



Inspection Report

COASTAL CAROLINA UNIVERSITY

Customer ID: **39090**

Certificate: **56-R-0116**

Site: 001

COASTAL CAROLINA UNIVERSITY

755 HIGHWAY 544

Type: ROUTINE INSPECTION

Date: Jun-16-2010

CONWAY, SC 29526

No non-compliant items identified during this inspection.

Exit briefing conducted with facility representative.

Prepared By:

LISA K MACELDERRY, D V M USDA, APHIS, Animal Care

Title: VETERINARY MEDICAL OFFICER Inspector 1055

Date:

Jun-16-2010

Received By:

(b)(6), (b)(7)(c)

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2.31 (c) **REPEAT**
INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

Section 2.31(c) states "IACUC functions. With respect to activities involving animals, the IACUC, as an agent of the research facility, shall:

(1) Review, at least once every six months, the research facility's program for humane care and use of animals, using title 9, chapter I, subchapter A--Animal Welfare, as a basis for evaluation;

(2) Inspect, at least once every six months, all of the research facility's animal facilities, including animal study areas, using title 9, chapter I, subchapter A-Animal Welfare, as a basis for evaluation; Provided, however, That animal areas containing free-living wild animals in their natural habitat need not be included in such inspection;

(3) Prepare reports of its evaluations conducted as required by paragraphs (c)(1) and (2) of this section, and submit the reports to the Institutional Official of the research facility; Provided, however, That the IACUC may determine the best means of conducting evaluations of the research facility's programs and facilities; and Provided, further, That no Committee member wishing to participate in any evaluation conducted under this subpart may be excluded. The IACUC may use subcommittees composed of at least two Committee members and may invite ad hoc consultants to assist in conducting the evaluations, however, the IACUC remains responsible for the evaluations and reports as required by the Act and regulations. The reports shall be reviewed and signed by a majority of the IACUC members and must include any minority views. The reports shall be updated at least once every six months upon completion of the required semiannual evaluations and shall be maintained by the research facility and made available to APHIS and to officials of funding Federal agencies for inspection and copying upon request. The reports must contain a description of the nature and extent of the research facility's adherence to this subchapter, must identify specifically any departures from the provisions of title 9, chapter I, subchapter A--Animal Welfare, and must state the reasons for each departure. The reports must distinguish significant deficiencies from minor deficiencies. A significant deficiency is one which, with reference to Subchapter A, and, in the judgment of the IACUC and the Institutional Official, is or may be a threat to the health or safety of the animals. If program or facility deficiencies are noted, the reports must contain a reasonable and specific plan and schedule with dates for correcting each deficiency. Any failure to adhere to the plan and schedule that results in a significant deficiency remaining uncorrected shall be reported in writing within 15 business days by the IACUC, through the Institutional Official, to APHIS and any Federal agency funding

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that activity."

Although the IACUC has met twice since the last USDA inspection on 8-19-08, they did not conduct an adequate program review, and the facility was not inspected. No animals have been in the facility, but it still is to be inspected at least once every 6 months. One report was sent to the Institutional Official in November, 2008, but this report did not contain all of the above required information and no members signed the report. The IACUC meetings were held 8 months and 4 months apart.

The IACUC needs to meet at least once every 6 months and conduct a program review and facility inspection. Then a report describing the program review and facility inspection needs to be written, reviewed by the IACUC members, and signed by a majority of the IACUC members. This report needs to follow the requirements stated above.

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2.31 (c) **REPEAT**
INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

Section 2.31(c) states "IACUC Functions. With respect to activities involving animals, the IACUC, as an agent of the research facility, shall:

- (1) Review, at least once every six months, the research facility's program for humane care and use of animals, using title 9, chapter I, subchapter A--Animal Welfare, as a basis for evaluation;
- (2) Inspect, at least once every six months, all of the research facility's animal facilities, including animal study areas, using title 9, chapter I, subchapter A-Animal Welfare, as a basis for evaluation; Provided, however, That animal areas containing free-living wild animals in their natural habitat need not be included in such inspection;
- (3) Prepare reports of its evaluations conducted as required by paragraphs (c)(1) and (2) of this section, and submit the reports to the Institutional Official of the research facility; Provided, however, That the IACUC may determine the best means of conducting evaluations of the research facility's programs and facilities; and Provided, further, That no Committee member wishing to participate in any evaluation conducted under this subpart may be excluded. The IACUC may use subcommittees composed of at least two Committee members and may invite ad hoc consultants to assist in conducting the evaluations, however, the IACUC remains responsible for the evaluations and reports as required by the Act and regulations. The reports shall be reviewed and signed by a majority of the IACUC members and must include any minority views.

The reports shall be updated at least once every six months upon completion of the required semiannual evaluations and shall be maintained by the research facility and made available to APHIS and to officials of funding Federal agencies for inspection and copying upon request. The reports must contain a description of the nature and extent of the research facility's adherence to this subchapter, must identify specifically any departures from the provisions of title 9, chapter I, subchapter A--Animal Welfare, and must state the reasons for each departure. The reports must distinguish significant deficiencies from minor deficiencies. A significant deficiency is one which, with reference to Subchapter A, and, in the judgment of the IACUC and the Institutional Official, is or may be a threat to the health or safety of the animals. If program or facility deficiencies are noted, the reports must contain a reasonable and specific plan and schedule with dates for correcting each deficiency. Any failure to adhere to the plan and

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schedule that results in a significant deficiency remaining uncorrected shall be reported in writing within 15 business days by the IACUC, through the Institutional Official, to APHIS and any Federal agency funding that activity."

