



Inspection Report

Comparative Biosciences, Inc.
786 Lucerne Drive
Sunnyvale, CA 94085

Customer ID: 1761

Certificate: 93-R-0398

Site: 003

COMPARATIVE BIOSCIENCES, INC.

Type: ROUTINE INSPECTION

Date: 19-AUG-2016

2.31(d)(1)(iv)(A)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

Approved proposal CB-I-9232 involving guinea pigs is a Category E study that states "The endpoint of this study is death." However, the section under "Justification for Classification E" is left blank. The IACUC approved the proposal "... for one experiment only" (one subgroup of animals), and had subsequently decided not to continue with this type of experiment for welfare reasons.

Category E studies are those where measures that would commonly be undertaken to minimize pain and distress, such as administering analgesics, cannot be undertaken because they would interfere with the goals of the study, and these studies must include a scientific justification. Without an explanation as to why pain medications cannot be administered, the proposal should not be approved. The IACUC must ensure that the investigator has carefully considered all possible means to minimize any possible pain and/or distress.

Steps should be undertaken immediately to ensure that no animals unnecessarily forego standard treatments to minimize pain and distress. No activities that might cause pain or distress in Category E studies should be conducted until the IACUC reviews such scientific justifications and approves such activities.

Correction date: The noncompliance cited above should be corrected for all future proposals.

2.31(d)(1)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

The proposal CB-I-9246 involves collection of bone marrow specimens in pigs. Bone marrow was collected from one animal on February 11, 2016. The Attending Veterinarian certified their involvement in the planning of the proposed activity on February 3, 2016. The IACUC members received the proposal and approved designated member review on or about February 3, 2016. However, the Designated Member did not complete review and the proposal was not approved by the IACUC until February 26, 2016. Therefore, procedures were completed on one animal prior to approval by the IACUC.

The IACUC must ensure that no proposed activities are initiated until after complete IACUC review and approval.

Prepared By: MICHAEL SCHNELL, D V M USDA, APHIS, Animal Care

Date:
24-JAN-2018

Title: VETERINARY MEDICAL OFFICER 6100

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Initiation of any procedure prior to approval precludes the IACUC from performing review and assurances under 2.31 (d) such as related to minimization of pain or distress, consideration of alternatives, that activities do not unnecessarily duplicate previous experiments, the complete description of activities and the rationale for using animals. Therefore, lack of prospective review and approval precludes the IACUC members to fulfill their function of safeguarding the welfare of the animals.

The IACUC must assure that no proposal-related activities occur prior to IACUC approval.

Correction date: From this date forward.

2.31(e)(3)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

The proposal CB-I-9234 that involves guinea pigs states "Histology is generally performed... biopsies... may be collected by procedures from which the animals are allowed to recover. Other tissues will be removed under anesthesia as terminal procedures." However, under the Surgery section of the proposal it states "Surgical Procedures – None" and under "Surgery" it states "Not Applicable." There is no description of the biopsy or terminal procedures in the version of the proposal approved by the Institutional Animal Care and Use Committee (IACUC).

The proposal CB-I-9218 that involves pigs states "Blood samples will be collected... via either surgically implanted catheter or direct venipuncture." However, under the "Surgery" section of the proposal it states "Not Applicable." There is no description of the surgical implantation procedures in the version of the proposal approved by the Institutional Animal Care and Use Committee (IACUC).

The IACUC must ensure that the investigator has provided a complete description of all procedures to be performed on the animals. Without a complete description, the IACUC members are not able to consider possible alternatives that might minimize pain and distress for the animals, to examine and ask questions about procedures and the effects on the animals. Therefore, such omission of these details precludes the IACUC members to fulfill their function of safeguarding the welfare of the animals.

Correction date: To be corrected in all approved proposals by 11/20/16 and from this date forward for new proposals.

2.31(e)(4)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

Approved proposal CB-I-9242 involving rabbits is a Category E study. The proposal form includes a section for "Other potential stressors and procedures to monitor and minimize distress," and the investigator states: "Rabbits showing indication of pain or distress may be administered any of the following as relevant: systemic analgesics

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(eg: buprenorphine); topical local anesthetics." Later in the "Justification for Classification E" section the investigator states: "... in most studies some toxicity will be intentionally produced and there may be attendant pain and/or distress, and even mortality. In general it is assumed that pain-relieving drugs may interfere with the toxicity to be observed, and such drugs are withheld." It is not clear whether there is any reason why these animals cannot receive pain medications.

Category E studies are those where measures that would commonly be undertaken to minimize pain and distress, such as administering analgesics, cannot be undertaken because they would interfere with the goals of the study, and these studies must include a scientific justification. Without an explanation as to why pain medications cannot be administered, the proposal should not be approved.

Correction date: The noncompliance cited above should be corrected for all future proposals.

This inspection and exit briefing were conducted with facility representatives.

Additional Inspectors

Smith Pamela, Veterinary Medical Officer

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Species Inspected

Cust No	Cert No	Site	Site Name	Inspection
1761	93-R-0398	003	COMPARATIVE BIOSCIENCES, INC.	19-AUG-16

No Animals were Inspected.

Count	Scientific Name	Common Name
000000	NONE	NONE
000000	Total	