service, and Clinical Professor & Chair, Environmental & Population Health, Attending Veterinarian at Cummings School of Veterinary Medicine at Tufts University*

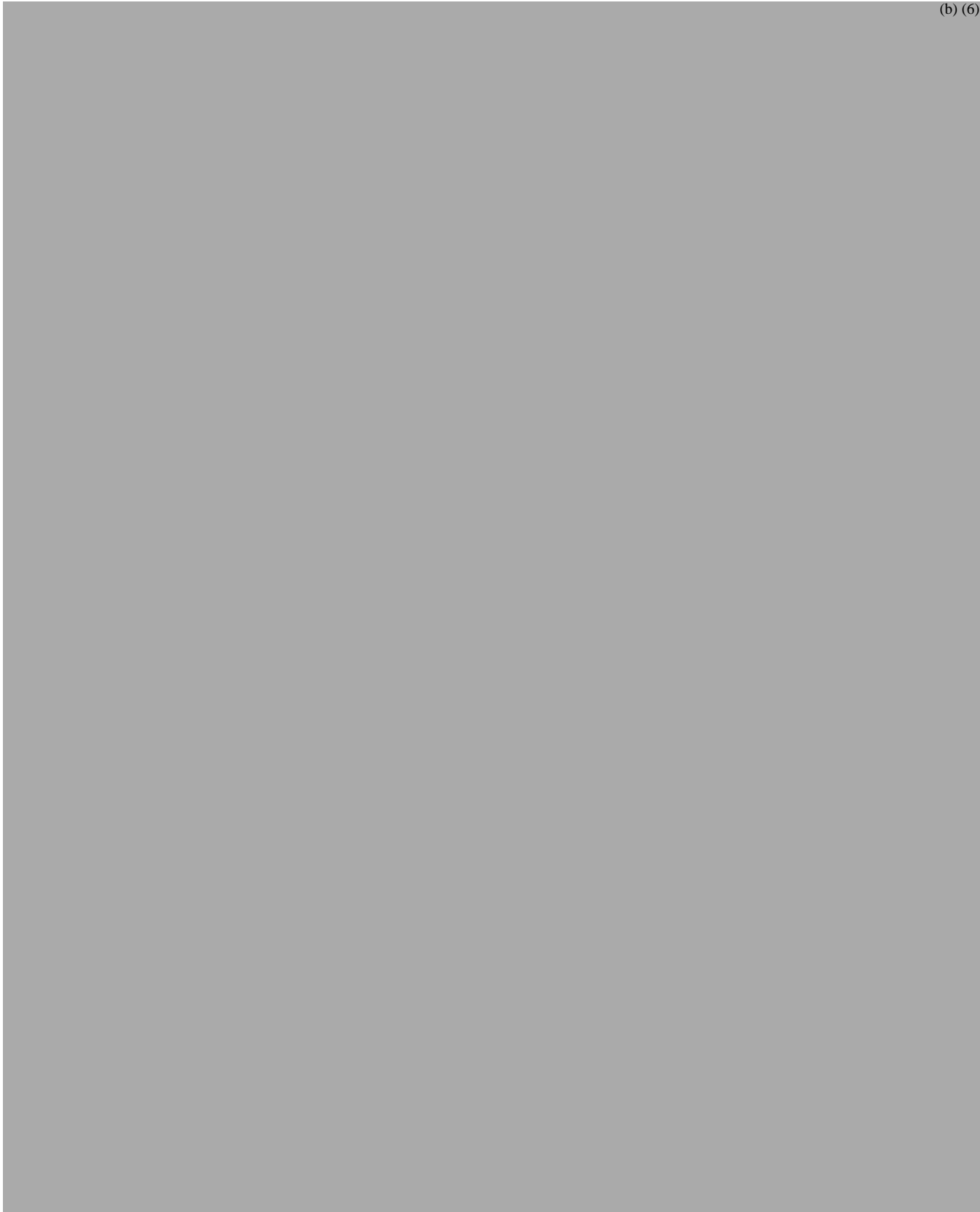
Scott E. Perkins, VMD, MPH, DAACLAM *Senior Director, Tufts Comparative Medicine Services, Attending Veterinarian at Tufts University-Tufts Medical Center, Clinical Professor, Environmental & Population Health*