The IACUC coordinator and administrative assistant left the University this year. The IACUC met on 10-11-07 and conducted a program review, but did not do a facility inspection because there were no animals in the facility. A facility inspection was done in December, 2007, but there is no documentation of that inspection. Even if the facility is empty of animals, a facility inspection is still required to be done at least once every six months. An IACUC meeting was held on 6-27-08, but only an agenda can be found for this meeting. At this meeting, the semi-annual report was signed from the 10-11-07 meeting. These two IACUC meetings were over 8 months apart, when program reviews and facility inspections are required at least once every 6 months. The report to the Institutional Official from the IACUC was not sent for over 8 months after the 10-11-07 meeting. These reports need to be sent on a timelier basis (such as a month). No report was written or submitted to the Institutional Official for the 6-27-08 meeting. IACUC meetings need to be held at least once every 6 months to review the facilities programs and facilities. IACUC signed reports from these meetings containing all of the above required information need to be sent to the Institutional Official on a timely basis.

2.31 (d) (1) (ii) REPEAT

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

Section 2.31(d)(1)(ii) states "IACUC review of activities involving animals. The principal investigator has considered alternatives to procedures that may cause more than momentary or slight pain or distress to the animals, and has provided a written narrative description of the methods and sources, e. g., the Animal Welfare Information Center, used to determine that alternatives were not available."

During the last inspection, protocol 2006.7 was cited for not providing a written narrative description of the methods and sources used to determine alternatives were not available for the potentially painful procedure of toe clipping for identification of shrews. There is no addendum in the protocol from the principle investigator providing this information.

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2.31 (c)

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Section 2.31(c) states "IACUC Functions. With respect to activities involving animals, the IACUC, as an agent of the research facility, shall:

(1) Review, at least once every six months, the research facility's program for humane care and use of animals, using title 9, chapter I, subchapter A--Animal Welfare, as a basis for evaluation;

(2) Inspect, at least once every six months, all of the research facility's animal facilities, including animal study areas, using title 9, chapter I, subchapter A-Animal Welfare, as a basis for evaluation; Provided, however, That animal areas containing free-living wild animals in their natural habitat need not be included in such inspection;

(3) Prepare reports of its evaluations conducted as required by paragraphs (c)(1) and (2) of this section, and submit the reports to the Institutional Official of the research facility; Provided, however, That the IACUC may determine the best means of conducting evaluations of the research facility's programs and facilities; and Provided, further, That no Committee member wishing to participate in any evaluation conducted under this subpart may be excluded. The IACUC may use subcommittees composed of at least two Committee members and may invite ad hoc consultants to assist in conducting the evaluations, however, the IACUC remains responsible for the evaluations and reports as required by the Act and regulations. The reports shall be reviewed and signed by a majority of the IACUC members and must include any minority views. The reports shall be updated at least once every six months upon completion of the required semiannual evaluations and shall be maintained by the research facility and made available to APHIS and to officials of funding Federal agencies for inspection and copying upon request. The reports must contain a description of the nature and extent of the research facility's adherence to this subchapter, must identify specifically any departures from the provisions of title 9, chapter I, subchapter A--Animal Welfare, and must state the reasons for each departure. The reports must distinguish significant deficiencies from minor deficiencies. A significant deficiency is one which, with reference to Subchapter A, and, in the judgment of the IACUC and the Institutional Official, is or may be a threat to the health or safety of the animals. If program or facility deficiencies are noted, the reports must contain a reasonable and specific plan and schedule with dates for correcting each deficiency. Any failure to adhere to the plan and schedule that results in a significant deficiency remaining uncorrected shall be reported in writing within 15 business days by the IACUC, through the Institutional Official, to APHIS and any Federal agency funding that activity."

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This newly registered university has an IACUC which has been operating for less than 2 years. Although meetings have been held every 6 months (which included at least one facility inspection) reports were not written, reviewed and approved (signed) by the IACUC members, and sent to the Institutional Official. Minutes are available for the 11-13-06 meeting, but are incomplete for the 3-19-07 meeting. Facility inspections and program reviews need to be conducted at least once every six months and a report of these evaluations, signed by a majority of IACUC members, sent to the Institutional Official. To be corrected with future reports.

2.31 (d) (1) (ii)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

Section 2.31(d)(1)(ii) states "IACUC review of activities involving animals. The principal investigator has considered alternatives to procedures that may cause more than momentary or slight pain or distress to the animals, and has provided a written narrative description of the methods and sources, e. g., the Animal Welfare Information Center, used to determine that alternatives were not available."

Protocol 2006.7 involves wild mammal field trapping and marking. The protocol states toe clipping will be used only for the shrews, instead of ear tags, but does not provide a written narrative description of the methods and sources used to determine alternatives were not available for this potentially painful procedure. To be corrected by 10-1-07.

NOTE: Electronic review and polling of protocols is being done for some protocols. Protocols need to have full committee review or designated reviewer review to allow for more complete discussion of protocols and interaction between IACUC members.

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