

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC)

POLICY ON ANIMAL OBSERVATION AND RECORD KEEPING

GENERAL POLICY

The well-being of research animals depends upon careful and frequent observation and monitoring of these animals by investigators and research staff, as well as by the veterinary staff. Every IACUC-approved protocol must include a plan for observation and monitoring of animals for signs of pain or distress based upon the research procedures performed on the animals and the possible effect of the procedures on animal health and well-being. Observation and monitoring is done by both the investigator/research staff and the veterinary staff, as dictated and described by both IACUC policies and by the specific research protocol.

The Animal Welfare Act Regulations (AWAR) and PHS policy require proper documentation of animal care and use to assess compliance with research protocols and clinical care procedures. This policy outlines the expectations with regards to appropriate and necessary record-keeping for research animals at MGH.

DEFINITIONS

USDA-covered species, non-rodents: Animal species that are taxonomically defined as lagamorphs or higher and covered by the Animal Welfare Act Regulations (AWAR), e.g., rabbit, cat, dog, ferret, sheep, goat, swine, non-human primate.

USDA-covered species, rodents: Animals that are taxonomically defined as rodents and covered by the AWAR, e.g., guinea pigs, hamsters, gerbils, ground squirrels, and mice/rats except for mice (*Mus*) and rats (*Rattus*) bred for research.

Non USDA-covered rodents: Mice (*Mus*) and rats (*Rattus*) bred for research.

Non-mammal: Vertebrate animals that are not classified as mammals. Animals included in this category are fish, amphibians, reptiles, and birds.

USDA-COVERED SPECIES

Individual Animal Medical Records (IAMRs) are required for all USDA-covered species at MGH. The IAMR is expected to contain documentation of all observations, treatments, and procedures for these species.

Individual Animal Medical Record (IAMR)

The IAMR serves as:

- A permanent record of animal health and research results;
- One means of communication among the research team, and between the research team and veterinary staff;
- Documentation of adherence to the protocol and standards of veterinary medical care; and documentation of compliance with regulations and standards required by the [Animal Welfare Act](#) and the [Public Health Service Policy](#).

The IAMR must contain at minimum:

- Basic demographic information (species, strain, stock or breed, source of the animal, animal identifier, protocol number, responsible investigator, contact info, and pertinent dates)
- Clinical information: detailed clinical and diagnostic information (e.g., lab results, x-rays, pathology reports)
- Dates of inoculations, routine physical examinations, quarantine clearance
- For survival and non-survival surgeries, complete surgical records to include animal history, IACUC protocol number, preoperative preparations, surgical reports, anesthetic monitoring records, intraoperative monitoring notes, postoperative care and recovery notes.
- Any animal manipulation, conscious or anesthetized, including imaging or behavioral training sessions, obtaining physiologic parameters (e.g., blood, urine, or spinal fluid collection), breeding notations, or any other non-surgical procedures.
- Any agents, whether research or treatment related, administered to the animal, including the agent name, dose, and route of administration.
- Behavior treatment progress and status
- Documentation of veterinary/clinical exemptions to the [Policy on Environmental Enrichment, Social Housing, and Exercise of Laboratory Animals](#). The veterinarian will record the basis for the exemption, the period of single housing and frequency of reevaluation, unless it is a permanent condition.
- Final disposition of the animal or euthanasia method (include agent, dose and route) and necropsy report, if applicable

The IAMR is created and maintained by the facility where the animals are housed. In order to facilitate compliance with required medical record elements, a series of forms has been created. Form templates may be found at on the CCM intranet site ([CCM - Forms and Documents](#)); hard copies are available in the CCM facilities. Investigators are highly encouraged to use these

templates and/or forms or confirm their own system includes the required components. IAMRs must remain near the animal and be available for review. Investigators must return complete IAMRs to the facility manager within two weeks after the end of study. IAMRs must be retained as described below in **Best Practices and Record Retention**.

Research Staff Responsibilities with Regard to IAMR

Investigators and research technicians should document in the IAMR the animal's general health status, as well as any treatment, medication, or procedures performed. If an animal is having an unanticipated health problem or if an animal is in unrelieved pain or distress, this must be communicated to the veterinary staff and this communication should be documented in the IAMR. Entries should be legible, and include the date, time, and initials of the person making the entry.

Veterinary Staff Responsibilities with Regard to IAMR

The documentation of routine veterinary care for healthy animals is governed by the IACUC Policy on Adequate Veterinary Care. For animals under treatment or observation for specific concerns/conditions, veterinary staff should document in the IAMR all observations, examinations, veterinary interventions, and response to such treatments. Each entry should include a future care and observation plan until the issue at hand is resolved. Communications to the PI regarding any of the above should also be documented. If an animal is having an unanticipated health problem or if an animal is in unrelieved pain or distress, this should be communicated to the research staff and this communication should be documented in the IAMR. CCM veterinary staff documents in the IAMR the general health status as well as any treatment, medications, procedures performed, and the resolution of any clinical problems whenever they observe or perform procedures on animals. The veterinarian will also record the basis for the exemption, the period of single housing and frequency of reevaluation, unless it is a permanent condition. Entries should be legible, and include the date, time, and initials of the person making the entry.

NON USDA-COVERED SPECIES

An IAMR is not required for non-USDA-covered vertebrate species. However, documentation of observations, treatments, and procedures is still required for these species, in accordance with the approved IACUC protocol.

Mice (genus *Mus*) and Rats (genus *Rattus*) bred for research.

