

Annual Report to OLAW

Institution: Ora Incorporated
Assurance Number: D20-01100
Reporting Period: October 1, 2020- September 30, 2021

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: December 22 nd , 2020	Date 2: June 4 th , 2021
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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:	December 22nd, 2020	Date 2:	June 11 th , 2021
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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: Harold Patterson	Name: David Bingaman
Signature:  (b) (6)	Signature:  (b) (6)
Date: 11/19/2021 <small>SignNow e-signature ID: 9394e1085e... 11/19/2021 17:22:52 UTC Hal Patterson (Signer)</small>	Date: 19-NOV-2021 <small>SignNow e-signature ID: 50ee66aaf0... 10/11/2021 17:22:52 UTC David Bingaman (Signer)</small>

V. Change in Institutional Official

Name: Dr. David Bingaman	
Title: Chief Development Officer	Degree/Credentials: DVM, Ph.D. Diplomate ACVO
Name of Institution: Ora Clinical	
Address: 300 Brickstone Square, Andover MA 01810	
Phone:  (b) (6)	Fax:
E-mail: dbingaman@oraclinical.com	

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

Institution: Ora Inc.			
IACUC Contact Information			
Address: 4 Corporate Drive Andover MA 01810			
E-mail: (b) (6)@oraclinical.com			
Phone: (b) (6)		Fax:	
IACUC Chairperson			
Name: Harold Patterson			
Title: Senior VP, Regulatory, CMC, Pre-clinical		Degree/Credentials: B.S.	
PHS Policy Membership Requirements***: Chair			
IACUC Roster [<i>Provide below or attach</i>]			
Name of Member/ Code*	Degree/ Credentials	Position Title/ Occupational Background**	PHS Policy Membership Requirements***
Scott Perkins	VMD, MPH, Diplomat ACLAM	Doctor of Veterinary Medicine	Attending Veterinarian/Vice Chair
(b) (6)			Scientist
			Non-Scientist
			Non-affiliated

* 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.

Amendment Policy Supplement: IACUC-Approved Guidance Documents for VVC

IACUC Approval Date: December 3, 2019

The following guidance documents used for VVC will be reviewed by the IACUC at least once every three years to ensure they remain appropriate and accurate. The most current version of the following textbooks, publications, references and institutional documents can be used for VVC review:

1. ACLAM Book Series. (2007). The Mouse in Biomedical Research Volumes 1-4. In *The Mouse in Biomedical Research Series* (Vol. 1–4). Elsevier, Inc.
2. ACLAM E-formulary
3. Fish, R., Danneman, P., Brown, M., & Karas, A. (2008). *Anesthesia and Analgesia in Laboratory Animals*. Elsevier, Inc.
4. Flecknell, P. (2009). *Laboratory Animal Anaesthesia*. Elsevier, Inc.
5. Fowler, M., & Miller, R. E. (2008). *Zoo and Wild Animal Medicine*. Elsevier, Inc.
6. Fox, J. G., & Bennett, B. T. (2015). *Laboratory Animal Medicine*. Elsevier, Inc.
7. Fox, J. G., & Marini, R. P. (2014). *Biology and Diseases of the Ferret: Third Edition*. Elsevier, Inc.
8. Green, S. L. (2009). *The Laboratory Xenopus sp.* CRC Book Press
9. Harkness, J. E., Turner, P. V, VandeWoude, S., & Wheler, C. L. (2010). Harkness and Wagner's Biology and Medicine of Rabbits and Rodents, 5th Edition. In *Wiley-Blackwell*.
10. Harper, C., & Lawrence, C. (2010). *The Laboratory Zebrafish*. CRC Book Press
11. Hawk, C. T., Leary, S. L., & Morris, T. H. (2005). *Formulary for Laboratory Animals* (3rd ed.). Wiley-Blackwell.
12. Leece, E. A. (2008). Lumb & Jones' Veterinary Anesthesia and Analgesia. *Veterinary Anaesthesia and Analgesia*. Wiley and Sons.
13. Plumb, D. (2008). Plumbs Veterinary Drug Handbook. Wiley-Blackwell.
14. Pritt, S., Cohen, K., & Sedlacek, H. (2012). *The Laboratory Rabbit, Guinea Pig, Hamster, and Other Rodents*. Elsevier, Inc.
15. Quesenberry, K. E., & Carpenter, J. W. (2003). *Ferrets, Rabbits and Rodents: Clinical Medicine and Surgery*. Saunders.
16. Turner, P. V, Pekow, C., Vasbinder, M. A., & Brabb, T. (2011). Administration of substances to laboratory animals: equipment considerations, vehicle selection, and solute preparation. *Journal of the American Association for Laboratory Animal Science: JAALAS*, 50(5), 614–627. Retrieved from:
<http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=3189663&tool=pmcentrez&rendertype=abstract>
17. Turner, P. V, Brabb, T., Pekow, C., & Vasbinder, M. A. (2011). Administration of substances to laboratory animals: routes of administration and factors to consider. *Journal of the American Association for Laboratory Animal Science: JAALAS*, 50(5), 600–613. Retrieved from:
<http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=3189662&tool=pmcentrez&rendertype=abstract>
18. Guidelines for Blood Collection, Injectable Volumes, and Needle Sizing
19. Guidelines for the Utilization of Anesthetics & Analgesics in Small Laboratory Animals & Buprenorphine SR-LAB Administration
20. [American Veterinary Medical Association \(AVMA\) Guidelines for the Euthanasia of Animals](#)
21. IACUC Policy on Methods of Euthanasia
22. IACUC Policy on Identification Methods, Genotyping, and Toe Clipping of Laboratory Rodents.

