

**The University of Western Ontario
Animal Use Subcommittee (AUS)
Standard Operating Procedure for the Protocol Review Process**

A. INITIAL PROTOCOL FORM SUBMISSION & PRE-REVIEW

1. Safety Pre-Authorization Requirement

All forms containing any hazardous and new (not within the eSirius Material and Device lists) agent, material, and imaging device, will receive related institutional safety officer(s) pre-approval prior to AUS approval. All agents are presumed hazardous and therefore subject to safety review until institutional safety officers determine otherwise. **The AUS is not responsible for any delays in the review of hazardous materials by institutional safety officers.**

- 1.1. *Semi-Annual eSirius Material & Device Lists' Assessment* - On a semi-annual basis, institutional safety officers will audit the eSirius *Materials & Devices* lists to ensure appropriateness of material and device type (hazardous vs. non-hazardous), class, and category.
- 1.2. *Single Reviewer per Hazardous Type* – The safety officer per hazardous category - Biological, Chemical, Radioactive/Imaging - from the institution to house the animals post-exposure will review and approve materials & devices within each *Animal Use Protocol*.
 - 1.2.1. *Biologicals Only* – The Principal Investigator (PI) will append the approved Biohazard Registry Form to the *Animal Use Protocol*. Only questions in addition to those within the BHRF form will require safety officer approval.
 - 1.2.2. *Chemicals Only* – The PI will append the related MSDS sheet to the *Animal Use Protocol*.
- 1.3. See Section C. for review workflows for all AUS reviewers, including safety officers.

2. Scientific Peer Pre-Review

Where peer review has not already been documented by the granting agency, the AUS must, in accordance with CCAC policy “solicit two reviews of the objectives, hypotheses, methods and contributions of the project by knowledgeable scientists who do not collaborate with the investigator.”¹ In order to expedite full approval, any protocol without a confirmed funding award involving scientific peer review will automatically be sent for scientific peer review by the assigned AUS AO. Scientific peer review approvals must be received by the AUS Administrative Officer (AUS AO) before the *Protocol Formal Review* (See Section C) process commences. **The AUS is not responsible for delays on the part of scientific peer reviewers.**

- 2.1. On a semi-annual basis, Research Western Administration will authorize a [list](#) of potential scientific peer reviewers sub-grouped according to major areas of scientific expertise, e.g. imaging, from which AUS AO's will randomly select.
- 2.2. Each sub-group will contain a minimum of 6 potential peer reviewers external to the AUS;
- 2.3. The PI will submit the first draft of an *Animal Use Protocol* or *Protocol Modification* form indicating within form Section B.3 the granting source scientific peer review status. In order to remove unnecessary barriers, PIs have the option to request internal scientific peer review, may provide an approved Grant number, or may provide the funding score

¹ Canadian Council on Animal Care CCAC Policy on the Importance of Independent Peer Review of the Scientific Merit of Animal-Based Research Projects (2000) Retrieved 09.30.08 from: http://www.ccac.ca/en/CCAC_Programs/Guidelines_Policies/POLICIES/PEER.HTM

- and/or funding source assessment, which may be considered in lieu of scientific peer review (e.g. minimum Grant Score of 3.2). However, if the funding source does not utilize scientific peer reviewers, the *Animal Use Protocol* will undergo internal scientific peer review.
- 2.3.1.** If 'Yes' to "Does this source conduct peer review?" is checked and the related Grant approval number is listed within the protocol form, the form will be assessed for review workflow (See Sect.C.1).
 - 2.3.2.** If 'Yes' to "Does this source conduct peer review?" is checked, and the PI has provided a copy of the Funding source assessment (see Sect.A.2.3.), the assigned AUS AO will forward funding source assessment to the designated review group (See Sect. C) for determination if an internal scientific peer review is required;
 - 2.3.3.** If 'Yes' to "Does this source conduct peer review?" is checked, but the related Grant approval number is not listed within the protocol form and the PI has not provided a copy of the Funding source assessment (see Sect.A.2.3.), the assigned AUS AO will contact RD&S Records Coordinator to request funding approval confirmation;
 - 2.3.3.1.** If funding approval is not confirmed, the assigned AUS AO will forward the protocol form for scientific peer review;
 - 2.3.3.2.** If funding approval is confirmed, the form will be assessed for review workflow (See Sect.C.1).
 - 2.3.4.** If 'No' or 'Unsure' to "Does this source conduct peer review?" is checked, the assigned AUS AO will forward the protocol form for scientific peer review;
- 2.4.** The assigned AUS AO will request scientific peer review via email and/or telephone from three scientists associated with the protocol's major research area listed within the *Scientific Peer Reviewers List*, and will request *Scientific Peer Review Template* submission:
- 2.4.1.** At least one peer reviewer must be external to the AUS;
 - 2.4.2.** Scientific peers have optimally **2 business days** to accept or reject the request;
 - 2.4.3.** If scientific peers decline or do not respond, the assigned AUS AO will request review by alternates on the *Scientific Peer Reviewers List*.
- 2.5.** Once accepted by reviewers, the assigned AUS AO will forward the protocol form, form-related documentation, and reviewer guidelines to two scientific peer reviewers requesting review via eSirius response **within 5 business days**.
- 2.6.** **Within 2 business days** of review receipt, if required, the assigned AUS AO will forward scientific reviewer comments & suggestions to PI for response;
- 2.7.** PI response to reviewer comments and/or questions is requested to be **within 5 business days** of email receipt;
- 2.7.1.** The review process will be put on hold until the PI response is received. If no response is received within 6 months, the protocol form will be completely removed from the workflow, and a new resubmission will be required.
- 2.8.** **Within 2 business days**, the assigned AUS AO will forward PI response to associated scientific reviewers for response;
- 2.9.** Scientific peer reviewer will send follow-up response to AUS AO **optimally within 2 business days**;
- 2.9.1.** If approved by both scientific peer reviewers, the form will be assessed for review workflow (See Sect.C.1);

