

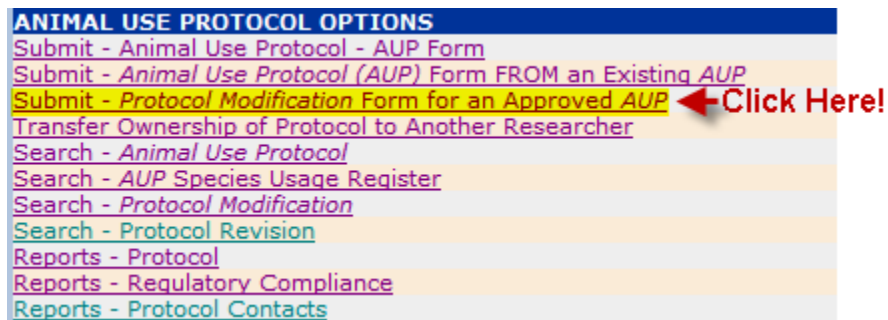
Section 4 – Submitting Protocol Modifications in eSirius

Protocol Modification in eSirius

eSirius allows you to request ‘*Protocol Modifications*’ to an approved AUP by re-submitting the protocol itself with requested updates to the form content. The protocol modification review process is similar to the new AUP application review process outlined in **Section 3 – AUP Review & Committee Approval – Workflow Process**. During the Protocol Modification review workflow process, you will **not** be able to access the protocol to make any further changes until the modification has been assigned either an ‘**Approved (w/out Stipulation)**’ or ‘**Not Approved (w/ Stipulation)**’ status by the AUS Office. Once the modifications to the AUP have been approved, the protocol is updated as per your requested changes in eSirius and you may choose to submit additional protocol modification(s) at this point.

4.1 – PI Submits a Protocol Modification For An Approved AUP (General Instructions)

- a) **PI Selects an AUP to be Modified**→ eSirius→PI Home Page→ Animal Use Protocol Options section→ Click ‘**Submit Protocol Modification Form for an Approved AUP**’ link→List of **Approved Protocols** page→Lists all of YOUR approved protocols (Note: To **View protocol**, Click Protocol # link)→ Select protocol from the list→Click ‘**Continue**’ button.





Submit an Amendment for an Existing Protocol

Bear, Yogi

List of Approved Protocols

To start a protocol modification, select the desired protocol and click **Continue**. To **View** in its entirety, click the protocol number link.

| Select | PI | Protocol # | Protocol Title |
|----------------------------------|------------|---------------------------|---|
| <input type="radio"/> | Bear, Yogi | 2009-0037 | FILL IN THE BLANKS! |
| <input type="radio"/> | Bear, Yogi | 2010-0001 | Protocol for Designated Review |
| <input type="radio"/> | Bear, Yogi | | Antibody production in pigs exposed to human cancer cells |
| <input type="radio"/> | Bear, Yogi | | TEST |
| <input type="radio"/> | Bear, Yogi | | Cardiocyte Myeloma and its relationship to Acute Colitis |
| <input type="radio"/> | Bear, Yogi | | TEST |
| <input type="radio"/> | Bear, Yogi | 2009-0042 | The Effects of Campers on National Parks |
| <input checked="" type="radio"/> | Bear, Yogi | 2010-045 | Stress-induced tachycardia in pigs |

Select desired protocol from the List of Approved Protocols by checking the 'Select' box beside the correct AUP #

Click Here once you've selected an AUP

Continue

Return to Home Page

- b) **PI Selects Specific AUP Sections to be Modified → Choose Protocol Modification Sections** page → Enter reason/justification for the protocol modification and select section(s) to be modified from list; Ensure that you fill out all sections related to your requested modification → The 'Instruction' section will indicate whether there are any associated sections to be filled out (e.g. If you are adding a new procedure to the Procedures Narrative list, you not only must select **Modification Section 10.2 – Procedures Narrative**, but also **Section 11.15 – Procedural Consequences**) → **NOTE: eSirius only allows protocol modifications to be processed ONE AT A TIME – therefore, you will NOT have the ability to submit additional protocol modification sections until requested modification has been APPROVED. Please ensure that you have included all of the required sections to be modified BEFORE you send the request to the AUS Office** → Click **'Continue'** button:

