



## Inspection Report

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Virtus Strategic Consulting, Inc.  
31915 Rancho California Rd. #200-305  
Temecula, CA 92591

Customer ID: **6003895**

Certificate: **93-R-0595**

Site: 001

Virtus Strategic Consulting, Inc.

Type: ROUTINE INSPECTION

Date: 14-JAN-2025

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### 2.31(b)(1)

#### **Institutional Animal Care and Use Committee (IACUC).**

The Chief Executive Officer (CEO) of the facility is the principal investigator and the IACUC chairman. The CEO prepares and submits the proposals for research activities and retains voting rights for approval of said proposals. In addition, the APHIS official observed that the CEO had not appointed the IACUC members to the committee. Serving in the roles of CEO and IACUC Chair while retaining voting rights as the principal investigator compromises the ability of the IACUC to ensure the proper care and treatment of animals used in the research program and the ability to perform the functions required by the Animal Welfare Act.

The Chief Executive Officer of the research facility shall appoint an Institutional Animal Care and Use Committee (IACUC), qualified through the experience and expertise of its members to assess the research facility's animal program, facilities, and procedures.

To be corrected by February 15, 2025.

### 2.31(c)(3)

#### **Institutional Animal Care and Use Committee (IACUC).**

The two semi-annual reports reviewed by the APHIS official for 2024 were not signed by a majority of the IACUC members. The semi-annual reports shall include a review of the research facility's program of humane care and use of animals as well as an inspection of the animal facilities at least every six months. Signatures of the IACUC members ensure that the committee is documenting their accountability for the oversight of the animal care and use program. Reports to the Institutional Official or CEO shall be reviewed and signed by a majority of the IACUC and updated upon completion of the required semi-annual evaluations.

To Be Corrected by the next semi-annual report to the Institutional Official in or before May 2025

### 2.31(c)(7)

#### **Institutional Animal Care and Use Committee (IACUC).**

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**Prepared By:** LEANN SARGEANT

USDA, APHIS, Animal Care

**Title:** VETERINARY MEDICAL  
OFFICER

**Date:**

17-JAN-2025

**Received by Title:** Registrant

**Date:**

17-JAN-2025



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Multiple pigs, on multiple dates, undergoing anesthesia for study related surgeries were not monitored while under anesthesia as specified in their assigned protocol. The protocol indicates that vital parameters including, but not limited to, heart rate, respiratory rate, and temperature are to be monitored and documented every hour. However, observation during inspection and review of records revealed that study personnel failed to monitor and document vital signs every hour on multiple animals during multiple sessions. This constitutes a significant change to the protocol reviewed by the IACUC.

Unapproved changes in animal use activities can be detrimental to animal health, because it could result in a failure to recognize and address pain and distress in animals. The IACUC must review and approve proposed significant changes regarding the care and use of animals in ongoing activities.

To be corrected by January 31, 2025.

### 2.31(d)(1)(ii)

Repeat

#### Institutional Animal Care and Use Committee (IACUC).

Review of the study protocol revealed the principal investigator did not provide a written narrative description of the methods and sources used to determine that alternatives were not available to the surgical procedures performed in the study.

Per this Section, 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 principal investigator has provided a written narrative description of the methods and sources used to determine that alternatives were not available. These requirements ensure that all procedures contained in the protocol minimize discomfort, distress, and pain to the animals. The IACUC needs to address this item.

### 2.31(e)(3)

#### Institutional Animal Care and Use Committee (IACUC).

The research facility's study protocol does not include a complete description of how animals will be used. The protocol discusses the use of animals as tissue models and describes anesthetic and euthanasia protocols. However, there is no description of the surgical procedures or activities that require the use of the animals as models for medical training. A complete description of animal use is required for Institutional Animal Use and Care Committee (IACUC) review and approval of activities related to the care and use of animals.

