

Office of Research Services Michael Williams Building, Room B202 uvic.ca/research-services

# Animal Use Protocol (AUP) Application Updates Help Sheet (for Amendments, Renewals and Completions) Research Administration Information System (RAIS)

# **Before You Begin**

This document provides instructions and guidance specifically for amending, renewing or completing approved AUP applications created and submitted via RAIS. These instructions are applicable to approved research or teaching AUPs.

If you have an approved AUP (**PDF format**), refer to the <u>PDF AUP Help Sheet</u> for guidance for amendments, renewals and completions.

If you wish to submit a NEW AUP on RAIS, refer to the <u>Research AUP Application Helpsheet</u> or <u>Teaching AUP</u> <u>Application Helpsheet</u> for instructions.

### Acronyms

AUP - Animal Use Protocol ACC - Animal Care Committee CCAC - Canadian Council on Animal Care PI - Principal Investigator AEL - Animal Ethics Liaison (<u>animalethics@uvic.ca</u>) SOP - Standard Operating Procedure RAIS – Research Administration Information System

# Policies and Guidelines, ACC Requirements and Deadlines

### **Policies and Guidelines**

- Visit the <u>Applying for animal ethics approval</u> website to review all of the ACC policies and procedures.
- Visit the <u>CCAC</u> website to review national guidelines and policies.
- The ACC follows <u>CCAC Guidelines on Animal Use Protocol Review</u>.

### ACC Requirements

- After approval, revisions to your AUP must be submitted as an amendment update and approved by the ACC before the work is undertaken.
- After approval, annual renewal (with or without revisions) or completion of your AUP must be submitted as an update and approved by the ACC before work can continue.
- All required sections of the AUP application updates (renewals, amendments and completions) must be completed (required items are marked with an \*).
- Animal-based research must comply with Canadian Council on Animal Care (CCAC) and UVic guidelines and policies.
- Teaching protocols must be reviewed for <u>pedagogical merit</u> prior to submission.
- Research protocols must be peer reviewed for scientific merit prior to submission.

### Deadlines

- ACC meetings are held on the second Friday of each month (third Friday in September and January); the ACC does not meet formally in July or August.
- Meeting dates and submission deadlines are set for the current academic year.
- Incomplete updates or those received after the deadline date will be deferred to the next meeting.

# Regular amendment of an approved RAIS AUP application

### How to start a regular amendment of an approved AUP application

- Only a PI may initiate a regular amendment.
- Sign in in directly to RAIS using your NetLinkID and password, or access via Online tools.
- Access from off-campus requires use of the UVic VPN for remote access. If your computer or laptop is not connected to the VPN, you receive an "Access Unavailable" message.
- From the RAIS homepage you can access funding, human ethics or animal ethics; choose Go to animal ethics to get started.
- From the researcher tab, select the AUP protocol # you are amending to access the summary page.
- To start a regular amendment, select "+*Update*" button from the Actions menu on the AUP summary page.
- In the protocol update coversheet, choose "Amendments only" under "This update application is for:\*"
- If you have any issues accessing RAIS or questions about updates for approved AUP applications, email <u>animalethics@uvic.ca</u> for guidance.

#### Navigating a regular amendment update

- A regular amendment update submission includes an update coversheet and the amended AUP.
  - An overview of the coversheet questions for a regular amendment is provided below.
  - For a detailed overview of the application sections A.- N. and what information the ACC requires, refer to the <u>AUP Application Helpsheet</u>.
- Update coversheet questions for a regular amendment:
  - Pilot project answer is drawn from Section B.5 of the approved application and cannot be changed after approval.
  - For a regular amendment choose "*No*" in response to: "*Is this an application for minor amendments that may qualify for expedited review?*\*"
  - If your amendment meets the criteria for an expedited review, refer to the instructions for Expedited Minor Amendments of An Approved RAIS Application below.
  - Provide a brief summary and justification for the proposed amendment.
  - You may save the amendment update coversheet "in progress" or "as complete".
  - o In pre-submission, you may return to the coversheet at any time and make additional edits.
  - As you are working on the update coversheet, save your information often.
- Amending the AUP:
  - Below the protocol update coversheet is the approved AUP application which may be accessed and amended.
  - Each section row header in the AUP application includes the section title and shows the status as "complete"; however, regardless of the "complete" status, you may expand (open) each section you need to amend by clicking on the section row header.
  - o In the pre-submission phase, you may return at any time and edit any section, in any order.
  - You may save the amended AUP sections "in progress" or "as complete".
  - As you are working on the amendment, save your information often.

