THE UNIVERSITY RESEARCH BOARD

(URB)

Revisions to MAPP 7.10: Standard Training in Animal Care and Use

Revision to MAPP 7.12: Policy and Procedures for the Use of Animals in Research Testing and Teaching

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FOR APPROVAL

1. Revisions to MAPP 7.10: Standardized Training in Animal Care and Use

Recommended: That Senate approve and recommend to the Board of Governors through the Vice-Chancellor, changes to the policy on Standardized Training for Animal Care and Use (MAPP 7.10) as set out in **Appendix 1**.

Background

The majority of the revisions incorporate non-substantive updates, or provide clarification to accurately reflect current procedures and processes.

Substantive changes:

- The policy was revised to comply with the new MAPP policy protocol, where a policy is separated from its procedure.
- The requirement to update the Animal Care and Use on-line course was removed as it is no longer required under CCAC rules.
- Accountability for animal user training and competence was defined.

2. Revisions to MAPP 7.12: Policy and Procedures for the Use of Animals in Research Testing and Teaching

Recommended: That Senate approve and recommend to the Board of Governors through the Vice-Chancellor, changes to the Policy and Procedures on Use of Animals in Research, Testing and Teaching (MAPP 7.12) as set out in **Appendix 2**.

Background

Some of the revisions incorporate non-substantive updates, or provide clarification to accurately reflect current procedures and processes.

Substantive changes:

- The policy was revised to comply with the new MAPP policy protocol, where a policy is separated from its procedures.
- A reference to Non-Arms-Length-Managed (NALM) Certification was included and clarification regarding animal procurement was added to the policy.

Western
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MANUAL OF ADMINISTRATIVE POLICIES and PROCEDURES

POLICY #7.10 – Standardized Training in Animal Care and Use

Policy Category: Research

Subject: Standardized training in animal care and use

Approving Authority: Board of Governors

Responsible Officer: Vice-President (Research)

Responsible Office: Office of the Vice-President (Research)

Related Procedures: Procedures for Standardized Training in Animal Care and Use [web link]

Related University Policies: MAPP 7.12 [http://www.uwo.ca/univsec/mapp/section7/mapp712.pdf]

Effective Date: November 22, 2012

Revised: January 27, 2005, November 29, 2009

I. PURPOSE & SCOPE

This policy applies to all individuals who care for and/or use animals, as defined by the Canadian Council on Animal Care (CCAC), in academic endeavours for research, teaching, and/or testing, or through their employment at the University and its affiliated institutions, herein referred to as "Animal Users," describes the training required by CCAC for such individuals, and assigns responsibility for the oversight of that training.

II. POLICY

1. "Animal Users," are required to complete the following CCAC-mandated animal training:
   - 1.1 *Animal Care and Use* Sakai course;
   - 1.2 Appropriate 'hands-on' workshops and their associated Sakai prerequisites.
2. Evidence that an equivalent course or experience has been obtained elsewhere *may* exempt the Animal User from the requirement outline in paragraph 1, above. Detailed information with respect to potential exemptions is found in the associated procedures for this policy [web link].
3. Documentation that the *Animal Care and Use* Sakai course and applicable workshops have been completed successfully must be confirmed prior to performing procedures on animals.
4. On behalf of the Animal Use Subcommittee (AUS), the Animal Care and Veterinary Services (ACVS) Research Education Team will administer the University's CCAC-mandated training programs.

5. The responsibility for institutional animal user training and competence assurance is shared among ACVS Research Education Team, as well as Principal Investigators and other supervisors, e.g. facility managers. Principal Investigators and supervisors are responsible to oversee all new animal users and ensure demonstrated competence of all individuals working with animals associated with AUS-approved Animal Use Protocols within AUS-approved areas,

6. Competence in animal procedures is defined as meeting the appropriate standards in accordance with all regulatory guidelines.

Procedures for Standardized Training in Animal Care & Use

I Training Program

1. On behalf of the AUS, the ACVS Research Education Team will:

    1.1 Develop appropriate training programs with reference to CCAC requirements;

    1.2 Assess the training requirements of all personnel at the University and its affiliated institutions that have been added to the *Personnel Training Requirements* section within *Animal Use Protocol, Annual Renewal,* and *Protocol Modification* forms, and those associated with animal care and use as employees of the University and its affiliates;

        1.2.1 Where problems of animal care and use occur, the AUS may require further individual training before animal work may resume.