(b) (6)



Office of the Vice Provost for Research
Institutional Animal Care and Use Committee



(b) (6)



October 25, 2021

Re: Tufts Institutional Official (IO) change to be reported to OLAW

To Whom It May Concern:

As of October 25, 2021, **Philip Hinds, PhD, Senior Director of Research Compliance**, replaces (b) (6) as the Institutional Official for:

- Tufts University Health Sciences, Boston: PHS Assurance #D16-00459 (A3775-01)
- Tufts University, Medford Campus: PHS Assurance #D16-00073 (A3115-01)
- The Cummings School at Tufts University, Grafton PHS Assurance #D16-00572 (A4059-01)

New IO: Philip Hinds, PhD
Address: Tufts University School of Medicine
136 Harrison Avenue
Boston MA 02111
Phone: (b) (6)
Fax: (b) (6)
Email: phil.hinds@tufts.edu

Sincerely,

(b) (6)

Gillian Beamer, VMD, PhD, DACVP
Chair of the Institutional Animal Care and Use Committee



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:

Office of Laboratory Animal Welfare
Division of Assurances
6700B Rockledge Drive
Suite 2500, MSC 6910
Bethesda, Maryland 20892-6910

FOR EXPRESS MAIL:

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

December 28, 2020

RE: Assurance Renewal #D16-00572 (A4059-01)

Heather Cosier, JD
Associate Vice Provost for Research Compliance
Tufts University
136 Harrison Avenue
Boston, MA 02111

Dear Ms. Cozier,

Thank you for your Assurance renewal application document. The Office of Laboratory Animal Welfare has completed an initial review. **Please include all responses in the Animal Welfare Assurance document and resubmit the updated version electronically in a Word document with updates highlighted or in a different color font for efficiency of review.**

- I.
 - Please update the Applicability section of the Assurance to include this statement:
This Assurance applies whenever this Institution conducts the following activities: all research, research training, experimentation, biological testing, and related activities involving live vertebrate animals supported by the PHS, HHS, NSF and/or NASA. This Assurance covers only those facilities and components listed below.
- III.B.
 - Clarify in your revised response that any back up veterinarian providing clinical care would have access to all animals.
- III.D.7.
 - Briefly describe what is considered a significant change at your institution. For guidance, please refer to FAQ D9 at the URL <https://olaw.nih.gov/guidance/faqs#D>
 - The Assurance indicates that "If the amendment contains significant changes regarding the use of animals in ongoing activities, procedures follow the "IACUC Policy on Review Procedures and Voting Categories" (as above) and the amendment is reviewed by one of the valid methods of IACUC review (Full Committee Review or *Expedited Review*)." According to the PHS Policy, there are only two valid methods of IACUC review: (1) full committee review by a convened quorum of the members of the IACUC, or (2) *designated member review* by one or more members, employed only after all voting members have been provided an opportunity to call for full-committee review. Please clarify that the method described in your institution's Assurance renewal is intended to be *designated member review (DMR)*. For guidance, please see OLAW FAQ D3 at URL <https://olaw.nih.gov/guidance/faqs#D>
- III.D.8.
 - If a protocol approval is withheld, does the investigator have an opportunity to respond in person or in writing as required by PHS Policy IV.C.4.? Please clarify this in your revised response.

III.D.9.

- Please describe how the IACUC monitors ongoing activities (postapproval monitoring). For guidance, please refer to OLAW FAQ G6 at <https://olaw.nih.gov/guidance/faqs#G>.

III.E.

