

Burlington, MA 01805

United States Department of Agriculture Animal and Plant Health Inspection Service

EKARR INS-0001055572

Inspection Report

LCF Foundation Inc Customer ID: 110

41 Mall Road Certificate: 14-R-0016

Site: 001

L C F FOUNDATION, INC.

Type: ROUTINE INSPECTION

Date: 27-JUN-2024

2.31(d)(1)(ii)

Institutional Animal Care and Use Committee (IACUC).

An IACUC approved surgical protocol includes a laparotomy procedure in swine. The written narrative description of the methods and sources used to determine that alternatives to that procedure were not available refers to the use of a database search. However, none of the terms used in the database search strategy pertained to the specific surgical procedure contained in the proposal.

Per this section of the regulations, whenever a proposal for animal use contains procedures that may cause more than momentary pain or distress to the animals, the IACUC shall determine that (1) the principal investigator has considered alternatives to those procedures and (2) that the written narrative description of the methods and sources used by the principal investigator to determine that alternatives were not available adequately addresses all of the potentially painful procedures contained in the proposal. These requirements ensure that all procedures contained in the protocol minimize discomfort, distress, and pain to the animals.

To be corrected by September 1st, 2024.

2.31(e)(2)

Institutional Animal Care and Use Committee (IACUC).

An IACUC approved protocol indicates that 5 animals will be used, but does not provide justification for the appropriateness of the number of animals for the research.

Another IACUC approved protocol indicates a need for 4 groups of 3 animals to achieve "statistical significance," but does not include the details of how that statistical analysis was conducted, such as the tests used or statisticians consulted.

Failure to include a rationale for the number of animals to be used in animal use protocols compromises the ability of the IACUC to evaluate the appropriateness of the numbers of animals requested. Per this section of the regulations, all proposals for animal use must include a rationale for the appropriateness of the species and numbers of animals to be used.

To be corrected by September 1st, 2024.

Prepared By:	EILIS KARR		Date:
Title:	VETERINARY MEDICAL OFFICER	USDA, APHIS, Animal Care	03-JUL-2024
Received by Title:	Facility Representative		Date: 03-JUL-2024



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2.31(e)(3)

Institutional Animal Care and Use Committee (IACUC).

An IACUC approved protocol for surgical device testing does not provide a complete description of the proposed use of animals. Laparotomy is mentioned in the procedures section of the protocol but there is no description of the surgical procedure. There are no specifics included as to the role of animals in the study design or the various laparoscopic procedures that may be involved in device testing.

In order for the IACUC to fulfill their responsibilities and ensure that pain and distress are minimized to that which is scientifically necessary, all proposals to conduct activity involving animals must contain a complete description of the proposed use of animals.

To be corrected by September 1st, 2024.

This inspection and initial exit interview were conducted with facility representatives on site. A final exit briefing was conducted on July 2, 2024 with the Institutional Official, Attending Veterinarian, and IACUC coordinators.

Prepared By:EILIS KARRDate:USDA, APHIS, Animal Care03-JUL-2024

Title: VETERINARY MEDICAL

OFFICER

Received by Title: Facility Representative Date:

03-JUL-2024



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Total

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Species Inspected

Cust No	Cert No	Site	Site Name	Inspection
110	14-R-0016	001	L C F FOUNDATION, INC.	27-JUN-2024

CountScientific NameCommon Name000000NONENONE