    1.3 Communicate outstanding training requirements and associated processes to individuals and their supervisors (Principal Investigator or Manager);

    1.4. Implement training programs;

    1.5 Document training requirements and history using a training database for all individuals requiring CCAC-mandated training.

2. Non-Compliance Response – Instances of procedural non-compliance will be pursued in accordance with the AUS Post Approval Monitoring Policy.

II Training Exemptions

1. Competency Assessment – Principal Investigators may request a competency assessment for themselves and their research staff in lieu of hands-on workshop completion. Competency assessments are available only to individuals with extensive and demonstrated experience in animal care and use. In lieu of instruction, participants will be asked to demonstrate skills as outlined within their Animal Use Protocols. The AUS Chair and/or the ACVS Director and/or an ACVS Veterinarian and/or arms-length Principal Investigators with recognized expertise may be asked to assist the ACVS Research Education Team in evaluating the Animal User's eligibility for a competency assessment or other training exemption.

2. Training exemptions *may* be considered if writt*en* documentation illustrating equivalent training obtained elsewhere is provided to the ACVS Research Education Team.

    2.1 The AUS has final authority for the granting of training exemptions

3. Individuals exempted through a competency assessment (2.1) will receive a *Certificate of Competence* from the ACVS Research Education Team.

4. The AUS may revoke a *Certificate of Competence* if evidence is presented to the Committee that the individual is no longer competent in a defined procedure or specialty. The individual will be required to take training indicated by the AUS Chair before resuming animal work.

Western

MANUAL OF ADMINISTRATIVE POLICIES and PROCEDURES

POLICY #7.12 – POLICY FOR THE USE OF ANIMALS IN RESEARCH, TESTING AND TEACHING

Policy Category:	Research
Subject:	Use of Animals in Research, Testing and Teaching
Approving Authority:	Board of Governors
Responsible Officer:	Vice-President (Research)
Responsible Office:	Office of the Vice-President (Research)
Related Procedures:	Procedures for the Use of Animals in Research, Testing & Teaching [web link]
Related University Policies:	MAPP 7.10 [http://www.uwo.ca/univsec/mapp/section7/mapp710.pdf]
Effective Date:	November 22, 2012
Revised:	September 26, 2006, November 26, 2009

I. PURPOSE & SCOPE

This policy and its associated procedures apply to all instances of research, testing and teaching involving animals performed at Western, its affiliated hospitals, affiliated university colleges and research institutes, to field research that involves more than simple observation (e.g., trapping, artificial provisioning), and to Principal Investigators or instructors.

The policy outlines the responsibilities and accountabilities of university officers and the various committees and subcommittees established in accordance with the regulations of the Canadian Council on Animal Care (CCAC).

Failure to comply with this policy and its associated procedures may prevent approval of *Animal Use Protocols* (AUPs), and may result in the withdrawal of AUP approval by AUS. As warranted by the severity of circumstances, this may also include revoking University approval for research, testing and teaching involving animals, and notification of this decision to Department Chairs, Institute Heads, and appropriate granting and licensing agencies.

II. POLICY

1. The University Council on Animal Care (UCAC), chaired by the Vice-President (Research), is responsible to Senate for all aspects of procurement, maintenance and use of animals as defined by the Canadian Council on Animal Care (CCAC), hereafter referred to as "animals," in research, testing and teaching. UCAC shall ensure adequate institutional oversight according to the outlined procedures in this document, and as outlined within its *Terms of Reference*.

2. The Vice-President (Research) is the senior administrative officer of the University responsible for the care and use of animals at the University and its affiliated institutions - London Health Sciences Centre/Lawson Health Research Institute, St. Joseph's Hospital, Robarts Research Institute, Siebens-Drake Medical Research Institute, Huron University College, Kings University College, Brescia University College, Child and Parent Resource Institute.

3. A subcommittee of the UCAC, the Animal Care Governance Steering Committee (ACGSC) is responsible for reviewing and administering matters on behalf of the UCAC and advising the Animal Use Subcommittee on matters requiring time-sensitive consideration, as outlined within its *Terms of Reference*.

