

Annual Report to OLAW

Institution: Intuitive Surgical, INC
Assurance Number: D17-00972
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 [\(PHS Policy IV.A.1.a-i.\)](#). [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: March 27, 2019	Date 2: September 18, 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 27, 2019

Date 2: September 18, 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: Jaime Wong	Name: Kara Andersen Reiter
Signature:  (b) (6)	Signature:  (b) (6)
Date: 4/29/2020	Date: 1/29/2020

V. Change in Institutional Official

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

IACUC Membership Roster

NAME	DEGREE	POSITION	PHS Policy Membership Requirement/AFFILIATION	VOTING STATUS
			(b) (6)	
				Voting
				Voting
				Non Voting
Bishop Curry	DVM	Director, Comparative Medicine/Attending Veterinarian	Veterinarian	Voting
Paula Ezell	DVM	Director, Laboratory Services	Scientific Member	Voting
			(b) (6)	
				Voting
				Voting
				Voting
				Voting
Takayuki Tanaka	DVM	Director, Lab Services, Japan	Scientific Member	Voting
Jaime Wong	MD	VP, Sr. Medical Officer, Product Ops	IACUC Chair	Voting

PHS Updates Reporting Period 2019

Applicability of Assurance:

Page 1, section A; include 1020 Kifer Road, Bldg. 108 (surgical suite); this surgical facility is captured in Section X of the approved Assurance but was not included here.

Section B; remove reference to Pork Power Farms. Intuitive no longer utilizes a satellite facility for housing USDA covered animals prior to shipment to Intuitive facilities.

Institutional Program for Animal Care and Use

Page 3, section B; add qualifications of veterinarians Dr. Bishop Curry, (b) (6)
(b) (6)

Bishop B. Curry, III, DVM, DACLAM:

Qualifications: Dr. Curry completed a three-year, non-degree, NIH sponsored residency in Comparative Pathology at the University of Texas Southwestern Medical Center in Dallas, TX and has over 25 years of experience in laboratory animal medicine. Prior to joining Intuitive, Dr. Curry held positions of increasing job scope and responsibility including: Director of Laboratory Animal Resources, Charles River Discovery and Development Services, Worcester, MA, Science Applications International Corporation (SAIC) Deputy Director Laboratory Animal Sciences Program, Frederick, MD, Animal Program Director National Cancer Institute, Bethesda, MD, Executive Director Comparative Medicine Pfizer, Inc., Groton, CT and Director of Laboratory Animal Sciences Program, Boston University.

Authority: As Attending Veterinarian, Dr. Curry 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% effort.

(b) (6)

Intuitive also utilizes contract veterinarians for additional backup coverage.

Page 12, section 8; Decision to approve or withhold approval of protocol submissions is sent via email by the IACUC administrator (cc to IO and Chair).

Page 13, section 9; adverse events are reported to the AV as they occur, are investigated per standard operating procedure, and are reported in the semi-annual inspection/program review.

Page 13, section 9; for a study to continue uninterrupted past the three-year anniversary, prior to expiration of the original protocol, the PI must conduct a full review of the protocol procedures and submit a new literature search. The protocol must be submitted for consideration by the IACUC for DMR or FCR.

Page 14, section E delete reference to FACOEM physician and completion of health history/risk assessment questionnaire. Add:

Intuitive partners with Concentra to provide occupational health services to employees. Concentra physicians review our program and administer care as needed. This care includes both acute (e.g. injury at the workplace) and preventative (e.g. vaccinations, pregnancy in the workplace, or other HIPAA protected conditions that may necessitate accommodations in the workplace) care.

All individuals requiring access to areas where laboratory animals may be present are provided training in the potential exposure hazards as well as procedures to be followed to minimize risk. Visitors must be accompanied by an Intuitive employee and comply with personal protective equipment requirements.

Intuitive utilizes a hierarchy of control strategies to mitigate risk (engineering controls, process controls, personal protective equipment controls). Access to the laboratory area is restricted; signage indicates hazards that may be present and entry requirements (e.g. PPE).

Page 16, engineering controls 1266 Kifer Road facility: HVAC issues identified in 2019 (lower ACH than previously reported in certain operating rooms) are being addressed in 2020 with an HVAC upgrade. The issues reported have had no known negative impact on animal or human health. The respiratory protection program offers opportunity for individuals to elect to wear a respirator during higher risk activities (e.g. cautery).

Page 19 Training of new IACUC members includes completion of Essentials for IACUC Members curriculum through the American Association of Laboratory Animal Science Learning Library, direct

mentorship from the AV or IACUC administrator and attendance at IACUC workshops (either in person or via webinar). IACUC members receive ongoing training during convened meetings; topics may include updates to scientific studies from principal investigators, program updates, and other topics as determined by the AV and IACUC chair.

Page 21 section d delete reference to email process for training verification. Add:

The PI provides documentation for personnel listed on protocol regarding training. When an individual has achieved competency based on established criteria, an amendment is submitted to promote the individual to independent surgeon.