- 2.9.2. If not approved by both scientific peer reviewers, the assigned AUS AO will forward reviewer comments to ACVS Director/Research Western administration (a faculty member with VP portfolio) for follow-up;
- 2.9.2.1. ACVS Director / Research Western senior administration will contact the PI and hear his/her appeal request; if appropriate, ACVS Director / Research Western senior administration will authorize the form's assessment by an alternate scientific peer reviewer.
- 2.10. Scientific peer review approvals must be received by the AUS AO before the *Protocol Formal Review* (See Section C) process commences.
- 2.11. Anonymous scientific peer reviewer and PI responses will be appended to the related *Animal Use Protocol* form and distributed to associated reviewers.

B. PROTOCOL FACILITATION SERVICE

- 1.1. Protocol facilitation is an optional service for all, except for forms identified by the AUS AO or ACVS Veterinarian as needing significant revisions or clarification.
- 1.2. **Protocol Facilitation Meeting** - The protocol facilitation meeting service, offered to all PIs for all *AUP* forms, and *MOD* forms involving potentially significant changes, provides an opportunity for the Researcher, Designate, ACVS Veterinarian and AUS AO to collaborate with the objective of developing a protocol application that facilitates a streamlined review. This meeting is also offered to PIs requesting advance assistance in initial form completion. Specific benefits of this service include:
- 1.2.1. Immediate response to Researcher questions and concerns by an ACVS Veterinarian and AUS AO;
- 1.2.2. The opportunity to receive ACVS Veterinarian expertise relating to refinements for animal-based project elements including species use and number justification and animal-related procedures (e.g. anesthesia and analgesia regimens, endpoints), if applicable;
- 1.2.3. The opportunity to receive suggestions from an AUS AO specific to AUS form content requirements that ensure a complete and understandable format (e.g. flow chart design).
- 1.3. **Meeting Process** - Within **10 business days** of initial form submission, the PI and/or PI Designate, if desired, will be given the opportunity to have an in-person or telephone preliminary review meeting with the assigned AUS AO and ACVS Veterinarian during which questions and suggested refinements will be discussed.
- 1.3.1. Pre-review meeting opportunities are offered during established weekly sessions (5 hours per week)
- 1.3.1.1. Each ACVS veterinarian will set aside a minimum of 1 hour per week (Protocol Support veterinarian 2 hours) for protocol facilitation participation.
- 1.3.1.2. Each ACVS veterinarian will communicate availability a month in advance to AUS AOs during weekly *AUS AO/ACVS Vet Update Meetings*.
- 1.3.1.3. AUS AOs will maintain updated web calendar with vet meeting availability and arrangement details.
- 1.4. Discussions/Correspondence will continue until the PI feels comfortable with his/her form content.
- 1.5. If the protocol facilitation service is not required or not desired by the PI, the AUS AO's and ACVS Veterinarian's comments and/or questions will be incorporated into the formal review process.

