



Inspection Report

MEMORIAL HEALTH UNIVERSITY MC

Customer ID: 971

Certificate: 57-R-0110

Site: 001

MEMORIAL MEDICAL CENTER

P.O. BOX 23089

Type: ROUTINE INSPECTION

Date: Jan-21-2010

SAVANNAH, GA 31403

2.31 (c) (3)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

Section 2.31(c)(3) states "IACUC functions. With respect to activities involving animals, the IACUC, as an agent of the research facility, shall: 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. The reports shall be reviewed and signed by a majority of the IACUC members and must include any minority views."

The 6-18-09 was only reviewed and signed by 3 of the 7 IACUC members, therefore a majority of members did not sign the report to the Institutional Official. To be corrected with future reports.

2.31 (d) (2)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

Section 2.31(d)(2) states "Prior to IACUC review, each member of the Committee shall be provided with a list of proposed activities to be reviewed. Written descriptions of all proposed activities that involve the care and use of animals shall be available to all IACUC members, and any member of the IACUC may obtain, upon request, full Committee review of those activities. If full Committee review is not requested, at least one member of the IACUC, designated by the chairman and qualified to conduct the review, shall review those activities, and shall have the authority to approve, require modifications in (to secure approval), or request full Committee review of any of those activities. If full Committee review is requested for a proposed activity, approval of that activity may be granted only after review, at a convened meeting of a quorum of the IACUC, and with the approval vote of a majority of the quorum present. No member may participate in the IACUC review or approval of an activity in which that member has a conflicting interest, except to provide information requested by the IACUC, nor may a member who has a conflicting interest contribute to the constitution of a quorum."

Due to last minute cancellations, the 6-17-09 IACUC meeting was only attended by 3 of the 7 members. This does not constitute a quorum, therefore, the review and vote for the protocols was not valid. The same protocols are reviewed twice a year at each meeting of the IACUC, so the protocols have had an annual review. A quorum needs to be available for protocol reviews. To be corrected with future reviews.

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Jan-21-2010

Received By:

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

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2.31 (e) (5)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

Section 2.31(e)(5) states "A proposal to conduct an activity involving animals, or to make a significant change in an ongoing activity involving animals, must contain a description of any euthanasia method to be used."

Although protocol #5, Gyn Resident Training Course, describes the euthanasia method as euthanasia solution while under anesthesia, it does not provide for early endpoints. During the last lab, near the end of the lab session on 8-12-08, the anesthesia record indicates the aorta was nicked in pig #5. The record shows the pig was worse 10 minutes later, having purple mucous membranes and increased capillary refill time. Then 10 more minutes later, the record states the pig died of exsanguination. (The pig was under anesthesia.) The protocol needs to provide early endpoints for euthanasia in instances where unexpected surgical errors could lead to the death of a pig. To be corrected before next pig lab.

2.33 (b) (5)

ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

Section 2.33(b)(5) states "Each research facility shall establish and maintain programs of adequate veterinary care that include adequate pre-procedural and post-procedural care in accordance with current established veterinary medical and nursing procedures."

During the last pig lab, conducted over 3 days, it is not clear if the 3 pigs were monitored in any way during the 1 hour lunch break on 8-11-08, and during the 2 hour lunch break on 8-12-08 (3 more pigs). The anesthesia records state during lunch break, but do not indicate if anyone was left monitoring the animals in any way while they were under anesthesia. The surgical training company was not available during this inspection to clarify the notation on the records. Animals under surgical anesthesia need to be continuously monitored.

To be corrected before next pig lab.

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Date: Jun-12-2008

SAVANNAH, GA 31403

2.31 (a)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

Section 2.31(a) states "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. Except as specifically authorized by law or these regulations, nothing in this part shall be deemed to permit the Committee or IACUC to prescribe methods or set standards for the design, performance, or conduct of actual research or experimentation by a research facility."

After the 5-3-07 IACUC meeting, the IACUC Chair retired, and the Attending Veterinarian and the unaffiliated member resigned from the committee. This research facility has not had a duly constituted IACUC since that meeting. The Chief Executive Officer needs to appoint members to the committee, following the membership guidelines in CFR 2.31(b).

To be corrected by 7-14-08.

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;
- (3) Prepare reports of its evaluations conducted as required by paragraphs (c)(1) and (2) of this section, and submit

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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.*

Because no animal use was planned or conducted since the last IACUC meeting on 5-3-08, no IACUC was re-constituted and no IACUC meetings were held in the last year. Even if there is no animal use, the IACUC must still meet at least once every six months for a program review and facility inspection, as long as the research facility maintains their USDA registration.

To be corrected by 7-14-08.

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