

## Annual Report to OLAW

Institution: Houston Methodist Research Institute
Assurance Number: A4555-01
Reporting Period: 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.](#)). *[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: April 26, 2019	Date 2: October 9, 2019
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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: March 28, 2019

Date 2: September 19, 2019

**III. Minority Views [Select A or B]**

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

**IV. Signatures**

IACUC Chairperson	Institutional Official
Name: David R. Baers	Name: Edward A Jones
Signature: 	Signature: 
Date: 20 Jan 20	Date:

**V. Change in Institutional Official**

Name:	
Title:	Degree/Credential:
Name of Institution:	
Address: [street, city, state, zip code]	
E-mail:	
Phone:	Fax:

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

<b>Institution: Houston Methodist Research Institute</b>			
<b>IACUC Contact Information</b>			
Address: [ <i>street, city, state, zip code</i> ] 7550 Greenbriar 4 <sup>th</sup> Floor, (b) (4) Houston, TX 77030			
E-mail: (b) (6)@houstonmethodist.org			
Phone: (b) (6)		Fax: (b) (6)	
<b>IACUC Chairperson</b>			
Name: David R. Beers			
Title: Associate Professor, Director, Neurology Transgenic Mouse Facility		Degree/Credentials: PhD	
PHS Policy Membership Requirements***: Scientist			
<b>IACUC Roster</b> [ <i>Provide below or attach</i> ]			
Name of Member/ Code*	Degree/ Credential	Position Title/ Occupational Background**	PHS Policy Membership Requirements***
Tanya Herzog	DVM, DACLAM	Director Comparative Medicine Program	Attending Veterinarian
Mary Clancy	MSN, CCRC, CIP	Director, Office of Research Protection	Member
Tetsuo Ashizawa	MD	Physician – Director, Neuroscience Research Program	Scientist – Vice Chair
(b) (6)			Scientist
			Non-Affiliated/Non-Scientist
			Veterinarian
			Scientist
			Non Affiliated/Non-Scientist
			Member
			Scientist
			Scientist
			Scientist

	(b) (6)	Member
		Scientific
		Scientific
		Member Alternate for Clancy or (b) (6)
		Veterinarian Alternate for Herzog or (b) (6)

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

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

\*\*\* [PHS Policy](#) Membership Requirements:

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

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

Amendments to the approved animal use protocol (AUP) are reviewed using the following criteria:

## **I. GENERAL STATEMENT**

Approved protocols grant permission to conduct only those activities listed in the protocol, conducted in the manner described, by the individuals listed, with no more than the number of animals indicated in the protocol. Any changes in procedures, personnel, endpoints, care or use of additional animals require IACUC approval before the changes are implemented. Review of requests for protocol Amendments may result in approval of the Amendment, a request for more information or disapproval of the request. Approval of an amendment does not alter the expiration date of a protocol. This policy is in accordance with PHS Policy on Humane Care and Use of Laboratory Animals ([IV.C.1.](#)), Animal Welfare Regulations ([9CFR 2.31 \(d\) \(1\) \(i\)-\(iv\)](#)), and are consistent with the Guide for the Care and Use of Laboratory Animals 8th edition ([Guide](#)). This policy conforms to guidance provided by the NIH Office of Laboratory Animal Welfare in [NOT-OD-14-126](#).

## **II. DEFINITIONS**

A. Full Committee Review (FCR): FCR is the review of any animal use activity where the item is reviewed at a convened meeting where a quorum of IACUC members is present. The amendment is submitted by the PI or Study Team via MORTI. Office of Research Protection (ORP) will conduct a pre-review of the amendment addressing any changes needed. The amendment will be forwarded to the CMP Veterinarians for review and if needed, changes will be made. Once Veterinary review is complete, the amendment is assigned to a Primary and Secondary Reviewer and scheduled for the next meeting.

B. Designated Member Review (DMR): DMR is a process of review where the IACUC Chair assigns a designated member(s) to review the submitted change in approved activity. The amendment will be submitted by the PI or Study Team via MORTI. ORP will conduct a pre-review of the amendment addressing any changes needed. The amendment will be forwarded to the CMP Veterinarians for review and if needed, changes will be made. Once Veterinary review is complete, the amendment is assigned to two designated members for review. At the same time, all IACUC members are notified of the amendment and given 72 hours to call the amendment to FCR. The DMRs may request changes, approve, or call the amendment to FCR.