2. Second Draft Form Submission -

- 2.1. PI or Designate will send via eSirius website the AUS AO a second draft of the *AUP* or *MOD* form with all revisions included, and will request *Protocol Formal Review (Sect.C)*.
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C. PROTOCOL FORMAL REVIEW

1. Protocol Form Workflow Assessment

- 1.1. A first draft of a completed electronic *AUP*, *REN* or *MOD* form, authorized by the Principal Investigator (PI) or Designate, will be submitted to the AUS Office via eSirius protocol management website
- 1.2. If a new *AUP* or a protocol involving *Teaching*, the Department Chair will also be cc'd.
- 1.3. Every protocol will be assigned to a specific AUS AO & ACVS Veterinarian.
- 1.4. The assigned AUS AO will have **2 business days** to assess form content and determine one of the following review workflows:
 - 1.4.1. Office Review
 - 1.4.2. Designated Review
 - 1.4.3. Full Review

1.5. Office Review Criteria

Office Review workflow will be used for requested '**minor**' changes within **Protocol Modifications that neither deleteriously impact the animal(s) nor require new skills**. Approval will be granted by either the AUS AO, or an ACVS veterinarian. Additionally, all office approvals will be presented to the full AUS on a monthly basis.

1.5.1. AUS AO may grant approval for the following *Protocol Modification* changes:

- 1.5.1.1. Staff & their training requirements
- 1.5.1.2. Protocol Title
- 1.5.1.3. Granting information
- 1.5.1.4. Animal Source (except involving transfer of previously 'used' animals between protocols)
- 1.5.1.5. Animal Strain - addition of non-genetically modified strains
- 1.5.1.6. Animal Number increase up to 10%

1.5.2. ACVS Veterinarian may grant approval for the following changes:

- 1.5.2.1. Protocol Modifications involving:
 - 1.5.2.1.1. Housing or Use location change (*Facility Managers will be included in review process*);
 - 1.5.2.1.2. Euthanasia method change (CCAC acceptable only) not involving SOPs;
 - 1.5.2.1.3. Acute procedures on a fully anesthetized animal that will not be recovered;
 - 1.5.2.1.4. Analgesia & anesthesia regime change;
 - 1.5.2.1.5. A change to a less invasive, distressful or painful procedure;

- 1.5.2.1.6. Animal Number increase up to 25%;
- 1.5.2.1.7. Transfer of animals between protocols (Protocol Transfers involving previous animal use, excluding breeders, moms & surplus animals)
- 1.5.2.1.8. Animal Strain – addition of genetically modified strains

1.5.3. For **Office Approval Process Detail**, see **Sect. C.2.1.4**

1.5.4. AUS Full Disclosure – On a monthly basis, the AUS AO will present protocol *Modification Detail* reports associated with forms having received Office Approval.

1.5.4.1. [Modification Detail Reports](#) will be

- 1.5.4.1.1. Posted to the eSirius Monthly Meeting Web-Agenda;
- 1.5.4.1.2. Presented for discussion at an AUS Meeting by the AUS AO.

1.6. Designated Review Criteria

1.6.1. The Designated Review process involves a Protocol Review Committee consisting of an alternating subset of 5 AUS members having the following roles:

- 1.6.1.1. AUS Chair/Vice Chair,
- 1.6.1.2. ACVS Veterinarian,
- 1.6.1.3. AUS Scientific Representative (PI, Grad. Student, or Animal Technician),
- 1.6.1.4. AUS Community Representative,
- 1.6.1.5. AUS Administrative Officer.

1.6.2. Following opportunity to call for full review (see C. 2.2.2.2.), the review and approval by the designated reviewers will be carried out during weekly Protocol Review Meetings (see Sect. C.2.2). Protocol forms involving the following elements will undergo Designated Review:

1.6.3. *Protocol Modifications* involving:

- 1.6.3.1. Chronic studies containing animal procedural changes;
- 1.6.3.2. Species change, except involving species deemed ethically sensitive by the AUS;
- 1.6.3.3. Animal number increase up to 100%
- 1.6.3.4. New agents, materials, or devices.

1.6.4. *Annual Renewals*;

1.6.5. Pilot study *Animal Use Protocol* submissions, excluding 'E' Category of Invasiveness and ethically sensitive species;

1.6.6. Final review and approval of *Animal Use Protocols* approved pending clarification during monthly meetings;

1.6.7. Interim approval of *Animal Use Protocols* to be used infrequently.

1.6.8. For the **Designated Review Approval Process** detail, see **Sect. C.2.2.5**

1.6.9. AUS Full Disclosure – On a monthly basis, the AUS AO will produce protocol Modification & Annual [Renewal Detail Reports](#) associated with forms approved by the Protocol Review Committee. These reports will be

- 1.6.9.1. Posted to the Monthly Meeting Web-Agenda;
- 1.6.9.2. Presented for discussion at an AUS Meeting by members of the Protocol

Review Committee.

