Annual Report to OLAW

Institution: Angiograft, LLC.				
Assurance Number: D17-01010				
Reporting Period: January 1 st ,2018- December 31 st , 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.]
- [X] 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)				
		[]]	AAALAC Accredited – Category 1
		r 1	1	Non-Accredited – Category 2

[X] 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.]
- [X] 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 28 th , 2018	Date 2: November 20 th , 2018

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.]

AOS (Animal housing)	Date 1: 03/25/2018	Date 2: 11/20/2018
ESAH (Clinic for surgical procedures)	Date 1: 03/28/2017	Date 2: Closed
AOS (Surgical and Study Facility)		Date 2: 11/20/18

ESAH closed as a satellite surgical facility. July 20, 2018 was the last recovery surgery performed and August 24, 2018 was the last non-recovery procedure performed at ESAH. Accommodations have been established at AOS for non-recovery procedures and recovery surgical procedures under the guidance of Jon Kemp and Associates Veterinarians of Attica, NY.

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 <u>PHS</u> <u>Policy IV.F.</u> for this reporting cycle are attached.

IV. Signatures

IACUC Cha	irperson	Institutional Official	
Name: Edm	und Egan	Name: Sindhu Row	
Signature:	(b) (6)	(b) (6) Signature:	
Date: 1/20/	19	Date:1/20/19	

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]

Institution: Angiograft LLC									
IACUC Contact Information									
Address: 1576 Sweet Home Rd Amherst, NY 14228									
E-mail: srow @angio-graft.com									
Phone: Fax:									
IACUC Chairperson									
Name: Dr. Edmund Egan									
Title: CSO ONY Biotech			Degree/Credentials:	MD					
PHS Policy Membership I	Requirements***: Sci	ienti	ist						
IACUC Roster [Provide	below or attach]								
Name of Member/ Code*	Degree/ Credential	Position Title/ Occupational Background**		PHS Policy Membership Requirements***					
Edmund Egan	Edmund Egan MD, Chief Medical Officer			Scientist					
Susan Greenbaum DVM			eterinarian	Veterinarian					
(b) (6)				Veterinarian					
				Nonscientist, Non Affiliated					
				Scientist					
				Veterinarian					
				Veterinarian					

^{*} 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:

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 (for example,

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)

Below is a summary of the changes to our Program Description:

The changes are relevant to a change in our contract facility to perform surgical procedures. We have switched from (b)(4) to (b)(4) who was also our previous contract facility for animal housing.

- 1) The facility for aseptic recovery and non-recovery surgical procedures is located at (b) (4)
- 2) Housing of all animals will be located at (b) (4)
- 3) There will no longer be any transport of animals between satellite facilities.
- 4) Cats have been added as a species that will be used in non-recovery, noninvasive procedures and housing.
 - Cats will be housed separately and follow all USDA guidelines for diet, enrichment, identification and housing requirements.
- 5) The (b) (4) facility now occupies a 2,400 sq. ft. space with the addition of the following areas (floors are concrete with epoxy covering, walls and ceiling are covered with vinyl interlocking panels and outside windows are glass block. This area opens into a common corridor with the previous animal housing area):
 - Surgical scrub room, 60 sq. ft.
 - Aseptic surgical operating room, 130 sq. ft.
 - Animal surgical prep room/non-recovery study room, 265 sq. ft.
 - Animal surgical recovery room, 140 sq. ft.
- 6) The (b) (4) facility and Staff will no longer participate in Angiograft, LLC Animal Research Facility (Angiograft ARF).
- 7) The (b) (4) staff will oversee and consult with the operation of the Angiograft ARF.
 - Susan Greenbaum, DVM will be the attending veterinarian and (b) (6) (6) (6) for Angiograft ARF.
 - (b) (6) with all animal procedures at Angiograft ARF.

Please let me know if you have any questions or need additional information,

Thanks, Dan

Daniel Swartz, PhD Angiograft, LLC; President 1576 Sweet Home Road Amherst, NY 14228 dswartz@angio-graft.com



DANIEL SWARTZ. PhD | Director Scientific and Clinical Research

0 (b) (6) | F (b) (6)

1576 Sweet Home Road | Amherst, New York 14228 dswartz@onybiotech.com | onybiotech.com

From: Daniel Swartz < <u>DSwartz@onybiotech.com</u>>
Sent: Wednesday, February 27, 2019 4:31 PM

To: OLAW-DOA Annual Reports (NIH/OD) <<u>olawarp@od.nih.gov</u>>

Cc: srow@angio-graft.com; Edmund Egan MD EEgan@onybiotech.com>

Subject: Re: 2018 Annual Report Notice

Dear OLAW,

I apologize for the lateness of the annual report, Our CEO/IO is (b) (6) and it was an oversight. Attached is the Annual Report and due to some changes in the program description we have attached an updated Angiograft ARF Program description and Angiograft assurance with changes denoted in blue font.

The changes are relevant to a change in our contract facility to perform surgical procedures. We have switched from (b) (4) who was also our previous contract facility for animal housing.

Please let me now if you have any questions or need additional documentation,

Thanks, Dan

Daniel Swartz, PhD Angiograft, LLC; President 1576 Sweet Home Road Amherst, NY 14228 dswartz@angio-graft.com



DANIEL SWARTZ. PhD | Director Scientific and Clinical Research

(b) (6) | F (b) (6)

1576 Sweet Home Road | Amherst, New York 14228 dswartz@onybiotech.com | onybiotech.com