#### Submitting a regular amendment update

- o Ensure that both the coversheet and amended sections of the AUP are saved "as complete."
- o Submit via RAIS directly to the Animal Ethics Office by selecting "Submit application" button.
- Sign-off by a signatory is not necessary for amendments.
- Please note: The submission may be returned to the PI by the Animal Ethics Office if additional information is required for review.
- Regular amendments will be reviewed at the next scheduled ACC meeting and will receive a response from the ACC in 4-6 weeks.

# Expedited Minor Amendment of an Approved RAIS Application

- Minor amendments may qualify for expedited review if changes are limited to the following:
  - <u>Team member changes</u> See additional details below
    - Sources of animals
    - Location of experiments or animal housing
    - $\circ$   $\,$   $\,$  Procedure changes that have neutral impact on animal welfare
    - Less than 10% increase in animal use numbers.
- The Veterinary Director approves <u>expedited minor amendments</u> on behalf of the ACC.

### How to start an expedited minor amendment of an approved AUP application

- Only a PI may initiate an expedited minor amendment of an approved AUP application.
- Log in directly to RAIS using your NetLinkID and password, or access via Online tools.
- Access from off-campus requires use of the UVic VPN for remote access. If your computer or laptop is not connected to the VPN, you will get a white screen with no instructions.
- From the RAIS homepage you can access funding, human ethics or animal ethics; choose *Go to animal ethics* to get started.
- From the researcher tab, select the AUP protocol # you are amending to access the summary page.
- To start an expedited amendment, select "+*Update*" button from the Actions menu on the AUP summary page.
- In the update coversheet, choose "Amendments only" under "This update application is for:\*"
- If you have any issues accessing RAIS or questions about updates for approved AUP applications, email <u>animalethics@uvic.ca</u> for guidance.

### Navigating an expedited amendment update

- An expedited amendment update submission includes an update coversheet and the amended AUP.
  - $\circ$  An overview of the coversheet questions for an expedited amendment is provided below.
  - For a detailed overview of the application sections A.- N. and what information the ACC requires, refer to the <u>AUP Application Helpsheet</u>.
- Update coversheet questions for an expedited amendment:
  - Pilot project answer is drawn from Section B.5 of the approved application and cannot be changed after approval.
  - For an expedited amendment, choose "Yes" in response to: "Is this an application for minor amendments that may qualify for expedited review?\*"
  - Provide a brief summary and justification for the proposed expedited amendment(s).
  - You may save the expedited amendment update coversheet "in progress" or "as complete".
  - o In pre-submission, you may return to the coversheet at any time and make additional edits.
  - As you are working on the update coversheet, save your information often.
- Amending the AUP:
  - Below the protocol update coversheet is the approved AUP application which may be accessed and amended.
  - Each section row header in the AUP application includes the section title and shows the status as "complete"; however, regardless of the "complete" status, you may expand (open) each section you need to amend by clicking on the section row header.
  - We recommend working through each section in the order presented; however, in the presubmission phase you may return and edit any section, in any order.
  - $\circ$   $\;$  You may save the amended AUP sections "in progress" or "as complete".
  - As you are working on the amendment(s), save your information often.

### Submitting an expedited minor amendment update

• Ensure that both the update coversheet and amended sections of the AUP are saved "as complete".

- Submit your expedited amendment update via RAIS to the Animal Ethics Office by selecting "Submit application" button. The Animal Ethics Office may return the submission if additional information is required for review.
- Expedited minor amendments usually receive a response from the Veterinary Director within one week.
- Sign-off by a signatory is not necessary for expedited minor amendments.