1.7. Full Review Criteria

Animal Use Protocol, Annual Renewal and Protocol Modification forms involving the following elements will be automatically considered to require Full Review:

- 1.7.1. Any protocol form upon request by any AUS Member, ACVS Veterinarian, or regulatory body (OMAFRA, CCAC);
- 1.7.2. All New *Animal Use Protocols*, except Pilot studies (see Sect.C.1.6.5.)
 - 1.7.2.1. Post Pilot Full *Animal Use Protocol* submission;
 - 1.7.2.2. Pilot *Animal Use Protocols* involving Level 'E' Category of Invasiveness;
 - 1.7.2.3. Interim-approved *Animal Use Protocols* (See Sect.C.1.6.7)
- 1.7.3. *Annual Renewals* as requested by the full AUS and/or AUS Protocol Review Committee;
- 1.7.4. Protocol Modifications involving:
 - 1.7.4.1. Animal procedural changes involving Category of Invasiveness level ' E'
 - 1.7.4.2. Use of animal models that employ ascites;
 - 1.7.4.3. Multiple major survival surgeries;
 - 1.7.4.4. Food and/or water deprivation resulting in pain or distress as determined by the reviewing ACVS Veterinarian;
 - 1.7.4.5. Species change involving species deemed ethically sensitive by the AUS.
- 1.7.5. For **Full Review Approval Process** detail, see Sect. C.2.3.12

2. Protocol Formal Review Process**2.1. Office Review (See Pg. 13 Timeline Flow Chart)**

- 2.1.1. Forms containing only elements identified within Office Review Criteria (See Sect.C.1.5.) will be reviewed and authorized by an AUS AO, an ACVS veterinarian, or both;
- 2.1.2. **Days 0 - 5 Form Posting, Review & Reviewer Question Submission** - Following the Office Review Criteria (See Sect.C.1.5), the AUS AO will **within 5 business days**:
 - 2.1.2.1. Perform a review for forms identified in C.1.5.1;
 - 2.1.2.2. Forward the protocol form requesting review by ACVS Veterinarian for form elements identified in C.1.5.2;
 - 2.1.2.3. Forward the protocol form to ACVS Teaching Coordinator for forms containing personnel additions and/or training requirement changes (no review response required);
 - 2.1.2.4. Forward the protocol form to Facility Manager(s) for forms involving housing or use location (no review response required).
 - 2.1.2.5. Within 5 business days of initial form receipt, reviewer questions will be sent

to the PI by the AUS AO via eSirius.

2.1.3. Days 5 - 10 - PI Review Response

2.1.3.1. PI response to reviewer comments is requested to be **within 5 days of review notice.**

2.1.3.2. The review process will be put on hold until the PI response is received. If no response is received within 6 months, the protocol form will be completely removed from the workflow, and a new resubmission will be required.

2.1.3.3. If form content is impacted by the review changes, the PI will also send via eSirius website a **revised protocol form** to include these changes.

2.1.4. Days 7 - 12 - Office Review Approval Determination - Within 2 business days of PI review response:

2.1.4.1. If 'Approved,'

2.1.4.1.1. The AUS AO will authorize forms via eSirius 'Approve Now' process involving elements outlined within Sect.C.1.5.1.

2.1.4.1.2. An ACVS Veterinarian will authorize via eSirius 'Approve Now' process forms involving elements outlined within Sect.C.1.5.2.

2.1.4.1.3. eSirius approval will be sent to the PI by the AUS AO.

2.1.4.1.4. Animal use may begin at this time.

2.1.4.2. If 'Not Approved,'

2.1.4.2.1. The AUS AO will forward the protocol form to the Designated Review workflow process. (See Sect. C.2.2)

2.1.5. AUS Full Disclosure – On a monthly basis, the AUS AO will present protocol *Modification Detail* reports associated with forms having received Office Approval.

2.1.5.1. Modification Detail Reports will be

2.1.5.1.1. Posted to the eSirius AUS Monthly Meeting web site;

2.1.5.1.2. Presented for discussion by the AUS AO at an AUS Meeting.

2.2. Designated Review - (See Pg. 14 Timeline Flow Chart)

2.2.1. Forms containing elements identified within Designated Review Criteria (See Sect.C.1.6.) will undergo Designated Review, as follows:

2.2.2. Days 0 – 5 Pre-Meeting Review

2.2.2.1. Days 0 – 2 Protocol Posting - Within 2 business days of second draft protocol form receipt (See Sect.B.2), the assigned AUS AO will send the form to all AUS members, Teaching Coordinator, Facility Manager(s), and Institutional Safety Officers, if applicable, via eSirius;

2.2.2.2. All AUS members will be given **3 business days from notice** to call for **Full Review**. If Full Review is requested by any AUS member, the AUS AO will redirect the associated form towards full review (*Go to Sect. C.2.3*)

2.2.2.3. Days 1 – 5 Pre-Meeting Reviewer Question Submission - Within 5 business days of form receipt:

2.2.2.3.1. Institutional Safety Officers are requested to submit their comments/form revisions to the AUS AO.

2.2.2.3.2. If Institutional Safety Officer review extends **beyond 5 days**, the Institutional Safety Officer will communicate directly with the PI to resolve all outstanding issues, and will request that the PI incorporate

suggested form revisions in the form when sent back to the AUS AO (See C.2.2.3).