4. A subcommittee of UCAC, the Animal Use Subcommittee (AUS) is responsible to UCAC for ensuring that the care and use of animals associated with the University's research, testing and teaching activities are in compliance with all Federal, Provincial, and University policy statutory requirements, regulations and guidelines, as outlined within the *Terms of Reference* of ACGSC.

5. The Department of Animal Care and Veterinary Services (ACVS), under the leadership of its Director and directly accountable to the Vice-President (Research), serves the University and its affiliated institutions, its associated committees, and the research community, by ensuring animal care and use meets all Federal, Provincial, and University policy statutory requirements, regulations, and guidelines, and by facilitating the research of scientists using CCAC-defined animal models.

6. ACVS Veterinary Services staff, Institutional Compliance Officers, Facility Managers, Animal Care staff, Principal Investigators, and research staff, share responsibility for the ongoing assessment and maintenance of appropriate animal care and welfare.

7. Any Principal Investigator or instructor intending to use animals for research, testing or teaching in association with the University or its affiliates must be a University faculty member or veterinarian or LHSC-Lawson appointed scientist, unless otherwise approved by the AUS.

Procedures for the Use of Animals in Research, Testing & Teaching

I Animal Use Protocols (AUPs)

1. AUP form content, review and approval policies and processes will be developed and undertaken in accordance with all Federal, Provincial, and University policy statutory requirements and guidelines, and as detailed within the *Animal Use Subcommittee's Terms of Reference*.

2. If any AUP content is at variance with the aforementioned guidelines, scientific justification will be required.

3. The review and approval of AUP forms by the AUS is required prior to the commencement of all research, testing and teaching involving animals.

4. Assurances to funding agencies will be provided upon AUP approval.

5. Pursuant to existing policy of the University and of the broader scientific community, the Protocol is considered to be the intellectual property of the researcher, available only for confidential use by authorized individuals and not for distribution.

II. Post Approval Monitoring and Non-Compliance Response

1. The *AUS Post Approval Monitoring Policy* will be followed in order to monitor animal care and use and ensure compliance with the approved AUP.

2. Post approval monitoring (PAM) is undertaken by multiple sources and centralized through the ACVS Protocol Support Veterinarian (PS Vet), as outlined within th*e AUS Post Approval Monitoring Policy.*

   2.1 All individuals under the jurisdiction of UCAC, including animal users, scientists, research staff, animal care workers, compliance officers, facility managers, and ACVS staff are required to report any and all unanticipated animal welfare, care or use problems, or complications to the AUS through the PS Vet.

3. Procedural and Ethical non-compliance are defined, and the associated response steps are outlined within the *AUS Post Approval Monitoring Policy* document.

   3.1 When matters of non-compliance are identified through PAM sources, non-compliance response involves the collaboration of the PS Vet or another ACVS veterinarian, AUS PI Representatives, other AUS members, as required, and animal users towards collegial issue resolution.

   3.2 The Principal Investigator will be informed in writing of the decision of AUS and the reasons for the decision.

   3.3 The Principal Investigator and any other personnel involved must comply with the decision of AUS pending the outcome of any appeal.

   3.4 If the decision is appealed by the investigator and AUS did not terminate animal use or procedures, the ACVS Director will determine whether or not animal use may continue during any period of appeal. If the Director of ACVS decides that there is an immediate and serious threat to the health or safety of the animals or personnel, he or she may suspend animal use until disposition of the appeal. Such a decision cannot be appealed.

4. Non-Arms-Length-Managed (NALM) Certification – The AUS will ensure that all NALM areas will undergo inspection and pre-approval prior to initial use and yearly recertification, as described within the Animal Certification of Animal Holding/Housing within Non-Arms-Length-Managed Facilities policy. This policy applies to all research groups intending to and/or actively holding animals, including overnight housing or housing beyond 12 hours, in an area not daily overseen by a facility manager or designate that is considered to be at arm's length from the research group.

5. Facility Access - In order to facilitate post approval monitoring and non-compliance response, the AUS Chair or designate(s) and ACVS Veterinarians will have unrestricted access to all

animal facilities at all times. The associated AUS-approved Standard Operating Procedure will be followed to ensure that access does not adversely impact the health status of any facility.

