Animal Care Committee:
Monitoring and Medical Records of Animals used for Research, Teaching and Testing
Policy 017

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PURPOSE:

The purpose of this document is to present requirements for appropriate animal monitoring. This policy is intended to assist investigators in fulfilling the expectations of the UBC ACC, in maintaining welfare standards in Animal Use Protocols (protocols) and for keeping appropriate records.

Monitoring (health and welfare assessment and record keeping) is a necessary step in safeguarding animal welfare. Effective monitoring helps detect welfare concerns in the early stages and minimizes suffering and improves quality of data by reducing confounding effects resulting from stressed and sick animals. The use of well-designed monitoring records provides a systematic basis for evaluating changes in an animal's condition and ensures all relevant variables are assessed. Continued use of the same 'checklist' ensures consistency when monitoring is performed by more than one individual and continuity of care over time. These records provide valuable data and can be used for future reference to refine various aspects of research as well as refine monitoring procedures and endpoints.

All Category of Invasiveness studies of Level D or higher require a monitoring record. Exceptions must be approved by the ACC. Many Level C protocols will require a monitoring record.

DEFINITIONS:

Monitoring Record: A monitoring record is a document where clinical health variables are recorded. The document can be either a paper or digital record.

Monitoring: There are two types of monitoring: experimental and routine daily monitoring.

1. **Experimental monitoring:** monitoring of animals that have been assigned to an experimental protocol and are undergoing experimental manipulations (including but not limited to surgeries, injections, blood collection, imaging etc.) or have abnormal phenotypes.
2. **Routine Daily Monitoring**: monitoring animals for common species-specific health conditions (e.g. murine ulcerative dermatitis in mice) or husbandry

related health problems in addition to identifying experiment-related conditions for which the PI and or study team members must be notified.

POLICY STATEMENTS:

1. All animals must be observed daily as per UBC ACC requirements.
2. All required experimental monitoring and procedures and treatments performed on individual animals must be clearly documented in monitoring records.
3. These records must be readily available to the facility staff, veterinarians, the UBC ACC and the CCAC, if requested.

RESPONSIBILITIES:

Principal Investigator

1. It is the ultimate responsibility of the principal investigator (PI) to ensure that experimental monitoring is performed as approved in each protocol. This includes using the monitoring records as approved in each protocol.
2. It is the ultimate responsibility of the principal investigator (PI) to ensure that all study team members monitoring animals are a) appropriately trained and b) that all people directly working with or caring for research animals (members of the research team) have a basic understanding of the research and the procedures that the animals are undergoing including the monitoring procedures.
3. The PI can delegate experimental monitoring to study team members or facility personnel.
4. If facility personnel have been delegated to perform experimental monitoring and/or fill out monitoring records on behalf of the study team then this must be arranged by the PI or designate with facility managers to ensure full understanding of responsibilities.

Facility Personnel

5. Facility personnel are responsible for routine daily monitoring. In some rare cases, the PI can choose to carry out routine monitoring for experimental reasons.
6. If animals have a normal phenotype and are not undergoing experimental manipulation, then routine facility monitoring may be sufficient during that period.

MONITORING REQUIREMENTS:

Duration and Frequency

1. It is a guideline of the CCAC (CCAC 1993) and a requirement of the UBC ACC that all animals will be observed on a daily basis as a minimum standard.
2. Once an animal is at risk of deterioration of health or welfare then more frequent monitoring is required.
3. Animals must be monitored if continued risk of unexpected complications arise and until risk of deterioration of health or welfare is minimized and must be extended if unexpected complications arise.
4. The frequency and duration of monitoring must be determined for each study and clearly stated in the associated animal protocol. Monitoring frequency and duration will depend on a variety of factors such as severity of clinical signs, potential for deterioration, the expected time course of the experiment, and unexpected complications. For example, in infectious/toxicity studies, more frequent (e.g. hourly) monitoring may be necessary to identify the earliest point the humane endpoint has been reached or at which supportive care is required. This minimizes animal pain and/or distress. For details refer to "Guidelines on Monitoring and Medical Records of Animals used for Research, Teaching and Testing".

Health and Welfare assessment

1. Adequate monitoring requires regular assessment of general health and welfare. For rodents, the signs assessed must be based on the "Guidelines on Monitoring and Medical Records of Animals used for Research, Teaching and Testing" (unless justification is provided) and are subject to approval by the ACC.
2. Health and welfare assessment applies not only to monitoring animals for signs of pain, suffering and distress associated with procedures, but also to the routine assessment of all animals to check for any health or welfare problems (NC3R^s 2014).
    a. Signs of health and welfare include behaviours, appearance, body functions, environment, and procedure-specific signs. These will include a mixture of subjective and objective measures.
    b. The health and welfare signs to be recorded will vary between studies. At a minimum these should capture overall health and study specific concerns.
3. Health and welfare assessment involves several steps:
    - Defining suitable signs for species and procedures
    - Observation of animal to assess identified signs
    - Classification of severity (grading)
    - Plan of action (e.g. euthanasia, treatment, monitoring)
    - Record keeping

3. The health and welfare signs that will be assessed must be clearly described in the protocol and include a discrete range in severity for each sign ("scoring" or "grading" system), where possible. This will ensure that all people caring for animals can consistently assess animal health and welfare and that the severity of the condition is documented. Assigning a score to each sign described is commonly used to facilitate record keeping and endpoint determination but is not required.
4. Weight is an important objective sign of health status in many species.
5. Experimental monitoring must include assessment for all expected and potential signs associated with experimental treatments/manipulations or phenotypes. These signs must be clearly outlined in the protocol and monitoring records must be designed accordingly. The signs assessed should be based on the guidelines and must be approved on a per protocol basis by the ACC.

MONITORING RECORDS:

Records must be appended to and used as outlined in the approved animal protocol. A monitoring record should be viewed as a 'living document.' Its effectiveness and relevance should be reviewed annually. The use and effectiveness of monitoring records will also be reviewed during post-approval monitoring (PAM) activities, which include PAM Reviews and Facility Audits, Facility Manager Reports, ACC site visits and protocol renewals. Changes made to monitoring sheets must be incorporated into approved protocols by submitting an amendment.

Minimal Requirements for Monitoring Records:

1. Records must include the protocol number, PI, primary and emergency contact name, contact details.
2. All experimental procedures, supportive care, and treatments must be recorded with the date performed. Administration of all compounds (including anesthetic drugs) must be documented with volume and route of administration.
3. Animals that have undergone any experimental procedures or manipulations (including surgeries, injections, imaging etc.) must be easily identifiable. This ensures that caretakers are aware that additional monitoring may be required. **At a minimum, the name of the procedure and date must be recorded on the cage card** and all remaining details recorded on the monitoring record.
4. The health and welfare signs used to assess the animal and recorded in the monitoring record must be sufficient to document the general health of the animals and the experiment specific clinical signs that might be expected.
5. The humane endpoint criteria must be clearly written on the monitoring record.

6. Date of death or euthanasia or experimental endpoint must be recorded on the monitoring record along with the type of termination.
7. The CCAC requires that all records be kept for one year past termination of the animal, but these records can be archived outside of the animal facility.

REFERENCES:

CCAC 1993. Guide to the Care and Use of Experimental Animals, CCAC, 1993 (http://www.ccac.ca/Documents/Standards/Guidelines/Experimental_Animals_Vol1.pdf)

NC3R^{s} Welfare Assessment 2014. https://www.nc3rs.org.uk/welfare-assessment