2.2.2.3.3. The AUS AO and ACVS Veterinarian, acting as pre-meeting reviewers, will prepare and send pre-meeting questions/comments to the PI requesting response.

2.2.3. Days 5 – 10 PI Pre-Meeting Review Response- PI response to pre-meeting reviewer comments (See C.2.2.2.3) is requested to be **within 5 days of pre-meeting review notice**. If form content is impacted by the review changes, the PI will revise the eSirius *Animal Use Protocol* form and send via eSirius to AUS AO.

2.2.3.1. The review process will be put on hold until the PI response is received. If no response is received within 6 months, the protocol form will be completely removed from the workflow, and a new resubmission will be required.

2.2.4. Days 7 – 12 - Pre-Meeting Reviewer Confirmation - Within 2 business days of PI response receipt, the AUS AO will:

2.2.4.1. Assess PI revisions to confirm AUS AO's comments/questions have been addressed.

2.2.4.2. Forward revised protocol to ACVS veterinarian requesting follow-up assessment of PI revisions;

2.2.4.3. If applicable, forward revised protocol to institutional Safety Officer requesting follow-up assessment of PI revisions;

2.2.4.4. AUS AO will add protocol to weekly Protocol Review Committee meeting Agenda.

2.2.5. Day 7+ - Designated Review & Approval Determination by Protocol Review Committee The pre-reviewed form will be presented to a Protocol Review Committee consisting of an alternating subset of 5 AUS members having the following roles: AUS Chair/Vice Chair, ACVS veterinarian, AUS Scientific Representative -PI, Grad. Student, Animal Technician-, AUS Community Representative, AUS Admin. Officer;

2.2.5.1. The assigned AUS AO/ACVS Vet will present the Protocol form, including PI response to pre-meeting review questions, during an upcoming weekly Protocol Review Committee Meeting;

2.2.5.2. The assigned AUS AO will record meeting minutes;

2.2.5.3. Protocol Review Committee members will have the opportunity to discuss form content and indicate one of three approval options during the meeting:

2.2.6. Day 7 - 9+ - Approved - If approved, within 2 business days of the Protocol Review Committee Meeting the assigned AUS AO will 'approve' and send approval notice to PI via eSirius.

2.2.7. Animal use may begin at this time.

2.2.8. Approval Pending Clarification - If approval is pending PI response to outstanding issues:

2.2.8.1. **Days 9 – 11+ - Within 2 business days** the assigned AUS AO will forward the Protocol Review Committee's outstanding issues the PI;

2.2.8.2. **Days 16+** Repeat Sect. C 2.2.3 – 2.2.6

2.2.9. Not Approved - If not approved, the assigned AUS AO will forward the form to the Full Review Workflow. (See Sect.C.2.3)

2.2.10. AUS Full Disclosure – On a monthly basis, the AUS AO will produce protocol Modification & Annual Renewal Detail Reports associated with forms approved by the Protocol Review Committees. These reports will be

2.2.10.1. Posted to the eSirius Monthly Meeting web site;

2.2.10.2. Presented for discussion at an AUS Meeting by members of the Protocol Review Committee.

2.3. Full Review (See Pg. 15 Timeline Flow Chart)

2.3.1. Day 0 - Protocol Posting: The assigned AUS AO will send notice of all

upcoming *Animal Use Protocol* forms via eSirius to all AUS Members, including Teaching Coordinator, related Facility Managers, and Institutional Safety Officers.

2.3.2. The AUS AO will assign an ACVS Vet, and two other AUS members to act as Primary and Secondary Presenters (1 having a strong science background) for this protocol, who will be responsible to:

2.3.2.1. Perform a thorough pre-meeting review – in addition to animal ethics (health & welfare), form completion and readability will be assessed;

2.3.2.2. The Primary Presenter is responsible to present the protocol content & review details during the associated AUS monthly meeting (See Sect.C.2.3.9). In the event that this individual is unavailable during the meeting, the Primary Presenter will pre-arrange with the Secondary Presenter to assume this responsibility.

