



Inspection Report

Joinn Laboratories
2600 Hilltop Drive, Building C
Richmond, CA 94806

Customer ID: **335594**
Certificate: **93-R-0594**
Site: 001
Joinn Laboratories CA Inc.

Type: ROUTINE INSPECTION
Date: 08-NOV-2023

2.31(c)(3)

Institutional Animal Care and Use Committee (IACUC).

In the letter to the Institutional Official (IO) regarding the semiannual report of the animal care and use program review and facilities inspection dated 7 August 2023, IACUC approval of the letter had not been given prior to delivery of the document. The Institutional animal care and use committee (IACUC) must prepare reports of its evaluations and submit the reports to the IO of the research facility. The reports shall be reviewed and signed by a majority of the IACUC members and submitted upon completion of the program review and inspection.

Correct by 11/29/2023

2.31(d)(8)

Institutional Animal Care and Use Committee (IACUC).

The facility has an umbrella protocol for the evaluation of the pharmacokinetic and pharmacodynamic evaluation of test materials. Each test material studied has its own separate detailed study protocol followed under the umbrella. It was noted by Inspectors that the study director/principal investigator for the umbrella protocol was different than the study director/principal investigator for the test material protocol. The AWA and regulations define the principal investigator as a single individual responsible for the proposal to conduct research and for the design and implementation of research involving animals. With separate study directors, it is not possible to know who is responsible for the design and implementation of the research. Proposed activities and proposed significant changes in ongoing activities that have been approved by the IACUC may be subject to further appropriate review and approval by officials of the research facility. However, those officials may not approve an activity involving the care and use of animals if it has not been approved by the IACUC.

Correct by 12/11/2023

2.33(a)(2)

Attending veterinarian and adequate veterinary care.

Several facility documents were noted during inspection that limit the Attending Veterinarian's authority to treat animals in their care. The facility's "Standard Operating Procedure for the Documentation and Response for Laboratory Animal

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Health Reports and Treatment Plans” describes actions veterinary staff should follow prior to administering treatment, including to “obtain permission from the SD (study director) and the Veterinarian before administering treatment. This requirement may only be waived for time-critical emergencies and only if the SD is not immediately available. The SD must approve or deny any treatments before implementation.” In addition, one of the facility’s study protocols states that “euthanasia of moribund animals will be authorized by the Study Director or Veterinarian with the concurrence of the Study Director.” The last document is an animal health report form which includes a “Review and Approval of Assessment/Plan” portion on the bottom of the form. This section allows the SD to approve or decline the proposed treatment plan, including the time the approval was obtained. An example of this occurred on 9/4/23, where the veterinarian recommended euthanasia due to the declining clinical condition of the animal and waited for SD approval to euthanize. If the attending Veterinarian cannot make decisions about veterinary care without consent from study directors, this could lead to unnecessary pain and suffering of the animals. Each research facility shall assure that the Attending Veterinarian has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

Correct by 12/4/2023

This inspection and exit interview were conducted with facility representatives.

Additional Inspectors:

KATHARINE FRANK, VETERINARY MEDICAL OFFICER

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Species Inspected

Cust No	Cert No	Site	Site Name	Inspection
335594	93-R-0594	001	Joinn Laboratories CA Inc.	08-NOV-2023

Count	Scientific Name	Common Name
000152	<i>Macaca fascicularis</i>	CRAB-EATING MACAQUE / CYNOMOLGUS MONKEY
000152	Total	