

Title: Animal Monitoring and Documentation, IACUC Policy CMU-P-0024-01

Effective Date: May 1, 2018

Authorized by: Institutional Animal Care and Use Committee, Office of Research Compliance

Revision History: Approved: 15-March, 2018

Revised: 16-March, 2018 (JC)

I. Background

The Central Michigan University Animal Welfare Assurance to Public Health Service A4076-01 (“PHS Assurance”) states that Central Michigan University (CMU) will comply with the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals. PHS Policy requires compliance with The Animal Welfare Act and Animal Welfare Regulations (AWARs) as well as the Guide for the Care and Use of Laboratory Animals (“The Guide”). According to The Guide, “Animals should be cared for by qualified personnel every day, including weekends and holidays both as a safeguard for their wellbeing and to satisfy research requirements”¹. The Animal Welfare Act regulations² (9 C.F.R. §§ 2.33(b)(3), 2.40(b)(3)) require “dealers, exhibitors, and research facilities to observe all animals daily to assess their health and well-being”. The Central Michigan University Institutional Animal Care and Use Committee (IACUC) is charged by the PHS Assurance and CMU Institutional Policies with ensuring institutional compliance with the AWARs and the Guide.

II. Policy

In compliance with the AWARs and The Guide, it is the Policy of the CMU IACUC that all animals utilized in teaching, research and outreach activities will be observed daily to assess their health and well-being, that these observations will be documented in writing and that the documentation will be maintained in the animal room. The Principal Investigator (PI) listed on an animal use protocol is responsible for ensuring that animals are observed and assessed daily.

III. Procedures:

A. Observation/Assessment:

1. All animals must have an environmental and visual health check performed daily, as defined in section IV below.
2. In addition, animals will be minimally observed and assessed during cage changes, as defined below, with any suspected clinical abnormalities (those not already documented) being reported to the PI.
3. When Environmental Health Checks or Cage Changes are conducted by Vivarium staff (as defined below), observations of suspected clinical abnormalities will be reported to the PI if they are not already documented in the room.

- a. Observations that require timely intervention, to reduce morbidity or mortality, will immediately be reported to the PI and the vivarium/facility manger.
 - b. If the PI does not respond in a timely manner the vivarium/facility manger can initiate an SOP appropriate treatment. When necessary (e.g. an SOP or standing treatment order does not exist), the Attending Veterinarian should be consulted.
 - c. Observations will be reported to the Attending Veterinarian when vivarium staff are unable to contact the PI or their supervisor/vivarium manager
4. Detailed animal health checks, as defined below, must include manipulation of animals and/or their enclosures unless it is not appropriate for the species (e.g. aquatic species).
 - a. When appropriate, body weight must be monitored.
 - b. The frequency of monitoring will be defined in an approved protocol or SOP.
 5. Animals identified with clinical abnormalities must be monitored as described below and their cages or enclosures must be properly identified.

B. Clinical monitoring (including post-surgical monitoring and care):

1. Once clinical monitoring has been initiated based on findings of an observation/assessment (described above), a clinical monitoring record must be initiated and the veterinarian must be contacted when appropriate (e.g. if a standing treatment plan is not already in place).
2. The record can be lab/protocol specific and does not have to follow a set format. The IACUC has example post-operative monitoring forms available to any lab that does not want to create their own.
3. Minimal required information in a clinical record must include either:
All information as specified in the protocol including endpoint criteria, or;
If not specified in the protocol, the minimal acceptable information set will include:
 - c. Animal identification including: 1. Species or strain, 2. Sex, 3. Cage number/location, 4. Tattoo or tag number (if available), 5. Protocol number (or PI if PI only has one protocol), and 5. Either age or date of birth or date received. If the cage card already contains this information, the animal ID and cage number with a note to see the cage card may be sufficient but a picture or copy of the cage card containing this information should be readily available to the AV upon request.
 - d. Identity and emergency contact information of the PI and the person maintaining the clinical record and/or the emergency contact for the animal/protocol ((unless posted elsewhere in the room). At a minimum the PI must be listed.
 - e. A description of any abnormal observations (e.g. dehydration, weight loss, lesions). If there have been no changes in the clinical status of an animal it should be noted, at a minimum, that the condition has not changed.
 - f. It is recommended that standardized assessment tools [e.g. body condition scores (BCS)] be implemented to minimize the subjectivity of an assessment.
 - g. If abnormalities have been observed and treatment has been initiated, a description of the treatment(s) and periodic updates to the treatment plan, including pain management when appropriate, should be documented.