6. CCAC-Mandated Training **-** The AUS will ensure that all personnel listed on the AUP have been appropriately trained according to the expectations defined in the CCAC Guidelines and Policy Statements and as provided for in MAPP 7.10 "Standardized Training in Animal Care and Use". The ACVS Research Education Team will facilitate CCAC mandated training on behalf of the AUS.

III Other Procedures

1. Animal Procurement – Animals may only be acquired on an approved AUP. With the exception of wild-caught animals, animal procurement must be managed centrally through an AUS-approved arm's-length facility manager, as per the AUS Animal Procurement Policy.

2. Animal Transfers – When animals are transferred from Western or its affiliates to an external institution, the AUS will ensure that an associated *Animal Use Protocol* approved by the external institution's animal care committee is in place.

3. Health Monitoring - Surveillance of animal health will follow AUS-approved standard operating procedures and will be centrally coordinated by ACVS so as to facilitate the transfer of animals between rodent barriers of equivalent health status; conventional facilities of equivalent health status; and specialized areas such as imaging equipment.

   3.1 Principal Investigators and Facility Managers shall:

   3.1(a) record all animal deaths in a logavailable readily available at all times and to be made available upon request to ACVS veterinarians, AUS members, and regulatory inspectors

   3.1(b) notify ACVS or an ACVS-assigned designate. Unless directed by an ACVS veterinarian, all bodies are to be held for post-mortem examination by an ACVS Veterinarian.

4. Cell Line & Biological Testing – Testing of cell lines and biologicals shall follow AUS-approved standard operating procedures.

IV Appeals

1. Appeals of AUS decisions must be made to the Chair of the Animal Care Governance Steering Committee (ACGSC), c/o the University Secretariat, in writing, within 30 days of a decision.

2. The Letter of Appeal must set out in detail a full description of the matter under appeal; the grounds of appeal; a copy of the AUS decision; and all supporting documentation. Appeals may be made on either, or both, of the following grounds: that the decision was inappropriate or unreasonable in light of the evidence (scientific or other) presented to AUS, and that the review of AUS lacked procedural fairness.

3. Within three weeks of receipt by the Chair of the ACGSC of an appeal notice, the ACGSC will hold a preliminary meeting and AUS will forward to the ACGSC Chair, c/o the University Secretariat, full documentation pertaining to the appeal.

4. Parties to the appeal shall be given copies of all material filed with the ACGSC, and given an opportunity to be heard. Opinions of external experts may be provided to the ACGSC by the parties.

5. Meetings of the ACGSC held for consideration of appeals shall include as non-voting members University legal counsel and the Secretary of Senate (or designate).

6. At the preliminary meeting the ACGSC will establish its own procedures for hearing an appeal and will determine its decision-making basis preference for either written submissions or an oral hearing.

6.1 If the appeal is made regarding a decision to disallow animal use or to terminate a research, testing, or teaching activity, the ACGSC must hold an oral hearing.

7. The parties will be advised of this decision.

8. In the case of an appeal by a Principal Investigator or instructor, the parties to the appeal are the Principal Investigator, AUS and the ACVS Director.

9. In the case of an appeal by an ACVS Veterinarian, the parties to the appeal are the ACVS veterinarian, AUS, the ACVS Director, and the Principal Investigator.

10. The right to be represented by counsel will be accorded to the principal parties to the appeal. The ACGSC also reserves the right to retain counsel.

11. Deliberations of the ACGSC will be held in camera.

12. The Committee's decision will be based on a "balance of probabilities" standard.

13. Each voting member of the Committee must cast a vote; there will be no abstentions.

14.` The ACGSC may:

14.1 Deny the appeal,

14.2 Grant the appeal and quash or modify the original decision, or

14.3 Direct AUS to re-hear the matter or reconsider some pertinent aspect of its decision.

15. The parties to the appeal will be informed in writing of the decision of the ACGSC, and the reasons for the decision, within a reasonable time following the hearing. The decision, including reasons, will be reported to UCAC and AUS at their next regular meetings. Other individuals will be notified of the decision on a need to know basis only as determined by the ACGSC.

16. The decision of the ACGSC is final.

17. Costs will not be awarded by the ACGSC.