United States Department of Agriculture
Animal and Plant Health Inspection Service

CDIGESUALDO
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Inspection Report

Texas A & M University System H.S.C.
Baylor College Of Dentistry
Office Of Accoc. Dean Of Res. & Adv. Ed.
3302 Gaston Avenue
Dallas, TX 75246

Customer ID: **1411**
Certificate: **74-R-0039**
Site: 001
BAYLOR COLLEGE OF DENTISTRY

Type: ROUTINE INSPECTION
Date: May-15-2013

2.31 (c) (7)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

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

(7) Review and approve, require modifications in (to secure approval), or withhold approval of proposed significant changes regarding the care and use of animals in ongoing activities.

****From January 8th, 2013 until May 15, 2013, 14 rabbits have had procedures done under protocol 2012-12. From the medical records provided on these rabbits, all 14 animals have had procedures done that were not described in the original protocol and do not appear to have been approved by the IACUC. They include:

#4493¸3/26/13: sedated, perfused with ethanol, sacrificed, cranial specimens dissected out.
This procedure is not justified or described in the original protocol.

#A¸1/8/2013: (Day 1) sedated, 3 MSI s placed, loaded with 200g; 1/22/13: Right MSI failed, removed; 1/29/13: (Day?) sedated, 2 MSI s placed, loaded with 200g; 2/12/13: (Day 35) calcein given; 2/26/13: (Day 49) alizarim red given; 3/8/13: (Day 58) calcein given; 3/12/13: euthanized.
A second procedure is not justified or described in the protocol. The calcein and alizarim administration is not done according to the schedule in the protocol.

#B¸1/15/13: (Day 1) sedated, placed 6 MSI s, loaded with 100g; 1/29/13 (day 14) calcein; 2/12/13 (day 28) alizarin; 2/22/13 (day 38) calcein; 2/26/13 (day 42) euthanized
The placement of 6 MSI s loaded with 100g was not described in the protocol. The calcein and alizarim administration is not done according to the schedule in the protocol.

#4490¸3/26/13 (Day 1) 6 MSI s, 100g load; 4/9/13 (Day 14) calcein; 4/23/13 (Day 28) alazarin
The placement of 6 MSI s loaded with 100g was not described in the protocol. The calcein and alizarim administration is not done according to the schedule in the protocol.

#4492¸3/26/13 (Day 1) 6 MSI s, 100g load; 4/9/13(Day 14) calcein; 4/23/13 (Day 28) 4 MSI s placed, 100g load, alizarin given; 5/2/13 (Day 37 or Day 9?) calcein

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Date: May-20-2013

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Title:
Date: May-21-2013

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A second procedure is not justified or described in the protocol. The calcein and alizarim administration is not done according to the schedule in the protocol.

#4489¸3/26/13 (Day 1) 6 MSI s placed, 100 g load; 4/9/13 (Day 14) calcein; 4/23/13 (Day 28) alizarin; 5/2/13 (Day 37) calcein
The placement of 6 MSI s loaded with 100g was not described in the protocol. The calcein and alizarim administration is not done according to the schedule in the protocol.

#4491¸4/9/13 (day 1) 6 MSI s, 100 g load; 4/23/13 (day 14) calcein
Placement of 6 MSI s loaded with 100g was not described in the protocol. The calcein administration is not done according to the schedule in the protocol.

#4487 ¸4/9/13 (day 1) 2 MSI s, passive load - Control animal; 4/23/13 (day 14) calcein
The calcein administration is not done according to the schedule in the protocol.

#4495¸4/9/13 (day 1) 2 MSI s, 100g; 4/23/13 (DAY 14) records taken, no calcein or alizarin
A load of 100g is not described in the protocol.

#4484¸4/9/13 (day 1) 2 MSI s, 100 g; 4/23/13 (Day 14) records taken, no calcein or alizarin
A load of 100g is not described in the protocol.