# Team Member Changes to an Approved RAIS Application

- Researchers, lab members, and/or teaching assistants who intend to handle animals must complete all required <u>animal research education and training</u> components **before** beginning work.
- New team members must complete the required animal education and training before they may be added to the AUP application (Section A).
- To initiate training for new team members, contact <u>animaltraining@uvic.ca</u>.
- Team member training will be recorded to the team member's profile on RAIS.
- Submit an **expedited minor amendment** (see above) to make changes to your team members on an approved AUP.

# **Renewal of an Approved RAIS Application**

- Approved RAIS AUP applications must be reviewed annually by the ACC.
- Researchers will be sent an email notification reminder when a renewal application update is required.
- Approved protocols expire after their third renewal and must be submitted as "new" at the end of every fourth year (a new protocol ID will be assigned).
  - If you have renewed this protocol three times, proceed to instructions for Completion of an Approved RAIS Application below.

### How to start a renewal update for an approved AUP application

- Only a PI may initiate a renewal update for an approved AUP application.
- Log in directly to RAIS using your NetLinkID and password, or access via Online tools.
- Access from off-campus requires use of the UVic VPN for remote access. If your computer or laptop is not connected to the VPN, you will get a white screen with no instructions.
- From the RAIS homepage you can access funding, human ethics or animal ethics; choose *Go to animal ethics* to get started.
- From the researcher tab, select the AUP protocol # you are renewing to access the summary page.
- To start a renewal update, select "+*Update*" button from the Actions menu on the AUP summary page.
- In the update coversheet, choose "Annual renewal of approval" under "This update application is for:\*"
- If you have any issues accessing RAIS or questions about updates for approved AUP applications, email <u>animalethics@uvic.ca</u> for guidance.

### Navigating an annual renewal update

- An annual renewal update submission includes an update coversheet and the amended AUP.
  - An overview of the coversheet questions for an annual renewal is provided below.
  - For a detailed overview of the application sections A.- N. and what information the ACC requires, refer to the <u>AUP Application Helpsheet</u>.
- Update coversheet questions for an annual renewal:
  - Pilot project answer is drawn from Section B.5 of the approved application and cannot be changed after approval.
  - The date the protocol was last renewed will be indicated.
  - o Confirm whether your team has conducted any research activities under this protocol since the

last renewal.

- If not, indicate whether you expect to resume activities in the next twelve weeks.
  - If not, respond to "*This update application is for:*\*" by selecting "*Completion of this protocol*" and proceed with answering the completion update coversheet questions.
  - Or, if you still wish to renew this protocol, provide an explanation to justify keeping the protocol open during an extensive period of inactivity.
- The annual renewal coversheet includes the following sections/questions. Detailed question guidance is available within the coversheet. If you require additional support or guidance, contact animalethics@uvic.ca.
  - Section 1 Project Summary
    - 1. What were the goals of the project?
    - 2. Did you achieve each of these goals? Summarize the successes and challenges you encountered.
    - 3. Briefly describe the scope of work performed under this AUP.
  - Section 2 Animal use numbers
    - 1. a. d. Report the number of animals used for each species/strain listed in the approved AUP (see Section F.2)
  - Section 3 Replacement, reduction, refinement
    - 1. Replacement: Describe progress you have made on replacement methods for animal use in this project.
    - 2. Reduction: Describe progress you have made on reduction methods for animal use in this project.
    - 3. Refinement:
      - a. Describe progress you have made on refinement strategies to improve the well-being of animals used in this project.
      - b. Reflect on the actual versus expected rates of anticipated complications experienced by each group of animals in this protocol.
      - c. Report any unanticipated complications experienced.
      - d. Reflect on your plan for monitoring and assessing the welfare of animals and how your findings will impact future work.
      - e. Reflect on the actual versus expected mortality rates experienced by each group of animals in this protocol.
      - f. Did any animal deaths require postmortem procedures and reporting to the veterinary director?
      - g. What changes will you make to your scientific or humane endpoints to reduce complications and mortality observed?
      - h. For animals not euthanized comment on the use of alternative final disposition method(s).