	Review of Veterinarian Responsibilities of VVC	Document Number: ARF-103-PCY
		Document Version: 2.0
		Effective Date: 03-12-2019

1. PURPOSE

As part of OLAW's guidance, Institutions may establish and IACUCs may approve policies (e.g., guidance documents, standard operating procedures, drug formularies) for the conduct of certain animal activities. These IACUC-reviewed and -approved documents may be used for the administrative handling of some significant changes in a process referred to as Veterinary Verification and Consultation (VVC).

2. RESPONSIBILITY

The Institutional Animals Care and Use Committee (IACUC) is responsible to review and approve significant changes to approved protocols. The Attending Veterinarian has the authority to administratively approve changes through the Veterinary Verification and Consultation process (VVC).

3. DEFINITIONS

IACUC: Institutional Animal Care and Use Committee

Attending Veterinarian: veterinarian who has direct or delegated authority over the Ora animal care and use program

Significant Changes: significant changes include changes that have, or have the potential to have, a negative impact on animal welfare. In addition, some activities that may not have a direct impact on animal welfare are also considered to be significant. The IACUC has some discretion to use IACUC-reviewed and -approved policies to define what it considers a significant change or to establish a mechanism for determining significance on a case-by-case basis in accordance with the PHS Policy [IV.C.1.a.-g.](#) It is the IACUC's responsibility to clearly define and communicate its policy for determining significance to investigators.

VVC: Veterinary Verification and Consultation

4. PROCEDURE


Significant Changes Handled by Veterinary Verification and Consultation (VVC)

VVC Requirements:

1. The VVC process may not be used to add new procedures to a previously approved protocol. If new procedures are proposed, they must undergo FCR or DMR.
2. Only the ORA attending veterinarian authorized to administratively verify changes through VVC. The VVC cannot be performed by a veterinarian who is the PI of the protocol.
3. VVC can only be utilized according to IACUC-reviewed and -approved guidance documents in consultation with an authorized veterinarian. The veterinarian is not conducting a DMR but is serving as a subject matter expert to verify that compliance with the IACUC-approved guidance document(s) is appropriate for the animals in the specific circumstance.
4. The veterinarian must refer any request that does not meet the parameters of the IACUC-approved guidance documents to FCR or ER. Additionally, the veterinarian can refer any request to FCR/ER for any reason.

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	Review of Veterinarian Responsibilities of VVC	Document Number: ARF-103-PCY
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- Proposed changes must be submitted using the amendment form and consultation with the veterinarian must occur prior to the change being implemented. The VVC must be documented and saved in the protocol file.
- A list of changes administratively handled by VVC will be provided to the IACUC on a regular basis.

VVC-Eligible Changes:

- The following changes may be handled by VVC, *only* if they meet the above requirements:
- Changes in anesthesia, analgesia, sedation (including agent, dose, frequency, or route)
- Changes in experimental substances (including dose, frequency, or route)
- The substance itself may be changed as long as it is within a similar class to what was included in the original protocol (including vehicles, solvents, diluents, chemotherapeutics, antibiotics, hormones, etc.)
- Changes in duration, frequency, type*, or number of approved procedures
- For some procedures, different variations can be approved (e.g. blood collection or genotyping methods) only if described in an IACUC-approved guidance document, included below.
- Euthanasia to any method approved in the [American Veterinary Medical Association \(AVMA\) Guidelines for the Euthanasia of Animals: 2020 Edition](#).

IACUC-Approved Guidance Documents for VVC:

Documents used for VVC will be reviewed by the IACUC at least once every three years to ensure they remain appropriate and accurate. Please see "Amendment Policy Supplement: IACUC-Approved Guidance Documents for VVC" which lists all approved documents available for VVC.

Administrative Changes:

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

- 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.
- Personnel changes (excluding changes in PI)
- Location changes to areas already part of the animal program overseen by the IACUC.

Version Number	Effective Date	Author (F. Last)	Change(s)
1.0	dd-mmm-yyyy		

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