C. Veterinary Verification and Consultation (VVC): This is a process of review where the change in approved activity is reviewed and verified by a Comparative Medicine Program (CMP) Veterinarian at the time of the activity. Verified means that the veterinarian determines that based on his or her experience and training, the significant change is reasonable for a particular animal or group of animals in a particular situation and meets the parameters of the IACUC reviewed and approved policies.

These changes may be made in consultation with a CMP Veterinarian and the study team at any time. The change may be made immediately, the written verification of VVC handling must be provided to the IACUC office copied to the PI, Study Coordinator, and Primary Study Contact within two working days and the IACUC office has 5 working days to add the change to the protocol. When a VVC is received by ORP, the change will be made in the MORTI protocol form administratively and the VVC notice will be attached in the history of the protocol.

D. Administrative Review:

This is a process of review of non-significant changes. ORP reviews a requested change to an approved activity. The Administrator may approve, require modification in to secure approval, or request Veterinary and Designated Member Review.

## **III. PROCEDURE**

### **A. Changes to IACUC approved activities requiring FCR**

These changes will be reviewed via FCR. The Chair may authorize an exception to be reviewed via DMR.

Significant changes to be reviewed via FCR include but are not limited to changes:

1. from non-survival to survival surgery;
2. in species from a lower sentient species to a higher sentient species. Example: Rodent to Canine;
3. in prolonged (more than 10 minutes) physical restraint;
4. in multiple (more than 1) major survival surgeries;
5. to category E;
6. cervical dislocation without anesthesia; and
7. to death as an endpoint.

**B. Changes to IACUC approved activities requiring DMR**

These changes will be reviewed via DMR unless an IACUC member requests FCR.

Significant changes to be reviewed via DMR include but are not limited to changes:

1. resulting in greater pain, distress, or degree of invasiveness;
2. in housing and or use of animals in a location that is not part of the animal program overseen by the IACUC;
3. in study objectives;
4. in Principal Investigator (PI);
5. that impact personnel safety;
6. in food or water restriction;
7. in use of adjuvants;
8. in study objectives/goals; and
9. in species, change of equal or lower sentient species. Example: Swine to Canine.
10. to increase previously approved animal numbers requested

**C. Changes to IACUC approved activities utilizing VVC**

These changes may be made in consultation with a CMP Veterinarian and the study team at any time.

The VVC process may not be used to modify existing procedures if the modification increases the opportunity for the animals' welfare to be compromised or meets any of the other criteria listed in A or B above.

Significant changes to be approved via VVC include changes:

1. in type, dose, duration, or frequency of administration of anesthesia, analgesia, sedation, clinical agents, or antibiotics;
2. in dose, duration, frequency of administration, or addition of experimental substances as long as A and B above do not apply;
3. in euthanasia to any method approved in the [AVMA Guidelines for the Euthanasia of Animals](#) (PDF - 1.4 MB);
4. in duration, frequency, type, number of procedures performed on an animal, or addition of procedures as long as A and B above do not apply;
5. minor modifications in surgical techniques that leads to no increase in clinical consequences to the animal
6. in genotyping procedures including tail snips, toe clips, and ear punches;
7. in imaging procedure duration or frequency;
8. in duration of surgical procedures; and
9. in blood collection including route, frequency (time-points), and amount per the IACUC Blood Collection Policy.

An example where VVC may NOT be used:

The VVC cannot be used to add new procedures to a previously approved protocol. For example, if a researcher's protocol does not include blood collection and he/she wishes to add this procedure to the protocol, the VVC process cannot be used even though the blood collection procedure has been IACUC approved as part of other protocols and/or an IACUC SOP.

**D. Changes to IACUC approved activities utilizing Administrative Review**

#### Administrative Review

Examples of these changes are:

1. to increase previously approved mouse or rat numbers that does not exceed 15% of the previously approved total number of mice or rats. The original rationale for the numbers of animals should continue to support the increase in number, range or percent being requested. If not, a revised rationale is required and the amendment will be reviewed via DMR;
2. in housing and or use of animals in a location that is part of the animal program overseen by the IACUC;
3. in correction of typographical errors;
4. in correction of grammar;
5. in contact information updates; and
6. in personnel, other than the PI. (There must be an administrative review to ensure that all such personnel are appropriately identified, adequately trained and qualified, enrolled in occupational health and safety programs, and meet other criteria as required by the IACUC.).

#### IV. APPROVAL

**NAME:** HMRI Institutional Animal Care and Use Committee

**DATE:** 3/26/2019