- The Assurance document discusses the assessment of risk based on the approved protocols, associated research, and the assessment of risk on a case-by-case basis for each animal user. Risk assessment and hazard identification are also *ongoing* processes involving qualified individuals. Please briefly describe in your revised response how the program, based on risk assessment and hazard identification, is a critical *ongoing* assessment that includes both the protocol related risks as well as the risks posed by the research animals and other potential hazards (e.g. animal bites, exposure to allergens, chemical cleaning agents, wet floors, ladder use, etc.). For guidance, please refer to the *Guide for the Care and Use of Laboratory Animals*, 8th edition (*Guide*), pages 18-19.
- Briefly describe in your revised response how other personnel such as maintenance, police and safety, security, housekeeping, summer students or visiting faculty are included in the program.
- Also, please describe the program for reporting injuries.

III.G.

- Clarify if the IACUC members are also provided training or instruction on research or testing methods that minimize the number of animals required to obtain valid results as well as the minimization of distress.

VI.A.

- The reporting period for the Annual Report to OLAW for the year 2020 will harmonize with the USDA reporting period which is October 1 through September 30. Therefore, the Annual Report to OLAW for the federal fiscal year 2020, will cover the period January 1, 2020 to September 30, 2020 (a partial year) and will be due to OLAW on or before December 1, 2020. In subsequent years, the Annual Report will cover the period October 1 to September 30 due to OLAW on or before December 1. Please replace the current section with the following:
“The institutional reporting period is the federal fiscal year (October 1 – September 30). The IACUC, through the Institutional Official, will submit an annual report to OLAW after September 30, but on or before December 1 of each year. The annual report will include:”
For guidance, please refer to the following URLs: <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-109.html>, and <https://olaw.nih.gov/resources/documents/annual-report.htm>

I look forward to hearing from you regarding the items listed above so that we can continue to process your Assurance renewal Document. If you believe it would be beneficial to discuss some of these matters before you revise your document, please feel free to contact me at 301-402-4325 or at bartletd@od.nih.gov at your convenience. **Please return your revised Assurance document (in Word format with updates highlighted or in a different color font) to me at bartletd@od.nih.gov within one month's time.** Thank you for your attention to these matters.

Sincerely,

 Expired certificate

 Doreen H. Bartlett

Signed by: Doreen H. Bartlett -S
Doreen H. Bartlett, BS, AA, RVT, LATG
Senior Assurance Officer
Division of Assurances, OLAW

cc: IACUC Contact(s)

Annual Report to OLAW

Institution: **Tufts University, Cummings School of Veterinary Medicine (Grafton)**

Assurance Number: **D16-00572 (A4059-01)**

Reporting Period: **January 1, 2017- December 31, 2017**

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.]

See Attachment

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.]

See Attachment

III. Minority Views [Select A or B]

- 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: Philip Hinds, PhD	Name: Heather Gipson-Cosier, JD, MA
Signature: (b) (6)	Signature: (b) (6)
Date: January 2, 2018	Date: 1-3-2018

V. Change in Institutional Official

Name: Heather Gipson-Cosier	
Title: Associate Vice Provost for Research Compliance	Degree/Credential: JD, MA
Name of Institution: Tufts University	
Address: 136 Harrison Avenue Boston, MA 02111	
E-mail: heather.gipson_cosier@tufts.edu	
Phone: (b) (6)	Fax: (b) (6)

VI. Change in IACUC Membership [Current roster]

Institution: The Cummings School of Veterinary Medicine, Tufts University			
IACUC Contact Information			
(b) (6)			
E-mail: (b) (6)			
Phone: (b) (6)		Fax: (b) (6)	
IACUC Chairperson			
Name: Dr. Philip Hinds			
Title: Professor and Chair, Department of Developmental, Molecular and Chemical Biology, Tufts University School of Medicine; Associate Director, Molecular Oncology Research Institute; Professor, Radiation Oncology, Tufts Medical Center; Deputy Director, Tufts Cancer Center			Degree/Credentials: Ph.D.
PHS Policy Membership Requirements***: Scientist			
IACUC Roster [Provide below or attach]			
Name of Member/ Code*	Degree/Credential	Position Title/ Occupational Background**	PHS Policy Membership Requirements***
(b) (6)			Scientist & Vice

