



## POLICY

<b>TITLE:</b>	<b>Protocol Submission, Review &amp; Approval</b>
<b>Policy Number:</b>	2014-042
<b>Responsible Department:</b>	Institutional Animal Care and Use Committee
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<b>Approval Date:</b>	10/8/14
<b>Reviewed Date:</b>	4/13/17; 6/10/2020
<b>Revised:</b>	10/12/16 (Assigning DMRs); 4/13/17 (editable format required; DMR may not decline activities; PI responsible for knowing when protocols expire); 6/10/2020 (Added use of electronic signatures; noting descriptions of potential adverse effects to animals health/welfare)
<b>Legislation:</b>	Animal Welfare Act (Title 9 CFR Subchapter A, Part 2, Subpart C, § 2.31(d))

**Purpose of Policy:** Describes the process and requirements for submission, review and approval of the use of animals in teaching or research at Western University of Health Sciences (WesternU).

**Policy Information:** The [Animal Welfare Act](#) and [Public Health Service Policy](#) require that the Institutional Animal Care and Use Committee (IACUC) review and approve the use of all animals in research and that such use be reviewed annually and at 3-year intervals to maintain approval of any such use of animals. Both policies also permit Designated Review of the use of animals in research.

The IACUC will meet once a month unless there is no new or urgent business before the committee. Special meetings may be called as deemed necessary by the IACUC chair. No animal, live or dead, may be used in teaching or research without prior approval from the IACUC. Investigators may request the IACUC for an exemption for observational studies that do not involve contact with animals or their tissues or alter their environment in any way.

### Submission:

- Investigators must submit to the Office of the IACUC an electronic copy of a completed Institution Animal Care and Use Protocol Application form as a Word-formatted, editable, document. In addition, a signed hard copy, or a copy with electronic signatures, of the form must be submitted. Do not submit electronic copies in pdf format as they may be returned to the principal investigator without review. The application form may be obtained from the IACUC secretary or from the [IACUC website](#).

- Protocol applications must be submitted on the latest version of the form at least two weeks prior to the next regularly scheduled IACUC meeting. Investigators may contact the IACUC chair for when the next meeting will be held.
- **Only one person may be identified on the application form as the Principal Investigator (PI).** This person must meet the criteria established in IACUC Policy 2014-013, “Principal Investigator Status & Protocol Submission”.
- **Only the PI may submit**
  - requests to amend a previously approved protocol,
  - revised protocols in response to IACUC concerns,
  - annual renewal and progress reports and
  - 3-year renewals.

#### Review:

- Prior to IACUC review, each member of the Committee shall be provided with a list of proposed activities to be reviewed.
- Written descriptions of all proposed activities that involve the care and use of animals shall be available to all IACUC members. Close attention should be given to explaining what animals might experience while on the protocol including descriptions of potential adverse impacts to animal health and welfare. Descriptions of plans for monitoring for changes in animal welfare and endpoints associated with decline are important for efficient protocol review.
- Any member of the IACUC may obtain, upon request, full Committee review (FCR) of those activities.
- If FCR is not requested, at least one member of the IACUC, designated by the Chair and qualified to conduct the review, shall review those activities and shall have the authority to approve, require modifications in to secure approval, or request FCR of any of those activities. This process is called designated member review (DMR). The DMR may not, however, decline any activities. Activities that are not approvable by the DMR must be referred for FCR.

If, for any reason, the DMR is unable to complete the review, the IACUC’s administrative staff may either assign the protocol review to the DMR’s named, appointed voting alternate member, barring a conflict of interest, or refer the protocol back to the IACUC Chair for reassignment of a DMR.

- If FCR is requested for a proposed activity, approval of that activity may be granted only after review at a convened meeting of a quorum of the IACUC and with the approval vote of a majority of the quorum present.
- No member may participate in the IACUC review or approval of an activity in which that member has a conflicting interest (e.g., is personally involved in the activity), except to provide information requested by the IACUC; nor may a member who has a conflicting interest contribute to the constitution of a quorum.
- The following policy is unanimously agreed to by the voting members of the IACUC:
  - A quorum of members present at a convened meeting of the IACUC can decide by unanimous vote to use DMR subsequent to FCR when modification is needed to secure approval of a protocol. However, any voting member of the IACUC may, at any time, request to see the revised protocol and/or request FCR of the protocol. The modified

protocol will be reviewed using either FCR or DMR as determined by a unanimous vote of the members present at the convened meeting.

- A request by the IACUC for additional information or modifications in a protocol will be made in writing. The PI must respond to the request within the time frame indicated by the IACUC or the protocol may not receive further consideration.
- IACUC-approved modifications to a protocol must be incorporated into the appropriate places in the application form.
- The IACUC reserves the right to administratively withdraw a protocol from further review if the PI fails to respond to the IACUC's review in a timely fashion. What constitutes a timely fashion will be determined at the discretion of the IACUC based on the situation involved.

#### **Approval:**

- Once modifications to a protocol are approved by the IACUC, the PI must submit an electronic copy and a signed hard copy of the final version of the protocol to the Office of the IACUC.
- PIs will be notified in writing if and when their submitted protocol has been approved or returned for clarification.
- An approved protocol involving species covered by the United States Department of Agriculture (USDA) will remain in effect for one year from the date of approval after which time a new protocol must be submitted for review and approval prior to continuing any work with animals covered by the protocol.
- An approved protocol involving species not covered by the USDA will remain in effect for three years from the date of approval after which time a new protocol must be submitted for review and approval prior to continuing any work with animals covered by the protocol.
- PIs must submit an Annual Renewal and Progress Report form which may be obtained from the IACUC secretary or from the [IACUC website](#). Failure to submit this report in a timely fashion may result in actions being taken by the IACUC.

**It is the PI's responsibility to keep track of when their protocols expire and when their annual reports are due and re-submit in a timely fashion.** However, as a service only, the IACUC Office will notify PIs two months in advance that their protocol is about to expire and that they must submit a new protocol in time for review and approval by the IACUC before the protocol expiration date. In the absence of a re-submission, the protocol will automatically be closed.

Animals housed under protocols that have expired before a new protocol is submitted and approved by the IACUC will be transferred to the IACUC's Holding Protocol and all research involving the use of animals covered by the original approved protocol will stop until such time a new protocol is submitted, reviewed and approved by the IACUC. At such time, the animals will be transferred from the Holding Protocol to the new protocol.

**Related Policies:** IACUC Policy No. 2014-038, Holding Protocol; IACUC Policy No. 2014-041, Conflicts of Interest; IACUC Policy No. 2016-054, Establishing a Quorum and Voting.