

MedStar Health Research Institute, Inc. George Hyman Memorial Research Building, Room 126 108 Irving St. NW Washington, DC 20010

CITATION AND NOTIFICATION OF PENALTY

We believe that you violated the Animal Welfare Act (7 U.S.C. § 2131 et seq.) (AWA), as described below.

Date of Violation: November 5, 2012

9 C.F.R. § **2.32(c)(4)** Personnel qualifications. (c) Training and instruction of personnel must include guidance in at least the following areas: (4) Methods whereby deficiencies in animal care and treatment are reported, including deficiencies in animal care and treatment reported by any employee of the facility.

You failed to provide adequate training and instruction regarding methods of reporting deficiencies in animal care and treatment. During an experimental procedure, a pig had to be euthanized due to an adverse event. The pig experienced ventricular fibrillation and required resuscitation. Both the primary defibrillator and back-up defibrillator were inoperable. Additionally, the emergency medication, epinephrine, was available but expired and therefore not usable. Your staff failed to report this adverse event to the principle investigator or attending veterinarian, and continued to perform study procedures on additional animals for the next two days, during which time two additional pigs experienced adverse events and had to be euthanized.

Date of Violation: November 5, 2012

9 C.F.R. § 2.33(b) Attending veterinarian and adequate veterinary care. (b) Each research facility shall establish and maintain programs of adequate veterinary care that include: (1) The availability of appropriate facilities, personnel, equipment, and services to comply with the provisions of this subchapter and (2) The use of appropriate methods to prevent, control, diagnose, and treat diseases and injuries, and the availability of emergency, weekend, and holiday care.

During an experimental procedure, a pig experienced ventricular fibrillation and required resuscitation. Both the primary defibrillator and back-up defibrillator were inoperable. Additionally, the emergency medication, epinephrine, was available but expired and therefore not usable. The pig was subsequently euthanized.

An Equal Opportunity Provider and Employer

Reference Number: DC130005 AC Issuance Date: December 30, 2013

Version: Final



Date of Violation: November 7, 2012

9 C.F.R. § **2.32(b)** Personnel qualifications. (b) Training and instruction shall be made available, and the qualifications of personnel reviewed, with sufficient frequency to fulfill the research facility's responsibilities.

You failed to make training and instruction on procedural equipment available with sufficient frequency to fulfill your responsibilities. The staff working on a study procedure failed to notice a leak that may have contributed to a study related adverse event resulting in the euthanasia of a pig. Although the personnel had experience and training in the use of the equipment, it had been two years since the last refresher training.

Date of Violation: November 7, 2012

9 C.F.R. § 2.33(b) Attending veterinarian and adequate veterinary care. (b) Each research facility shall establish and maintain programs of adequate veterinary care that include: (1) The availability of appropriate facilities, personnel, equipment, and services to comply with the provisions of this subchapter and (2) The use of appropriate methods to prevent, control, diagnose, and treat diseases and injuries, and the availability of emergency, weekend, and holiday care.

During an experimental procedure, a pig experienced ventricular fibrillation and required resuscitation. Both the primary defibrillator and back-up defibrillator were inoperable. Additionally, the emergency medication, epinephrine, was available but expired and therefore not usable. The pig was subsequently euthanized.

The penalty for the alleged violation(s) described above is \$3,071.

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