

United States Department of Agriculture Animal and Plant Health Inspection Service

EKARR INS-0000892103

Inspection Report

CBSET Inc Customer ID: 38804

500 Shire Way Certificate: 14-R-0183 Lexington, MA 02421

Site: 002

CBSET, Inc

Type: ROUTINE INSPECTION

Date: 13-SEP-2023

2.31(c)(7)

Institutional Animal Care and Use Committee (IACUC).

On 5/15/2023, a pig underwent a surgical procedure and received only one of two pain medications required by the IACUC approved protocol. This oversight was detected later that day by facility staff and the animal was provided with the missed dose of analgesia at that time.

On 8/3/2022, 3 pigs that had undergone biopsy procedures did not receive post-procedural analgesia as required by the IACUC approved protocol. According to facility records, post-procedural observations to evaluate for pain were conducted and no pain was noted.

Deviation from IACUC approved pain control procedures constitutes a significant change to ongoing activities, as changes in the pain control regimen has the potential to negatively impact animal welfare. The IACUC must review and approve all significant changes in ongoing activities prior to their implementation in animals.

These incidents had been identified by the facility and corrective measures were implemented prior to inspection. To remain corrected from September 15, 2023.

2.31(e)(3)

Institutional Animal Care and Use Committee (IACUC).

An IACUC approved protocol describes a procedure for the placement of a large cranial implant. The surgical procedure description states that incisions will be sutured closed in multiple layers. On 5/15/2023, a pig underwent a procedure on this protocol and an additional "rotational scalp incision" was created to be able to appose the skin over the implant site. This surgical repair necessary to completely close the incision over a large implant was not described in the protocol.

Procedures must be completely described to enable the IACUC to conduct a thorough review of the components of the activities related to the care and use of animals, including surgical procedures, to be able to determine that the proposed activities are in accordance with the Animal Welfare Act.

The facility must ensure that all proposals to conduct activities involving animals include a complete description of the

Prepared By: EILIS KARR USDA, APHIS, Animal Care 15-SEP-2023

Title: VETERINARY MEDICAL OFFICER

Received by Title: Attending Veterinarian Date:



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proposed use of animals. Any activities conducted in animals must be completely described from September 15, 2023 forward.

2.38(f)(1) Critical

Miscellaneous.

During measurement of the rectal temperature of an anesthetized rabbit on 4/4/2023, a thermometer was inserted into the animal and could not be retrieved by hand. When imaging was conducted to identify the location of the thermometer, it was shown to have penetrated the colon and was partially within the abdominal cavity. Failure to handle the animal as carefully as possible while monitoring body temperature caused trauma to the animal that required veterinary care and necessitated the animal's removal from study.

Handling of all animals shall be done as carefully as possible and in a manner that does not cause trauma or physical harm.

This incident had been identified by the facility and corrective measures had been implemented prior to inspection, which included retraining of all staff. To remain corrected from September 15, 2023.

This inspection and exit interview were conducted with facility representatives.

Prepared By:EILIS KARRDate:USDA, APHIS, Animal Care15-SEP-2023

Title: VETERINARY MEDICAL

OFFICER

Received by Title: Attending Veterinarian Date:

15-SEP-2023



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Species Inspected

| Cust No | Cert No | Site | Site Name | Inspection |
|---------|-----------|------|------------|-------------|
| 38804 | 14-R-0183 | 002 | CBSET, Inc | 13-SEP-2023 |

| Count 000060 000006 000012 | Scientific Name Sus scrofa domestica Ovis aries aries Oryctolagus cuniculus | Common Name DOMESTIC PIG / POTBELLY PIG / MICRO PIG SHEEP INCLUDING ALL DOMESTIC BREEDS DOMESTIC RABBIT / EUROPEAN RABBIT |
|-------------------------------------|---|---|
| 000078 | Total | |