2.3.2.3. In the event that both the Primary and Secondary Presenters are unavailable for the scheduled meeting, the ACVS vet involved in pre-meeting review will assume the Presenter role. If unavailable, persons in attendance at the meeting will be solicited for this role.

2.3.3. Day 5 – Pre-Meeting Reviewer Question Submission - Within **5 business days** of email notification, all AUS members will perform a thorough pre-meeting animal ethics review and submit their pre-meeting review comments &/or questions to the AUS AO via eSirius;

2.3.3.1. Facility Managers, Teaching Coordinator, and Institutional Safety Officers will review their related sections within the *Animal Use Protocol* form.

2.3.3.2. No response by other AUS members (not including Primary and Secondary Presenters), or Facility Manager is presumed to indicate that they have no outstanding pre-review animal ethics questions/concerns relating to the protocol form.

2.3.3.3. If Institutional Safety Officer review extends **beyond 5 days**, the Institutional Safety Officer will communicate directly with the PI to resolve all outstanding issues, and will request that the PI incorporate suggested form revisions in the form when sent back to the AUS AO (See C.2.3.5).

2.3.4. Day 7 - Reviewer Question Distribution - Within 2 days beyond the review deadline listed in C.2.3.3, the AUS AO will compile all pre-meeting reviewers' questions and comments, and then send the combined reviewer questions to the PI via eSirius.

2.3.5. Day 12 - PI Response - PI response to reviewer questions (See C.2.3.4) is requested to be **within 5 days of review notice**. If form content is impacted by the review changes, the PI will make changes to the eSirius *Animal Use Protocol* form and resend it to the AUS AO via the eSirius website

2.3.5.1. The review process will be put on hold until the PI response is received. If no response is received within 6 months, the protocol form will be completely removed from the workflow, and a new resubmission will be required.

2.3.6. Day 14 - PI Response Posting - Within 2 business days of PI response receipt the AUS AO will:

2.3.6.1. Post revised protocol to AUS requesting that those reviewers who submitted questions/comments (See Sect. C.2.3.3) confirm via eSirius that adequate PI revisions have been made;

2.3.6.1.1. No reviewer response indicates confirmation.

2.3.7. Day 19 – Pre-Meeting Reviewer Confirmation - Within 5 business days, pre-meeting reviewers with questions/comments will confirm via eSirius whether the PI's response and/or revision(s) have resolved their question(s)/concern(s);

2.3.8. The AUS AO will record pre-meeting reviewer confirmations, and then add these along with the protocol to the AUS Monthly Meeting Agenda.

2.3.9. Day 20 - AUS Monthly Meeting - Protocol forms must be 'readied' (Complete Sect.C.2.3.1 – 2.3.8) a **minimum of 1 day prior** to an AUS Meeting to be added to its Agenda.

2.3.10. The AUS AO will add the protocol form to the eSirius AUS Meeting Agenda

2.3.11. The Primary (Secondary, if Primary is unavailable) Presenter for this protocol will be responsible during the upcoming AUS meeting to:

2.3.11.1. Present a very brief (maximum 2 minutes) protocol summary;

2.3.11.2. Summarize the Pre-Meeting Reviewer Questions (Sect.C.2.3.4); confirm all reviewer-requested protocol form revisions made by the PI during the pre-review process (Sect.C.2.3.7); and identify outstanding issues.

2.3.11.3. The Presenter makes a motion for one of three meeting approval options (See Sect.C.2.3.12).

2.3.11.4. The AUS Chair will lead a discussion opportunity for attending AUS members;

2.3.11.5. AUS members will vote on the motion;

2.3.11.6. The assigned AUS AO will record discussion elements involving clarification requests and other directives within meeting minutes;

2.3.12. Meeting Approval Options

2.3.13. Day 22 - Approved – If the protocol form is approved at the meeting with no additional Committee questions, the AUS AO will send approval via eSirius to the PI, designated research staff, Facility Manager, Research Services and/or LHSC financial officers, if required, within **3 business days** of AUS approval.

2.3.14. Animal use may begin at this time.

2.3.15. Days 25 – 37 Approval Pending Clarification - If AUS approval is pending PI response to outstanding issues:

2.3.15.1. Day 25 - Question Distribution - Within 5 business days the assigned AUS AO sends the PI associated AUS Meeting outstanding issues;

2.3.15.2. Day 30 – PI Response - The PI will optimally respond **within 5 business days**;

2.3.15.2.1. The review process will be put on hold until the PI response is received. If no response is received within 6 months, the protocol form will be completely removed from the workflow, and a new resubmission will be required.