### • Section 4 – Records & Training

- 1. Have you verified that all substances administered to animals have not expired and that any expired substances have been disposed of properly?
- 2. Describe where surgery, monitoring, and/or welfare assessment records are stored and upload an example.
- 3. Describe your lab member training process and provide examples of your labspecific training program, including competency benchmarks.
- 4. What 3Rs-related continuing education have you or your team members undertaken?
- Section 5 Post approval Renew (PAR) Update
  - 1. Provide a status update on recommendations made through the PAR Program. Indicate how these recommendations have been or will be addressed and a

timeline for resolution.

- You may save the renewal update coversheet "in progress" or "as complete".
- In pre-submission, you may return to the coversheet at any time and make additional edits.
- As you are working on the update coversheet, save your information often.
- Amending the AUP for your annual renewal submission:
  - Each section row header in the AUP application includes the section title and shows the status as "complete"; however, regardless of the "complete" status, you may expand (open) each section you need to amend by clicking on the section row header.
  - The following sections of the application **must** be reviewed annually and updated if necessary:
    - your team members (Co-PI, Emergency Contact, and others) listed in Section A of the AUP.
    - Review and update funding information in Section C.
    - Update the protocol year number in Section F (F.1).
    - Review and update your team member assignments for procedures in Section H and/or K.
    - Review and update attachment versions in Section M (e.g., project timelines, supporting appendices, licences/permits, SDS information). Remove all attachments that are no longer relevant (e.g., PDF annual review/field study report, SOPs not being revised, licences/permits.
  - We recommend working through each section in the order presented; however, in the presubmission phase you may return and edit any section, in any order.
  - You may save the amended AUP sections "in progress" or "as complete".
  - As you are working on the renewal amendment(s), save your information often.

#### Submitting an annual renewal update

- Ensure that all the required questions in the update coversheet are answered.
- o Ensure that the update cover sheet and amended sections of the AUP are saved "as complete".
- Submit your annual renewal update to your signatory for sign-off via RAIS by selecting "Submit application" button. Sign-off by a signatory is necessary for annual renewal submissions.
- After sign-off by your signatory, the renewal update will be submitted to the Animal Ethics Office via RAIS.
- The Animal Ethics Office may return the submission if additional information is required for review.

## **Completion of an Approved Application**

- Pls should submit a completion update at the end of the research project or, if research is ongoing, at the end of the fourth year of the project.
- Approved protocols may only be renewed three times and must be submitted as "new" at the end of every fourth year (a new protocol ID will be assigned).

### How to start a completion update for an approved AUP application

- Only a PI may initiate a completion update for an approved AUP application.
- Log in directly to RAIS using your NetLinkID and password, or access via Online tools.
- Access from off-campus requires use of the UVic VPN for remote access. If your computer or laptop is not connected to the VPN, you will get a white screen with no instructions.
- From the RAIS homepage you can access funding, human ethics, or animal ethics; choose *Go to animal ethics* to get started.
- From the researcher tab, select the AUP protocol # you are completing to access the summary page.
- To start a completion update, select "+*Update*" button from the Actions menu on the AUP summary page.

- A protocol update will be created and will be assigned its own ID number, based off the AUP number (e.g., YY-###-01).
- Under "This update application is for:\* choose "Completion of this protocol."
- If you have any issues accessing RAIS or questions about updates for approved AUP applications, email <u>animalethics@uvic.ca</u> for guidance.