Choose Protocol Modification Sections

Protocol Info

| | |
|--------------|------------------------------------|
| PI_FULL_NAME | Bear, Yogi |
| AUP_NUMBER | 2010-045 |
| AUP_TITLE | Stress-induced tachycardia in pigs |

Protocol Modification > Justification

| | |
|--|---|
| Protocol Modification Number | |
| Date Started | // |
| Reason/Justification for Protocol Modification | Reason for adding new procedure goes here; This is a required field |

Protocol Modification > Choose Applicable Section(s)

| Select | Section | Instruction |
|-------------------------------------|---|--|
| <input type="checkbox"/> | 15. Protocol Personnel List | Select this selection to add, remove or change personnel information |
| <input type="checkbox"/> | 1. Investigator Contact Information | Select if PI contact information has changed |
| <input type="checkbox"/> | 2. Protocol Title & Project Type | Select if Protocol Title has changed |
| <input type="checkbox"/> | 3. Lay Summary & Glossary | Select if Lay summary or glossary requires update |
| <input type="checkbox"/> | 4. CCAC Animal Procedural Outline | Select to update CCAC procedural outline |
| <input type="checkbox"/> | 5.1 Funding Source List | |
| <input type="checkbox"/> | 5.1.1 Funding Source Detail: Ontario Mental Health Foundation | |
| <input type="checkbox"/> | 5.1.1 Funding Source Detail: Other1 | |
| <input type="checkbox"/> | 6. Scientific Peer Review Requirements | |
| <input type="checkbox"/> | 7.1 Hazardous Material Types Used | |
| <input type="checkbox"/> | 8. Acute & Chronic | |
| <input type="checkbox"/> | 9. Purpose of Animal Use | |
| <input type="checkbox"/> | 10.1 Animal Groups Overview | Select if change in animal groups - Flow Chart. Also, select 10.2 Procedures Narrative to update details AND 11.1 Species Information if Animal Numbers have changed |
| <input checked="" type="checkbox"/> | 10.2 Procedures Narrative | Select if change in procedural narrative. Also, select 11.15 to update Procedural Consequences |
| <input type="checkbox"/> | 11. Species List | Select if change in species type |

Continue **Clear Form** **Return to Home Page**

Provide the reason for the protocol modification

Select the section(s) of your AUP that you would like to modify and all related sections as well

Click Here to continue to selected section(s)

- c) **PI Updates Selected AUP Sections** → **Update Protocol Modification Sections** page → Click ‘**Section Name**’ link to access protocol page(s) to be revised → If you have selected a Protocol Modification Section in error, click the ‘**Select**’ checkbox beside the Section Name and select the ‘**Remove Selected Section**’ button.

Submit an Amendment for an Existing Protocol Bear, Yogi PI

Update Protocol Modification Sections

Protocol Info

| | |
|--------------|------------------------------------|
| PI_FULL_NAME | Bear, Yogi |
| AUP_NUMBER | 2010-045 |
| AUP_TITLE | Stress-induced tachycardia in pigs |

Protocol Modification > Justification

| | |
|--|--|
| Protocol Modification Number | 0002 |
| Date Started | 08/04/2010 |
| Reason/Justification for Protocol Modification | I would like to add a new procedure: Cardiac stress test |

Protocol Modification > Selected Sections

| Select | Section | Revised |
|-----------------------|--|---------|
| <input type="radio"/> | 10.2 Procedures Narrative | No |
| <input type="radio"/> | Piq: 11.15 Procedural Consequences | No |

Remove Selected Section

Continue Return to Protocol Modification Options Cancel Un-finished Protocol Modification Finish Later

Click Section Link to revise selected section(s)

'No' Indicates that section has not yet been revised

Click Here to remove a section once it has been selected

Click Here AFTER revising ALL required sections

Click Here to return to previous page

Click Here to cancel all changes

Click Here to Save & Modify section(s) later - AUP will now appear in your Alerts - Un-Finished Protocol Modifications' Section

d) **Instructions For the Next Page**→Protocol page opens→*Your original answers will appear beside each question for you to view only (please see illustration on next page)*→ You may choose between the following modification options on this page:

- **ADD** information (e.g. new contact, new hazardous agent, etc.)
- **REMOVE** information (e.g. remove a contact from the protocol, remove a funding source, etc.)
- **EDIT** information (change email address for protocol contact, change numbers assigned to CCAC Categories of Invasiveness, etc.)
- **NO CHANGE** – Do NOT delete any of the previously entered text; Enter ‘**No Changes (MOD / Current Date)**’ below the text to indicate that the information is current.

e) **Save Changes**→Click ‘**Save & Continue**’ button→**Update Protocol Modification Sections** page→Verify all changes to protocol sections→ Click ‘**Continue**’ button **OR** if you would like to finish your protocol modification(s) at a later time, click the ‘**Finish Later**’ button (**do NOT close out of eSirius before selecting one of these two save options or some information may be lost**).