#4485¸3/26/13 (Day 1) 6 MSI s placed, passive load; 4/9/13 (Day 14) calcein; 4/23/13 (Day 28) alizarin; 5/2/13 (day 37) calcein
Placement of 6 MSI s is not described in the protocol. The calcein and alizarim administration is not done according to the schedule in the protocol.

#4486¸3/26/13 (Day 1) 6 MSI s, 100 g; 4/9/13 (Day 14) calcein; 4/23/13 (Day 28) alizarin; 5/2/13 (day 37) calcein
The placement of 6 MSI s loaded with 100g was not described in the protocol. The calcein and alizarim administration is not done according to the schedule in the protocol.

#4488¸3/26/13 (Day 1) 6 MSI s, 100 g; 4/9/13 (Day 14) calcein; 4/23/13 (Day 28) alizarin; 5/2/13 (Day 37) calcein
The placement of 6 MSI s loaded with 100g was not described in the protocol. The calcein and alizarim administration is not done according to the schedule in the protocol.

#4494 ¸3/26/13 (Day 1) 6 MSI s, passive load; 4/9/13 (Day 14) calcein; 4/23/13 (Day 28) alizarin; 5/2/13 (Day 37) calcein
The placement of 6 MSI s was not described in the protocol. The calcein and alizarim administration is not done according to the schedule in the protocol.

The IACUC is responsible for ensuring animal procedures are conducted according to the approved

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protocol. Investigators cannot deviate from the approved protocol unless changes are approved by the IACUC. This IACUC needs to improve their post approval monitoring of animal protocols and ensure that proposed changes are approved by the IACUC prior to implementation.

To be corrected immediately.

2.31 (e) (2)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

(e) A proposal to conduct an activity involving animals, or to make a significant change in an ongoing activity involving animals, must contain the following:
(2) A rationale for involving animals, and for the appropriateness of the species and numbers of animals to be used;

****Protocol 2012-12 does not appear to have been carefully reviewed by the IACUC prior to approval. It does not provide an adequate detailed justification for the use of rabbits in this project. Under the heading "justify the appropriateness of the species", an explanation stating that rabbits are a "convenient model" and "a popular choice" does not justify the need to use this species. All proposals involving covered species must adequately justify the need for the species being used in the project.

To be corrected immediately.

2.31 (e) (3)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

(e) A proposal to conduct an activity involving animals, or to make a significant change in an ongoing activity involving animals, must contain the following:
(3) A complete description of the proposed use of the animals.

****Protocol 2012-12 does not appear to have been carefully reviewed by the IACUC prior to approval. It does not provide a clear, complete description for the use of the regulated species. The information provided in the facility' s protocol proposal does not adequately answer it's own proposal questions. For example, under "Specific Aims" the explanation outlines what they will be looking at but not why. Under " Research Plan and Experimental Setup" the explanation is confusing and incomplete. There is no explanation for why two different types of screws are being used. The pilot study mentioned is not explained. There is no explanation for how the two types of screws are to be divided evenly between the 3 treatment groups. The description of "proposed use" does not describe what day the rabbits will be sacrificed. All proposals involving covered species must thoroughly describe the procedures involved. This IACUC must improve their method for reviewing protocols prior to approval.

To be corrrected immediately.

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2.32 (c) (2)

PERSONNEL QUALIFICATIONS.

(c) Training and instruction of personnel must include guidance in at least the following areas:
(2) The concept, availability, and use of research or testing methods that limit the use of animals or minimize animal distress;

****It is the responsibility of the research facility to ensure all personnel involved in procedures using covered species are qualified to perform their duties. This includes training on writing adequate protocols that thoroughly explain and justify the proposed procedures and minimize discomfort, distress, and pain to animals. Sound scientific method should be evaluated in order to minimize the need for additional procedures and therefore additional discomfort, distress, and pain to the animals.

To be corrected immediately.

Inspection and exit interview conducted with the licensee.

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