A complete description of procedures of proposed animal use is necessary to ensure that the IACUC has all information needed to approve animal activities, that all study staff understand what the approved procedures are, that painful procedures will be performed with appropriate anesthetics, and the attending veterinarian has been involved in the planning.

To be corrected by 2/15/2025.

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**2.31(e)(4) Direct**

**Institutional Animal Care and Use Committee (IACUC).**

On January 14, 2024, an anesthetized pig, patient #6, was undergoing a study-related surgery and observed to be reacting to surgical stimuli. The pig was observed to be exhibiting a palpebral (blink) response, moving its head towards its chest, and retracting its limbs when study personnel applied surgical stimuli multiple times during a one-hour period. Study personnel administered additional anesthesia six times during the one-hour period from 1100 hours to 1200 hours. They would attempt surgical manipulation after administering anesthetic injection, but the pig continued to react to painful (or surgical-if you prefer) stimuli. Failure to provide adequate analgesic and anesthetic drugs may result in unnecessary pain and distress to the animals.

In addition, the study protocol does not describe the point at which an animal that is experiencing problems would be removed from study to prevent animals being subjected to procedures and unnecessary pain or distress beyond that which is necessary for scientifically valuable research.

A proposal to conduct an activity involving animals must provide a description of procedures designed to assure that discomfort and pain to animals will be limited to that which is unavoidable for the conduct of scientifically valuable research, including provision for the use of analgesic, anesthetic, and tranquilizing drugs where indicated and appropriate to minimize discomfort and pain to animals.

Corrected at time of inspection.

**2.33(b)(2) Critical**

**Attending veterinarian and adequate veterinary care.**

According to facility records, on October 22, 2024, during a training session under the facility's protocol, three pigs died under general anesthesia. Anesthesia records indicate the animals developed hyperthermia with temperature ranges from approximately 105° F to 108° F at the time of death. Veterinary treatment for this condition was not provided to these animals and training procedures continued for 2-5 hours before the pigs died. In addition, on November 17, 2024, records indicate two pigs died under anesthesia from suspected respiratory distress. For the health and safety of the animals, appropriate methods should be in place in the event of emergencies or animals in distress. Each research facility shall establish appropriate methods to prevent, control, diagnose, and treat diseases and the availability of emergency care.

To be corrected by close of business January 15, 2025.

**2.36(a) Repeat**

**Annual report.**

The facility's annual report for fiscal year 2024, which was due to the Deputy Administrator on or before December 1st, 2024, was not submitted. Annual reports from 2021, 2022, and 2023 were also not received by the required deadline. In order to assure that professionally acceptable standards governing the care and use of animals are followed, each

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reporting facility shall submit an annual report covering the use of live animals in the previous federal fiscal year on or before December 1st of each calendar year.

The Annual Report of Research Facility (APHIS Form 7023), Continuation Sheet for Annual Report of Research Facility (APHIS Form 7023A), and Annual Report of Research Facility Column E Explanation (APHIS Form 7023B) are forms which may be used to submit the information required by paragraph (b) of this section.

### 2.38(l)

#### Miscellaneous.

This facility has not yet developed and documented an appropriate plan for their animals in event of an emergency or disaster.

Research facilities must develop, document, and follow an appropriate plan to provide for the humane handling, treatment, transportation, housing, and care of their animals in the event of an emergency or disaster (one which could reasonably be anticipated and expected to be detrimental to the good health and well-being of the animals in their possession).

To be corrected by February 15, 2025

This inspection and exit interview were conducted with facility representatives.

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United States Department of Agriculture  
Animal and Plant Health Inspection Service

Customer: 6003895  
Inspection Date: 14-Jan-2025

**Species Inspected**

Cust No	Cert No	Site	Site Name	Inspection
6003895	93-R-0595	001	Virtus Strategic Consulting, Inc.	14-JAN-2025

Count	Scientific Name	Common Name
000023	<i>Sus scrofa domestica</i>	DOMESTIC PIG / POTBELLY PIG / MICRO PIG
000023	<b>Total</b>	