Amendment Info

| | |
|------------------------------------|--|
| Principal Investigator | Bear, Yogi |
| Protocol Number | 2010-045 |
| Protocol Title | Stress-induced tachycardia in pigs |
| Amendment No. | 0002 |
| Amendment Status | Un-Finished |
| Reason/Justification for Amendment | I would like to add a new procedure: Cardiac stress test |
| Amendment Started Date | 08/04/2010 |

Protocol Modification Info appears at the top of the selected page

11.15 Procedural Consequences

From a **project overview perspective**, and taking into account **all animal-related events**, including animal procedures and agents/materials used and their potential impact (s), identify all possible **Procedural Consequences** for the species listed below. Include potential behavioural, physical, biochemical, physiological, and reproductive impacts.

Identify all possible **Pain, Distress, or Impairment** this species may experience from the overall project. If pain, distress or impairment is anticipated, detail **relief** to be provided. If relief is not provided, offer **scientific justification**.

For CCAC guidelines relating to the control of animal pain, link to [CCAC Guide, Vol. 1, X, Control of Animal Pain in Research, Teaching and Testing](#).

The following fields pertain to the species listed below.

| Species Name | Pig |
|--|--|
| 1. From BOTH the project OVERVIEW & DETAIL perspectives, IDENTIFY and DESCRIBE specific PROCEDURAL or OTHER ELEMENTS that may produce PAIN, DISTRESS, or IMPAIRMENT - and identify all possible consequences - Behavioural, Physical, Biochemical, Physiological, and Reproductive - for this species. | Constant exposure to loud Christmas carols may result in behavioural distress as well as physical impairment (ringing in the ears/deafness). The exposure to a mall environment on Christmas Eve may result in physical stress due to a lack of rest as well as emotional stress due to the hustle and bustle around the animals. Constant exposure to loud Christmas carols may result in behavioural distress as well as physical impairment (ringing in the ears/deafness). The exposure to a mall environment on Christmas Eve may result in physical stress due to a lack of rest as well as emotional stress due to the hustle and bustle around the animals. The Cardiac Stress Test may cause the pigs' heart rate to rise very quickly resulting in shortness of breath and chest pain. |
| 2. Detail RELIEF to be provided in response to the possible consequences identified within Q.1, or offer SCIENTIFIC JUSTIFICATION for not providing relief for this species. | Relief will not be provided as it is necessary to create conditions which mirror those experienced by humans during the holiday season. Should relief be provided, the results may not be entirely accurate. Relief will not be provided as it is necessary to create conditions which mirror those experienced by humans during the holiday season. Should relief be provided, the results may not be entirely accurate. No changes (MOD 07.01.2010) |

Your original answers appear for you to VIEW as you make the required changes.

All previous answers also appear within the modification text fields; do NOT erase any information that is still relevant to the AUP as the protocol modification rewrites the protocol information itself

Enter any NEW information within the protocol modification text field

If no changes to an AUP section, please do NOT delete any of the previously entered text; Enter 'No changes (MOD / current date)' below the text in order to let the AUS Office know that the content is still current

BUTTON USE -

- **SAVE & CONTINUE** - Updates this page's current information and automatically proceeds to the next *Animal Use Protocol* form page.
- **CLEAR PAGE REVISIONS** - Defaults to previously saved fields. Then click the 'Save & Continue' button, or click the next item on the **Table of Contents** (left margin) to proceed with this *Animal Use Protocol*
- **RETURN TO SPECIES LIST** - Click to return to web page **11. Species List** without saving and without completing details for currently chosen species. **Note:** Completion of this page and subsequent species-specific information are required before form submission.

Click Here to Clear all revisions that you have made to the web page

Click 'Save & Continue' when all revisions are complete to Save changes

Protocol Modification > Selected Sections

| Select | Section | Revised |
|-----------------------|--|---------|
| <input type="radio"/> | 10.2 Procedures Narrative | Yes |
| <input type="radio"/> | Pig: 11.15 Procedural Consequences | Yes |

Remove Selected Section

'Yes' indicates that sections have been modified

Click Here!

