

JAN 31 2020

Initial: me**Annual Report to OLAW**

Institution: Inotiv
Assurance Number: A4690-01
Reporting Period: 01 Jan 2019 - 31 Dec 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.]*
- ☒ **OTHER:** Institution name has changed from PreClinical Research Services, Inc. to Inotiv.  
\*Effective Dec 01, 2019

**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: 16 January 2019	Date 2: 15 July 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: : 09, 16 January 2019



Date 2: 12, 15 July 2019

**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: Bridget Knox, BS, CPIA	Name: Donald H. Maul, DVM, MS, ACLAM
Signature:  (b) (6)	Signature:  (b) (6)
Date: 28 Jan 2020	Date: 28 Jan 2020

**V. Change in Institutional Official**

Name: N/A	
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: Inotiv</b>			
<b>IACUC Contact Information</b>			
Address: [street, city, state, zip code]  1512 Webster Court Fort Collins, CO. 80524			
E-mail: bridget.knox@preclinicalresearch.com			
Phone: (b) (6)		Fax: (b) (6)	
<b>IACUC Chairperson</b>			
Name: Bridget Knox			
Title: Study Director		Degree/Credentials: BS	
PHS Policy Membership Requirements***:			
<b>IACUC Roster</b> [ <i>Provide below or attach</i> ]			
Name of Member/ Code*	Degree/ Credential	Position Title/ Occupational Background**	PHS Policy Membership Requirements***
Lon Kendall	DVM, PhD, ACLAM	Director, Laboratory Animal Resources, Colorado State University	Veterinarian
Bridget Knox	BS	Study Director	Chairperson, Scientist
(b) (6)			Nonscientific Member
			Nonaffiliated
			Scientist

\* Names of members, other than the chairperson and veterinarian, may be represented by a number or symbol in this report to OLAW. Sufficient information to determine that all appointees

are appropriately qualified must be provided and the identity of each member must be readily ascertainable by the institution and available to authorized OLAW or other PHS representatives upon request.

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

\*\*\* PHS Policy Membership Requirements:

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

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



OLAW 2020 Annual Report Attachment  
Assurance Number: A4690-01

Two changes have been made to our program for animal care and use.

1) The institution name has changed from PreClinical Research Services, Inc. to Inotiv (separate letter submitted from the IO). The IO is still Donald H. Maul, DVM, MS, ACLAM; however, his title is now Senior Vice President, Surgical Models.

2) The IACUC policy for protocol amendment review has been revised to include Veterinary Verification and Consultation (VVC). Significant changes to the protocol, as defined in the policy, still must be submitted to the IACUC via DMR or FCR. The VVC covers changes to the IACUC protocol that may be handled administratively without IACUC review by FCR or DMR. The Attending Veterinarian or Staff Veterinarian may approve the changes through VVC. These changes briefly include: change in strain or source; increase in animal number for non-USDA species; change in planned anesthesia, analgesia, sedation, or other clinically relevant medication; changes in experimental substance administration or biological sample collection (e.g. dose, route, frequency, etc.); change in instrumentation (e.g. suture); change in study endpoint; and change in final disposition. The policy includes guidelines and published references for changes that can be approved by VVC, and also stipulates that the procedures cannot alter the objectives of the original proposal, create welfare concerns, or result in increased pain, distress, or invasiveness.

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