Rodent Record Cards are to be used for mice and rats as part of the record-keeping requirements, outlined below, and may be supplemented by other sources including laboratory notebooks. Rodent Record Cards, cage cards, notebooks and other documents must be

available for audit by the IACUC, and must have sufficient detail such that compliance with IACUC policy and approved protocols can be confirmed. These records must also be easily accessible to veterinary staff. The Rodent Record Card is available from CCM staff and in rodent procedure rooms. Instructions for using the card are posted in rodent procedure rooms and are available on the IACUC Web site ([Rodent Record Card Instructions](#)). Additional information and record templates are also available on the IACUC website ([Rodent Record Card](#)).

Anesthesia record-keeping requirements.

Anesthetic events must be documented on the Rodent Record Card, as outlined in the instructions for using the record card (date, agent, initials). Additional information that is not required on the Rodent Record Card must be recorded elsewhere and may be captured on the Rodent Record Card, in the laboratory notebook, or using another method (e.g., dose and route).

Adequacy and depth of anesthesia must be confirmed before initiating a procedure, and animals must be monitored for anesthetic depth every 15 minutes. There is no requirement to document that anesthetic depth was checked. Instead, the attestation on the Rodent Record Card, that monitoring will be conducted in accordance with the approved protocol, must be checked, and the animal must be monitored as outlined in the protocol and per this policy.

Procedural and surgical record-keeping requirements.

Any procedure performed that has a procedure form or surgery form in the approved IACUC protocol must be documented on the Rodent Record Card. For all survival and non-survival surgical procedures, the record card must include the IACUC protocol number, and the name and date of surgical procedure. Exceptions are genotyping and identification procedures.

All agents administered to the animal(s) must be documented on the Rodent Record Card.

The information recorded on the Rodent Record Card must be consistent with the instructions for the use of the card. A group of animals in one cage may be documented on a single Rodent Record Card.

Post-operative and post-procedure record-keeping requirements.

At a minimum, all treatments administered to the animal(s), including analgesics and anesthetics, must be documented on the Rodent Record Card.

An attestation must be provided on the cage card that animals will be monitored in accordance with the approved protocol. Monitoring checks may be documented on the Rodent Record Card, in the laboratory notebook, or using another method.

Observations about the animal(s) and any additional information such as animal weights, body condition scores, tumor sizes, laboratory test results (e.g., CBC), radiographs and other imaging information, histopathology/necropsy records, etc., may be documented on the Rodent Record Card, in the laboratory notebook, or using another method. Information about the animal must be recorded in accordance with the approved protocol and IACUC policy.

A group of animals in one cage may be documented on a single Rodent Record Card.

Non-mammals (fish, frogs, reptiles, birds bred for research)

For non-mammals, a Rodent Record Card or equivalent, or the laboratory notebook may be used to document all experimental manipulations of the animals. Records should also include all observations, treatments, laboratory test results (e.g., CBC), radiographs and other imaging information, and histopathology/necropsy records.

Records must be easily accessible to veterinary staff and must be available for audit by the IACUC; records must have sufficient detail such that compliance with IACUC policy and approved protocols can be confirmed.

BEST PRACTICES AND RECORD RETENTION

All entries in IAMRs, on Rodent Record Cards, in laboratory notebooks, etc., should be made proximally to the time of the treatment or observation (that is, write it down as it happens). The records must be sufficiently detailed so that compliance with IACUC policies and approved IACUC applications can be audited easily. All records must be readily available for inspection by CCM staff, Office of Animal Welfare Assurance staff, IACUC members, MGH officials, and outside regulatory agencies.

IAMRs, Rodent Record Cards, and other records are considered to be research materials that must be retained according to the [MGB Guidelines on Retention of Research Data, Materials, and Records](#).

- IAMRs must be kept while the animal is living and will be retained by CCM for seven years after the end of a research project/activity or as required by MGB guidelines, whichever is longer. Principal Investigators are responsible for retaining IAMRs for the same period in non-CCM housing areas.
- Rodent Record Cards and other records must be retained while the animal(s) is living. If the Rodent Record Card is the sole research record, it must be retained for seven years after the end of a research project/activity or as required by MGB guidelines, whichever is longer. If the information from the Rodent Record Cards was copied into a laboratory notebook, the notebook must be retained in accordance with the MGB guidelines.

RELATED POLICIES

[Policy on Adequate Veterinary Care](#)

[Policy on Anesthesia and Analgesia](#)

[Policy on Food and Fluid Restriction in Laboratory Animals](#)

[Policy on Post-Operative and Post-Procedural-Care](#)

REFERENCES

American College of Laboratory Animal Medicine (ACLAM). Position Statements: [Medical Records for Animals Used in Research, Teaching, and Testing](#). September 30, 2020.

U.S. Department of Agriculture. [Animal Welfare Act and Regulations](#) (Animal Care Blue Book). Code of Federal Regulations (CFR), Title 9, Chapter 1, Subchapter A, Parts 1-4. 2020.

U.S. Department of Health and Human Services, Office of Research Integrity. Responsible Conduct in Research: [Notebook and Data Management](#).

U.S. Department of Health and Human Services. [Public Health Service Policy on Humane Care and Use of Laboratory Animals](#). Office of Laboratory Animal Welfare, National Institutes of Health: Bethesda, MD, 2015.

v1.1, 20 February 2008

v1.2, 19 October 2011

v1.3 16 July 2014

v1.4, 1 June 2016

v1.5, 19 July 2017

v1.6, 16 June 2021