			(b) (6) Chair
			Nonscientist & Nonaffiliated
			Nonscientist & Nonaffiliated
			Veterinarian
Dr. David Lee-Parritz	DVM, DACLAM	Director, Laboratory Animal Medicine Service, Clinical Professor & Chair, Environmental & Population Health, Cummings School of Veterinary Medicine at Tufts University, Attending Veterinarian at Cummings School of Veterinary Medicine at Tufts University	Veterinarian
			(b) (6) Veterinarian
			Vice Chair, Scientist
			Scientist
			Scientist
			Scientist
			Scientist
			Scientist
			Scientist
			Scientist
			Scientist

(b) (6)

Scientist

Scientist

Scientist

Alternate for (b) (6)
(b) (6)

Alternate for (b) (6)
(b) (6)

Alternate for (b) (6)
(b) (6)

Scientist

R

Semiannual Evaluations (Attachment #1)

January	February	March
<p style="text-align: center;">Program Review Review and finalize Semiannual Report to Institutional Official. Signed by Committee and sent to Institutional Officials January 4, 2017</p>	<p style="text-align: center;">Program Review Institutional Policies and Responsibilities (1-4) Animal Care and Use Program Disaster Planning and Emergency Preparedness IACUC IACUC Protocol Review Feb 1, 2017</p>	<p style="text-align: center;">Program Review Institutional Policies and Responsibilities (5-7) IACUC Membership and Function IACUC Training IACUC Records and Reporting Requirements Mar 1, 2017</p>
April	May	June
<p style="text-align: center;">Program Review Institutional Policies and Responsibilities (9-12) Personnel Qualifications and Training Occupational Health and Safety of Personnel Personnel Security Investigating & Reporting Animal Welfare Concerns April, 5, 2017</p>	<p style="text-align: center;">Facility Inspections May 16, 2017 Program Review Veterinary Care (1-6 & 8) Clinical Care and Management Animal Procurement and Transportation/ Preventive Medicine Surgery Pain, Distress, Anesthesia and Analgesia Euthanasia Drug Storage and Control May 3, 2017</p>	<p style="text-align: center;">Facility Inspections June 8, 12 & 14, 2017</p>
July	August	September
<p style="text-align: center;">Program Review Review and finalize Semiannual Report to Institutional Official. Signed by Committee and sent to Institutional Officials July 5, 2017</p>	<p style="text-align: center;">Program Review Institutional Policies and Responsibilities (1-4) Animal Care and Use Program Disaster Planning and Emergency Preparedness IACUC IACUC Protocol Review Aug 2, 2017</p>	<p style="text-align: center;">Program Review Institutional Policies and Responsibilities (5-7) IACUC Membership and Function IACUC Training IACUC Records and Reporting Requirements Sept 6, 2017</p>
October	November	December
<p style="text-align: center;">Facility Inspection October 2 & 11, 2017 Program Review Institutional Policies and Responsibilities (9-12) Personnel Qualifications and Training Occupational Health and Safety of Personnel Personnel Security Investigating & Reporting Animal Welfare Concerns Oct 4, 2017</p>	<p style="text-align: center;">Facility Inspection November 2, 13 & 15, 2017 Program Review Veterinary Care (1-6 & 8) Clinical Care and Management Animal Procurement and Transportation/ Preventive Medicine Surgery Pain, Distress, Anesthesia and Analgesia Euthanasia Drug Storage and Control Nov 1, 2017</p>	<p style="text-align: center;">Facility Inspections December 20, 2017</p>



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:

Office of Laboratory Animal Welfare
Rockledge One, Suite 360
6705 Rockledge Drive B 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

February 25, 2019

Re: Animal Welfare Assurance
A4059-01 [OLAW Case O]

Ms. Heather Cosier
Associate Vice Provost for Research Compliance
Tufts University
136 Harrison Avenue
Boston, MA 02111

Dear Ms. Cosier

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your February 12, 2019 letter reporting a serious deviation from the provisions of the *Guide for the Care and Use of Laboratory Animals* at Tufts University- Cummings School of Veterinary Medicine. According to the information provided, OLAW understands animal care staff failed to conduct daily health checks for twelve days and five *Peromyscus* mice died.