- h. Humane Endpoints should be considered for animals that have undergone prolonged treatment without improvement in consultation with the AV.

C. Reports of mortality:

1. Vivarium staff, where applicable, will report deceased animals to the research staff. A list of deceased animals, by protocol number and date, will be compiled for each room. The reports should be made the same day.
2. The PI and research staff will maintain in the animal room a consolidated list, by protocol number, of all animals that have been found dead including those that have been reported to them by the vivarium staff.
3. The PI and research staff must provide a monthly report of animals found dead for each protocol. The report must include date animals found, number found dead, and the total number of animals on the protocol.

IV Definitions

Environmental Checks (Macroenvironment): Daily environmental checks of the room which may include documenting and reporting: unusual odor, photoperiod abnormalities, temperature/humidity extremes, and inadequate ventilation (stuffy, excessive odor), inadequate supply of food or water, lack of feces or urine, decreased food or water consumption, wet or flooded enclosure, moisture condensation on micro-isolator enclosure, broken enclosure or excessively soiled enclosure.

Cage Changes: Moving animals from a soiled cage to a clean cage. Animals are observed when cages are changed and if any animals have clinical problems that are not described and addressed in clinical records maintained by the PI, this will be reported to the PI.

Reports of Morbidity and Mortality: A system to communicate observations of clinical issues impacting animal health up to and including death of the animal.

Clinical Monitoring: Daily monitoring that occurs after an animal has been determined to have an abnormality or condition that requires or may require treatment.

Detailed Animal Health Check: Health checks that may require manipulation of enclosures and physical manipulation of animals **by trained personnel** to observe appearance and behavior. Examples of conditions which should be documented during detailed health checks include but are not limited to: abnormalities of the eyes, ears, nose, mouth, or face, vocalization, inappetence, excessive sneezing, excessive scratching, cage aggression, self-mutilation, hunched posture, unkempt hair or ruffled fur, lethargy, separation or different behavior from the group, dehydration, hypothermia/hyperthermia, hair loss, skin irritation, lacerations, ulcers, tumors/masses, bleeding or discharge from an orifice, excessive weight loss (emaciation) or weight gain, , head tilt/circling in cage, lameness, diarrhea, vaginal, rectal, or penile prolapse, dystocia, red pigment around eyes (rats), difficulty breathing, convulsions/tremors or seizures. Observation of any of these or other clinical issues must result in the cage or enclosure being appropriately identified and the initiation of a clinical monitoring record.

Visual Health Check (Microenvironment): A visual check of each animal enclosure that ensures there is an adequate amount of food and water, animals are bright, alert, and responsive, absence/presence of feces or urine, wet or flooded enclosure, moisture condensation on micro-isolator enclosure, broken enclosure or excessively soiled enclosure. Visual checks may be conducted without manipulation of the cage or animal.

Principal Investigator (PI): The individual identified by an IACUC approved protocol as being responsible for the conduct of a research, teaching or outreach program. The supervisor of research staff described on an IACUC approved protocol.

Research Staff: Persons supervised by the PI and listed on an IACUC approved protocol

Vivarium Staff/Animal Care Staff: Persons who report to a vivarium manager or other institutional representative and not to the PI.

V References:

1. The Guide for the Care and Use of Laboratory Animals, 8th ed. 2011. National Research Council of the National Academies. Washington, D.C.: The National Academies Press.
2. Animal Welfare Act: [*United States Code*, Title 7 (Agriculture), Chapter 54 (Transportation, Sale, and Handling of Certain Animals), Sections 2131– 2159]; and Animal Welfare Regulations: Title 9 - Animals and Animal Products. Chapter I - Animal and Plant Health Inspection Service, Department of Agriculture.
3. Public Health Service Policy on Humane Care and Use of Laboratory Animals (2015).

Additional Information:

For questions, additional details or to request changes to this policy, please contact the IACUC Office IACUC_Admin@cmich.edu or Office of Research Compliance RESCOMPLIANCE@cmich.edu with questions.