



Inspection Report

Pennsylvania State University
Office For Research Protections
The 330 Building Suite 205
University Park, PA 16802

Customer ID: 306
Certificate: 23-R-0021
Site: 002
HERSHEY MEDICAL CENTER

Type: ROUTINE INSPECTION
Date: 13-JUN-2017

2.31(c)(7)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

On 9 March 2017 an adult sheep underwent a cardiac bypass procedure under "protocol C." This sheep was euthanized by the veterinary staff on 13 March 2017 for complications. "Protocol C" was not approved for survival surgeries or the cardiac bypass that was conducted on the sheep. Since Protocol C contained no survival surgeries, the IACUC had not reviewed requirements for after care such as recovery, analgesia, post-operative monitoring. Following the animals death, lab personnel tried to transfer the deceased animal to another approved protocol which contained a cardiac bypass and recovery. The incident was investigated by the IACUC and according to facility documentation the change was made by lab staff post-mortem to avoid noncompliance.

On 3 March 2017 another incident was noted involving a lamb was scheduled under "protocol A" for a cardiac device implant. After the animal had been anesthetized and prepped for surgery it was decided by the investigator that animal was not a candidate for the "protocol A" surgery. The animal was recovered from surgery and several weeks later the investigator decided to use this animal under "protocol B" in which a by-pass would be conducted. This animal was not approved for transfer between "protocol A" and "protocol B" prior to the surgery being conducted. The by-pass conducted is not an approved procedure under the protocol in which the animal was assigned.

The university has re-trained staff and created several safeguards to help prevent future re-occurrence. Under the current Veterinary Verification and Consultation SOP, the veterinary staff will review animal transfers at least 24 hours in advance of the procedure.

Procedure conducted by investigators that are unapproved by the IACUC may lead to unnecessary pain and distress for the animals. IACUC must review and approve, require modifications in (to secure approval), or withhold approval of proposed significant changes regarding the care and use of animals in ongoing activities.

Correct by: 13 June 2017

2.31(d)(1)(ix)

Prepared By: NEAFSEY MICHAEL, D V M USDA, APHIS, Animal Care

Date:
13-JUN-2017

Title: ASSISTANT DIRECTOR 6094

Received by Title: ATTENDING VETERINARIAN

Date:
13-JUN-2017



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The large animal surgical suite cannot be appropriately sanitized to ensure that aseptic surgeries can be conducted. The surgical suite and surgical prep areas have a concrete ceiling with many pipes running through the area. These pipes are directly adjacent to the surgery table. These exposed pipes are difficult to clean and sanitize and harbor dust and bacteria that can expose patients to unnecessary risk. The exposed pipes do not allow for the surgery suite to be maintained under aseptic conditions. Major operative procedures on will be conducted only in facilities intended for that purpose which shall be operated and maintained under aseptic conditions.

Correct by: 13 August 2017.

The inspection was conducted on 12 June 2017 and 13 June 2017 with the Attending Veterinarian and veterinary staff.

The exit briefing was conducted on 13 June 2017 with the Attending Veterinarian, IACUC Chair, IACUC vice-chair and IACUC administrators.

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Species Inspected

Cust No	Cert No	Site	Site Name	Inspection
306	23-R-0021	002	HERSHEY MEDICAL CENTER	13-JUN-17

Count	Scientific Name	Common Name
000127	<i>Oryctolagus cuniculus</i>	DOMESTIC RABBIT / EUROPEAN RABBIT
000027	<i>Ovis aries aries</i>	SHEEP INCLUDING ALL DOMESTIC BREEDS
000154	Total	