2.31  (c)  (7)
INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

A significant change was made to protocol 4307-01 without IACUC approval. The investigator added two 3mm tissue biopsies from the wings of wild bats (one biopsy per wing) without first obtaining IACUC approval. The facility reported the oversight to OLAW (Office of Laboratory Animal Welfare) stating that biopsies had been obtained from 176 captured bats that were then released prior to IACUC approval. Some species of bats approved in the initial protocol to measure bite pressures were as small as four to six grams in weight. Because the animals were released immediately following the procedure, the effect of the biopsies is not known.

Significant changes in the care and use of animals in ongoing activities may adversely affect animal well-being. The IACUC should review proposed significant changes to activities involving animals prior to the implementation of the activities.

Correct immediately.

2.31  (e)  (3)
INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

Three Institutional Animal Care and Use Committee (IACUC) approved protocols contained incomplete descriptions of activities using animals.

Protocol #4187-04 contains an incomplete description of an activity using nonhuman primates. In the survival surgery under this protocol the investigator states that incisions would be made in the skin over leg muscles with subsequent injections of a tracer substance. There was no description of the length of the incisions or which leg muscles would be used.

Protocol #4187-03 contains an incomplete description of activities using nonhuman primates. Animals in this activity are approved for multiple major operative procedures including skull implants, arm implants, and vertebral implants. There is no description of the size of incisions for any of the activities. There is no
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description of the size or locations of defects created in the skull or the instrumentation to be implanted. The only reference to the size of the vertebral incision and implant are the statements A laminectomy of several vertebrae, including dorsal spinous processes, is performed A stainless steel or plastic chamber with cap is cemented to the exposed surfaces of the vertebrae with acrylic cement. There is no description of which specific vertebrae or any maximum number of vertebrae that are to be used in the activity. There is no description of the various implanted devices or their sizes.

Three animals used on this protocol had significant health issues following the above surgical procedures. All three animals were euthanized due to the severity of the health issues attributed to the IACUC approved activities in the above protocol.

Protocol #4167-01 contains an incomplete description of activities using nonhuman primates. Animals on this activity are approved for up to three skull implants however there is no description of the size or locations of the implants. NHP #10101 was observed to have two large skull implants plus a smaller post that, in total, involved a large portion of the surface of the skull. The implants appeared to be causing the right side of the eyebrow to be depressed.

Inadequate descriptions of activities using animals may prevent the IACUC from identifying deficiencies in activities. It is the responsibility of the IACUC to ensure that the investigator provides a complete description of proposed activities that involve the use of animals in order that those activities may be adequately reviewed and determined to be in accordance with the Animal Welfare Act.

Correct by October 10, 2015 for the above protocols and during the next annual protocol review for all other protocols.

An exit briefing was conducted with a facility representative. Accompanied by Dr. Pam Smith.

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