2.3.15.3. Days 31 - 35 – Protocol Review Committee Meeting - The assigned AUS AO will submit the revised protocol to the weekly Protocol Review Committee for final discussion and approval, if appropriate.

2.3.15.4. Day 33 - 37 – Approval Notice - If 'Approved,' within 2 business days the assigned AUS AO will 'approve' and send approval notice to PI via

eSirius.

2.3.15.5. Animal use may begin at this time.

2.3.15.6. If not approved, the assigned AUS AO will request direction from the full AUS.

2.3.16. Days 25 - 40+ Tabled - If the AUS tables the protocol:

2.3.16.1. Day 25 - Question Distribution - Within 5 business days the assigned AUS AO sends the PI associated post-AUS Meeting outstanding issues;

2.3.16.2. Day 30 – PI Response - The PI will optimally respond within 5 business days;

2.3.16.2.1. The review process will be put on hold until the PI response is received. If no response is received within 6 months, the protocol form will be completely removed from the workflow, and a new resubmission will be required.

2.3.16.3. Days 35+ - Repeat Pre-Meeting Review Processes- The protocol form will undergo repeat review processes (see **Sect. C 2.3.6 – 2.3.8**) until approved by the AUS, or withdrawn by the PI.

2.3.16.4. Day 40+ - 2nd AUS Monthly Meeting – ‘Not Approved’ - If final approval is not recommended, AUS AO will request direction from the AUS, which may seek guidance from the Animal Care Governance Steering Committee, and/or the University Council on Animal Care.

D. PROTOCOL REVIEW APPROVAL TIMEFRAMES

1. Optimal Pre-Review Services

- 1.1. Pre-Review Meeting Service = 1 - 10 business days
- 1.2. Scientific Peer Review = 3 – 16 business days

2. Optimal Formal Review & Approval Timeframes

- 2.1. Office Review = 2 - 7 business days
- 2.2. Designated Review = 7 - 10 business days
- 2.3. Full Review
 - 2.3.1. Approval = 22 business days
 - 2.3.2. Approval Pending Clarification = 25 - 37 business days
 - 2.3.3. Tabled = 42+ business days

3. Possible Approval Delays

The following review elements may delay AUS approval:

- 3.1. Institutional Safety Officer Pre-Approval – Contact Institutional Safety Officer(s) directly;
- 3.2. Institutional Biosafety Committee Review – BHARF form pre-submission & review – Contact Institutional Biosafety Officer
- 3.3. Scientific Peer Review Pre-Approval - Contact AUS AO
- 3.4. Delayed PI response to outstanding questions or concerns
- 3.5. Personnel, including PI, on Protocol with previously outstanding training: Contact training@uwo.ca

3.6. AUS AO Vacation Coverage – During vacation time periods, workloads double for the remaining AO, which may result in protocol processing delays.

E. REPORTS

1. **Scientific Peer Reviewers List –**

On a semi-annual basis, Research Western Administration, ACVS Veterinarians and Western's scientific community will assist the AUS AO in maintaining a list of potential scientific peer reviewers, which is grouped by scientific research focus, e.g. transplantation, imaging. Each group will contain a minimum of 6 potential peer reviewers external to the AUS. The *Scientific Peer Reviewers List* - authorized semi-annually by Research Western Administration - will be used by the AUS AOs to request scientific peer review for all protocols with non-peer-reviewed funding sources as well as for forms not containing an approved Grant funding number.

2. **Modification & Renewal Detail Reports**

Modification & Renewal Detail & Pilot 'List of Protocols' Reports outlining all *Protocol Modification, Annual Renewal* and *Pilot Animal Use Protocol* detail within a given time period will be produced from Sirius/eSirius by the AUS AO and posted to the AUS secure web site or via eSirius on a monthly basis. These reports will also be presented by an AUS member during each AUS monthly meeting.

3. **Post Approval Monitoring**

Reference the *AUS Post Approval Monitoring Program* for details associated with post approval monitoring. Monthly reports are presented by the Protocol Support Veterinarian, or designate, and discussed during regular AUS meetings.