The corrective actions consisted of retraining all animal caretakers on the appropriate conduct of daily health checks and changing the daily workflow to ensure all animals are checked.

Based on its assessment of this explanation, OLAW understands that measures have been implemented to prevent recurrence of this problem. OLAW concurs with the actions taken by the institution to comply with the PHS Policy on Humane Care and Use of Laboratory Animals.

Sincerely,

 (b) (6)

Axel Wolff, M.S., D.V.M.
Deputy Director
Office of Laboratory Animal Welfare

cc: IACUC Chair
Robert Gibbens, D.V.M., USDA-APHIS-AC

Institutional Animal Care and Use Committee

Tufts University & Tufts Medical Center

136 Harrison Avenue

Boston, Massachusetts 02111

Phone: (617) 636-6599 Fax: (617) 636-8354

Dr. Axel Wolff
Office of Laboratory Animal Welfare
National Institutes of Health RKL1,
Suite 360-MSC 7982
6705 Rockledge Drive
Bethesda, MD 20892-7982

February 12, 2019

Dear Dr. Wolff:

We are writing to notify OLAW of the circumstances and actions taken with respect to the following issue of non-compliance, as required by the PHS Policy on Humane Care and Use of Laboratory Animals (section IV.F.3) at The Cummings School of Veterinary Medicine at Tufts University (Grafton Campus) Assurance Number is D16-00572 (A4059-01). The following issue of non-compliance was discovered as having occurred in the centralized animal facilities. It was not protocol non-compliance.

Regular daily health checks were not performed by members of the Laboratory Animal Medicine Service (LAMS) animal care staff on one cage of animals, as required, for approximately 12 days. As a result, a LAMS animal care technician found one cage with 5 dead *Peromyscus*/deer mice. The remaining animals in the cage were active and alert and appear well.

The LAMS Director responded that the animal technicians involved acknowledged their responsibility and were deeply distressed and truly remorseful. The entire LAMS staff has been retrained on the required steps to conduct a daily health check and workflow changes have been implemented to avoid a repeat occurrence.

At an IACUC meeting, this issue was voted to be significant and therefore reportable to OLAW. This letter provides the summary of the issue and resolution to OLAW as voted by the IACUC. If you have any questions, please contact us. Thank you.

Sincerely,

(b) (6)

Heather J. Cosier, JD, MA
Associate Vice Provost for Research Compliance
Office of the Vice Provost for Research
Tufts University
75 Kneeland Street, (b) (4)
Boston, MA 02111
(b) (6)

Heather.cosier@tufts.edu

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Thursday, February 21, 2019 11:31 AM
To: (b) (6) OLAW Division of Compliance Oversight (NIH/OD)
Cc: Gipson-Cosier, Heather
Subject: RE: Report of a Noncompliance

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

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.

From: (b) (6)
Sent: Thursday, February 21, 2019 10:39 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Gipson-Cosier, Heather <Heather.Cosier@tufts.edu>; (b) (6)
Subject: Report of a Noncompliance

Hello,

Please find attached a report of a noncompliance that the IACUC voted as significant.

Thank you,
(b) (6)

(b) (6)





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) 402-7065

August 15, 2019

Re: Animal Welfare Assurance
A4059-01 [OLAW Case P]

Ms. Heather Cosier
Associate Vice Provost for Research Compliance
Tufts University
136 Harrison Avenue
Boston, MA 02111

Dear Ms. Cosier

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your August 14, 2019 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Cummings School of Veterinary Medicine at Tufts University. According to the information provided, OLAW understands that a moribund rat was directed to be euthanized by the Attending Veterinarian (AV) but the laboratory technician failed to do so. The next day the technician weighed the rat, found it to have reached the established humane endpoint weight loss criteria, and euthanized it. Changing the treatment plan in this fashion caused the rat to experience unnecessary pain and distress.