- f) **Associated Web Pages within Protocol Modification Sections** → When modifying an AUP section with associated web pages (e.g. **15. Protocol Personnel List**), you will automatically be guided to fill out all associated pages (e.g. **15.1 – Personnel Information**) as you complete the modification. All additional sections will appear within the **Protocol Modification > Selected Sections** list and will indicate 'Yes' since they have already been revised.

Protocol Modification > Selected Sections

| Select | Section | Revised |
|-----------------------|--|---------|
| <input type="radio"/> | Pig: 11.16 CCAC Categories of Invasiveness | Yes |
| <input type="radio"/> | 15. Protocol Personnel List | Yes |
| <input type="radio"/> | 15.1 Personnel Information: Lemon, Lily | Yes |

Remove Selected Section

Indicates that sections have been modified

New protocol modification sections are added automatically when you add information to a section that has associated page(s) (e.g. Personnel Information)

- g) **PI Enters Electronic Signature** → **Electronic Signature** page → Enter your login password into the 'Password' field → Click 'Continue' button

Submit an Amendment for an Existing Protocol Bear, Yogi

Electronic Signature

By electronically signing this protocol modification, you will confirm that you wish to submit your changes to the AUS Office

| | |
|--|--|
| Investigator Name | Bear, Yogi |
| Protocol Number | 2009-0059 |
| Protocol Title | Study of the effects of stress on pigs |
| Protocol Modification Number | 0001 |
| Date Started | 01/05/2010 |
| Reason/Justification for Protocol Modification | I would like to add another contact to this protocol as well as update the CCAC Categories of Invasiveness |
| Password | ●●●●● <input type="text"/> |

Enter your Login password

Click Here

- h) **PI Submits a Protocol Modification to the AUS Office** → **Submit Protocol Modification** page → Click 'Submit to AUS Office' button → Email notification is sent to the AUS

Office → Protocol Modification (#0001) will now appear in the **Alerts-New Protocol Modifications** section of your Home Page.

Submit an Amendment for an Existing Protocol Bear, Yogi **PI**



Submit Protocol Modification

You have successfully completed your submission for a protocol modification. When you click on **Submit to AUS Office**, an email notification is sent out. You may follow the status of your application by periodically checking your **eSirius** alerts.

Protocol Modification Information

| | |
|--|--|
| Investigator Name | Bear, Yogi |
| Protocol Number | 2009-0059 |
| Protocol Title | Study of the effects of stress on pigs |
| Protocol Modification Number | 0001 |
| Date Started | 01/05/2010 |
| Reason/Justification for Protocol Modification | I would like to add another contact to this protocol as well as update the CCAC Categories of Invasiveness |

[Submit to AUS Office](#) ← [Click Here to send email to the AUS Office](#)

Home Page Bear, Yogi **PI** [SIGN OUT](#) [REFRESH](#) 01/22/2010

Alerts... [Protocols: Un-Finished](#) [Protocols: New](#) [ProtMod: Un-finished](#) [ProtMod: New](#)

[Animal Use Protocol Options](#)

[Change Password](#)

ALERTS - UN-FINISHED PROTOCOLS

| AUP_NUMBER | FORM TYPE | AUP_TITLE | UPDATED |
|---------------------------|-----------|-----------|------------|
| 2010-0008 | New | | 01/18/2010 |
| 2010-0010 | New | | // |

ALERTS - NEW PROTOCOLS

| AUP_NUMBER | AUP_YR | PI_FULL_NAME | SUBMITTED | FORM TYPE | FROM | TO | WORKFLOW DATE | ACTION |
|---------------------------|--------|--------------|------------|----------------------|----------|----------|---------------|---------------------|
| 2009-0029 | 1 | Bear, Yogi | 11/09/2009 | New | IACUC | AUS | 11/10/2009 | Workflow Cancelled |
| 2009-0037 | 1 | Bear, Yogi | 11/19/2009 | New - Under Revision | | AUS | 01/08/2010 | |
| 2009-0060 | 1 | Bear, Yogi | 12/30/2009 | New - Under Revision | Reviewer | AUS | 01/08/2010 | Designated Reviewed |
| 2010-0007 | 1 | Bear, Yogi | 01/16/2010 | New | PI | AUS | 01/16/2010 | Requests Review |
| 2009-0031 | 1 | Bear, Yogi | 01/04/2010 | New - Under Revision | AUS | Reviewer | 01/19/2010 | Review |
| 2009-0035 | 1 | Bear, Yogi | 11/25/2009 | New - Under Revision | AUS | Reviewer | 01/19/2010 | Review |
| 2009-0052 | 1 | Bear, Yogi | 12/16/2009 | New - Under Revision | AUS | Reviewer | 12/23/2009 | Review |
| 2010-0006 | 1 | Bear, Yogi | 01/15/2010 | New | AUS | Reviewer | 01/15/2010 | Review |