OFFICE REVIEW TIMELINES

**Business Day 0 - 5
Protocol Posting &
Review**

- AUS AO sends Protocol forms to & notifies appropriate reviewers (ACVS vets, facility managers, teaching coordinators)
- Office reviewers send review questions/comments to AUS AO's

**Business Day 5 - 10
PI Response**

- PI response to reviewer comments

**Business Day 7 - 12
Office Review
Approval**

- Office reviewers authorize form, if appropriate
- AUS AO 'approves' form in eSirius and distributes approval to PI

**Business Day 7+
Office Review
'Not Approved'**

- Office reviewers do not authorize form.
- AUS AO forwards form to Designated Review Workflow

DESIGNATED REVIEW TIMELINES

Business Day 0 - 2 Protocol Posting	<ul style="list-style-type: none"> •AUS AO sends Protocol forms to & notifies appropriate reviewers (AUS members, safety officers, facility managers, teaching coordinators)
Business Day 0 - 3 Call for Full Review	<ul style="list-style-type: none"> •AUS members have option to request Full Review Workflow process for protocol form.
Business Day 1-5 Pre-Meeting Reviewer Question Submission	<ul style="list-style-type: none"> •AUS Reviewers to send review questions/comments to AUS AO's
Business Day 5 - 10 PI Response	<ul style="list-style-type: none"> •Requested timeframe for PI to respond to AUS Reviewer questions/comments, to include submission of revised protocol form
Business Day 7 - 12 Pre-Meeting Reviewer Confirmation	<ul style="list-style-type: none"> •Pre-meeting reviewers to confirm PI response
Business Day 7 - 12+ Next Weekly Protocol Review Meeting	<ul style="list-style-type: none"> •Pre-meeting Reviewers present outline of pre-meeting review elements (reviewer questions/comments & PI responses/form revisions) during AUS Protocol Review Committee (PRC) meeting •PRC participants discuss and determine protocol approval status: approved, approved pending clarification, not approved. •AUS AO records meeting minutes
Business Day 9 - 14+ Approval Notice Distribution	<ul style="list-style-type: none"> •If 'approved' by AUS Protocol Review Committee AUS AO's distribute approval notices to PIs, designated staff, facility managers, etc.
Business Day 15+ 'Approved Pending Clarification'	<ul style="list-style-type: none"> •Repeat process from 'Pre-Meeting Reviewer Question Submission,' using AUS Protocol Review Committee questions.
Business Day 15+ 'Not Approved'	<ul style="list-style-type: none"> •AUS AO forwards form to Full Review Workflow

FULL REVIEW TIMELINES

Business Day 0 Protocol Posting	<ul style="list-style-type: none"> •AUS AO's post Animal Use Protocols on AUS secure web site •AUS AO's notify AUS Reviewers (AUS members, safety officers, facility managers, teaching coordinators)
Business Day 5 Pre-Meeting Reviewer Question Submission	<ul style="list-style-type: none"> •Deadline for AUS Reviewers to send review questions/comments to AUS AO's
Business Day 7 Question Distribution	<ul style="list-style-type: none"> •AUS AO's compile Reviewer questions/comments •AUS AO's send compiled questions to PIs requesting response & form modification, if required
Business Day 12 PI Response	<ul style="list-style-type: none"> •Requested deadline for PI response, including revised form, to AUS reviewer questions/comments, to include changes requested by Institutional safety officers
Business Day 14 PI Response Posting	<ul style="list-style-type: none"> •AUS AO's to post PI responses, including revised AUP forms, to AUS secure web site •AUS AO's notify AUS Reviewers via email
Business Day 19 Pre-Meeting Reviewer Confirmation	<ul style="list-style-type: none"> •Deadline for AUS Reviewers with questions/comments to confirm PI responses/form revisions
Business Day 20 AUS Monthly Meeting	<ul style="list-style-type: none"> •AUS 'Presenters' provide outline of pre-meeting review elements (reviewer questions/comments & PI responses/form revisions) for all AUP's •AUS Committee discusses AUPs and determines approval status: approved, approved pending clarification, tabled
Business Day 22 AUPs Approved: Approval Notice Distribution	<ul style="list-style-type: none"> •AUS AO's distribute approval notices to PIs, facility managers, etc.
Business Day 25 AUPs Approved Pending Clarification or Tabled: Question Distribution	<ul style="list-style-type: none"> •Deadline for AUS AO's to send outstanding questions to PI's
Business Day 30 AUPs Approved Pending Clarification or Tabled: PI Response	<ul style="list-style-type: none"> •Requested deadline for PI response to AUS Meeting questions/comments, - may include submission of revised AUP form
Business Day 37 AUPs Approved Pending Clarification : Protocol Review Com. Review & Approval	<ul style="list-style-type: none"> •AUS Protocol Review Committee to review PI responses/ form revisions and determine approval status •If Approved, AUS AO's distribute approval notices to PIs, facility mgmt, etc •If Not Approved, review process to repeat from Day 25
Business Days 35 -39 AUPs Tabled: PI Response Posting & Reviewer Confirmation	<ul style="list-style-type: none"> •Repeat Days 14 & 19
Business Day 40 AUPs Tabled: 2nd AUS Monthly Meeting	<ul style="list-style-type: none"> •Repeat Day 20