### Navigating a completion update

- A completion update submission includes only the completion update coversheet. **Do not amend the AUP application when submitting a completion update.**
- Update coversheet questions for a completion:
  - Pilot project answer is drawn from Section B.5 of the approved application and cannot be changed after approval.
    - If the project you are completing is a pilot project, indicate (yes or no) if you plan to continue the pilot project under a new AUP#.
      - If yes, provide the new AUP # (see detailed instructions #1 6 below under "*To start a new AUP and obtain the protocol number:*").
      - If no, provide the date of completion for the project. (**Note**: If you will be transitioning the research to a full protocol, based on procedures from the pilot project, select "no" here and provide completion date).
      - Confirm whether (yes or no) you intend to create a full protocol **based** on procedures/principles **from** the pilot project. If yes, then provide the new AUP #.
  - For regular projects (not a pilot), confirm whether (yes or no) you intend to submit a new AUP for review that follows this same project (i.e., research is ongoing):
    - If yes, provide the new AUP number.
      - To start a new AUP and obtain the protocol number:
        - Select the "Save as in progress" button for the completion update coversheet (scroll down past Section 5 – Post Approval Review (PAR) Update to see "Save as in progress" button)
        - 2. Next, scroll down past the AUP application row headers and select *Go to summary* located at the bottom of the screen.
        - 3. On the summary page for the completion update, select the parent protocol number highlighted in the box under the (pink) Update header (top left). This will take you to the summary page for the parent application.
        - 4. On the parent application summary page, under Actions (top left), select "*Copy application*" and confirm OK. The copy function will copy the information in the application which can then be updated and/or amended prior to submission. You will receive a success notification and the new protocol # will be indicated. The new AUP application will be available at the top of your researcher landing page. Make a note of the protocol number (e.g., AE-YY-###).
        - 5. To return to the completion update coversheet, scroll down the landing page and select the ID # for the completion update (this returns you to the update summary page).
        - 6. On the update summary page, under Actions (top left), select *Edit application* and enter the new AUP # in the text box provided.
  - The completion update coversheet includes the following sections (1 5). Detailed question guidance is available within the coversheet. If you require additional support or guidance, contact <u>animalethics@uvic.ca</u>.
    - Section 1 Project Summary
      - 1. What were the goals of the project?
      - 2. Did you achieve each of these goals? Summarize the successes and challenges you encountered.

- 3. Briefly describe the scope of work performed under this AUP.
- 4. For pilot projects: Has this pilot project been used to define procedures that could be developed into a lab-specific standardized procedure (e.g., SOP)?

### Section 2 – Animal use numbers

- a. d. Report both the approved and actual number of animals used for each species/strain listed in the approved AUP (for reference, see Section F.2 of the AUP).
  - Important: Ensure that numbers for all animals listed in the AUP during the past year are reported here (i.e., if amendments were made during the year to remove animals/species, you must still report on usage for that animal/species).
  - If actual usage exceeded approved for any listed animal, an explanation must be provided.

### • Section 3 – Replacement, reduction, refinement

- 1. Replacement: Describe progress you have made on replacement methods for animal use in this project.
- 2. Reduction: Describe progress you have made on reduction methods for animal use in this project.
- 3. Refinement:
  - a. Describe progress you have made on refinement strategies to improve the well-being of animals used in this project.
  - b. Reflect on the actual versus expected rates of anticipated complications experienced by each group of animals in this protocol.
  - c. Report any unanticipated complications experienced.
  - d. Reflect on your plan for monitoring and assessing the welfare of animals and how your findings will impact future work.
  - e. Reflect on the actual versus expected mortality rates experienced by each group of animals in this protocol.
  - f. Did any animal deaths require postmortem procedures and reporting to the veterinary director?
  - g. What changes will you make to your scientific or humane endpoints to reduce complications and mortality observed?
  - h. For animals not euthanized comment on the use of alternative final disposition method(s).

### Section 4 – Records & Training

- 1. Have you verified that all substances administered to animals have not expired and that any expired substances have been disposed of properly?
- 2. Describe where surgery, monitoring, and/or welfare assessment records are stored and upload an example.
- 3. Describe your lab member training process and provide examples of your labspecific training program, including competency benchmarks.
- 4. What 3Rs-related continuing education have you or your team members undertaken?

### Section 5 – Post approval Renew (PAR) Update

- 1. Provide a status update on recommendations made through the PAR Program. Indicate how these recommendations have been or will be addressed and a timeline for resolution.
- You may save the Completion Update coversheet "in progress" or "as complete."
- In pre-submission, you may return to the completion update coversheet at any time and make additional edits.
- o As you are working on the update coversheet, save your information often.

• **Do not** make any changes to the AUP application when submitting a completion update. If the research project is continued under a new protocol number, amendments should be made to the "new" AUP application created earlier via the "*copy application*" action.

### Submitting a completion update

- Ensure that all the required questions in the update coversheet are answered.
- Ensure that the update coversheet is saved "as complete."
- Submit your completion update to the Animal Ethics Office via RAIS.
- The Animal Ethics Office may return the submission if additional information is required for review by the ACC.