The preventive actions consisted of notifying the Principal Investigator who counseled the technician to always follow the AV's directives. The laboratory staff was retrained on following AV instructions and on euthanizing animals that have reached the humane endpoint as described in the protocol.

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 institution to comply with the PHS Policy.

Sincerely,

(b) (6)

Axel Wolff, M.S., D.V.M.
Deputy Director
Office of Laboratory Animal Welfare

cc: IACUC Chair

A4059-P



Office of the Vice Provost for Research
Institutional Animal Care and Use Committee

August 14, 2019

Dr. Axel Wolff
Office of Laboratory Animal Welfare (OLAW)
National Institutes of Health
6700B Rockledge Drive, Suite 2500, MSC 6910
Bethesda, MD 20892

Dear Dr. Wolff:

We are writing to notify OLAW of the circumstances and actions taken with respect to the following issue of non-compliance, as required by the PHS Policy on Humane Care and Use of Laboratory Animals (section IV.F.3). The Cummings School of Veterinary Medicine at Tufts University (Grafton Campus) Assurance number is D16-00572 (A4059-01).

According to the approved IACUC protocol, the veterinarian would be consulted to advise on animals that show gross signs of distress (e.g. decreased grooming, hunched posture) and animals that had lost >15% of their original body weight would be euthanized. The Attending Veterinarian (AV) examined a rat which was severely depressed, dyspneic and moribund. After a discussion with the lab technician, the AV directed the lab technician to euthanize the rat. Before the lab technician euthanize the animal, she re-evaluated the animal and it appeared somewhat brighter, therefore she did not follow through with euthanasia, as directed by the AV. The next day, the lab technician weighed the rat, then euthanized it because the humane endpoint of >15% body weight loss had been reached.

The Principal Investigator was sent a letter of non-compliance regarding this incident since the lab technician changed the treatment plan without the AV's advance approval. This action caused the rat to experience pain and distress beyond the humane endpoints approved in the protocol.

The PI responded to the IACUC with the following action plan in order to prevent a recurrence. The PI met privately with the lab technician involved to discuss the importance of following the AV's directives, so that the pain and distress experienced by the animals is limited to the euthanasia criteria approved in the IACUC protocol. Also, a training session was held at a lab meeting with all lab personnel that included the AV. It was made clear that any diversion from an approved treatment plan requires agreement from the AV. For future studies on their protocol, it is now clear to the lab personnel that animals must be euthanized when they reach the humane endpoint and any decisions regarding animal health are the purview of the AV.

Since the rat experienced pain and distress beyond the endpoints in the IACUC protocol, the IACUC voted the issue to be considered "significant" at a convened meeting. This letter provides a summary of the issue and resolution to OLAW as voted by the IACUC. Internal funds covered this animal work. No grant funding was used.

If you have any questions, please contact us. Thank you.

Sincerely,

(b) (6)

Heather Gipson-Cosier, JD
Associate Vice Provost for Research Compliance
Tufts University

Ward, Joan (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Wednesday, August 14, 2019 1:37 PM
To: (b) (6) OLAW Division of Compliance Oversight (NIH/OD)
Cc: Gipson-Cosier, Heather; (b) (6)
Subject: RE: Report of a Noncompliance

Thank you for this report (b) (6) Dr. Wolff will respond soon.

Regards,
Joan

From: (b) (6)
Sent: Wednesday, August 14, 2019 11:26 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Gipson-Cosier, Heather <Heather.Cosier@tufts.edu>; (b) (6)
Subject: Report of a Noncompliance

Hello,

Please find attached a report of noncompliance that the IACUC voted as significant.

Thank you,
(b) (6)