ALERTS - UN-FINISHED PROTOCOL MODIFICATIONS

| AUP_NUMBER | AUP_YR | PROT MOD # | AUP_TITLE | ProtMod Date | REASON JUSTIFICATION |
|---------------------------|--------|------------|--|--------------|----------------------|
| 2010-0001 | 1 | 0001 | Protocol for Designated Review | 01/21/2010 | |
| 2010-0003 | 1 | 0002 | Effects of Apomoxillan on immunodeficient pigs | 01/19/2010 | |

Protocol Appears Here →

ALERTS - NEW PROTOCOL MODIFICATIONS

| AUP_NUMBER | AUP_YR | PI_FULL_NAME | PROT MOD # | AUP_TITLE | FROM | TO | WORKFLOW DATE | REASON JUSTIFICATION | ACTION |
|---------------------------|--------|--------------|------------|--|------|-----|---------------|--|-----------------|
| 2009-0056 | 1 | Duck, Donald | 0001 | Study of the effects of stress on pigs | PI | AUS | 01/05/2010 | I would like to add another contact to this protocol as well as update the CCAC Categories of Invasiveness | Requests Review |

Indicates that this is the first modification for this protocol

Indicates that PI has sent protocol modification to the AUS office for review

- i) **PI Designate Completes a Protocol Modification on Behalf of the PI** → A PI Designate will be given access to the PI Group to which they belong: they will have the ability to sign in the PI's Home Page and complete a Protocol Modification on behalf of the PI, following the same process as described previously → **The PI Designate CANNOT submit an AUP directly to the AUS Office**; the Designate must submit the Protocol Modification to the PI and the PI can then verify and send

the AUP to the AUS Office→ The Protocol Modification will appear within the Alerts-Un-Finished Protocol Modifications section of the PI's Homepage→ The following example illustrates the Submit Page view for a PI Designate who has completed a Protocol Modification for Doctor Blue:

The PI Designate is signed in to Doctor Blue's PI Group

Submit an Amendment for an Existing Protocol | **Designate, Pi/Blue, Doctor** | PI | SIGN OUT | HOME | 10/13/2010

Step 5: Submit Protocol Modification

You have successfully completed your submission for a protocol modification. When you click on **Submit to AUS Office**, an email notification is sent out. You may follow the status of your application by periodically checking your **eSirius** alerts.

Note for PI Designates: When you click **Submit to PI**, the application will be sent to the PI who will then forward the Protocol Modification to the AUS Office for review.

Protocol Modification Information

| | |
|------------------------|---|
| PI FULL NAME | Blue, Doctor |
| AUP NUMBER | 2010-100 |
| AUP TITLE | Study of the neurological effects of eSirius Training over an extended period of time |
| PROT MOD # | 0001 |
| START DATE | 10/12/2010 |
| PROT MOD JUSTIFICATION | Justification for Protocol Modification |

Submit to PI

* Required Fields

Click 'Submit to PI' to send the Protocol Modification to the PI for verification. The PI will then submit the AUP to the AUS Office for review

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www.ntmcs.com

- j) **Protocol Modification Review**→ The protocol modification review process is similar to the review process outlined in **Section 3 – AUP Review & Committee Approval – Workflow Process**. You may track the progress of your requested protocol modifications(s) by clicking the **protocol #** link in the **Alerts-New Protocol Modifications** section of your **Home Page**→ **Protocol Modification Workflow** page→**Pages Under Protocol Modification** section→Once protocol is returned to you by the AUS Office with **Questions/Recommendations**, you may access the modification sections by clicking the **Page Name** link→You will receive an email notification (see Section 3.4 example) from eSirius once your protocol has been assigned a status during the weekly or monthly AUS Committee Meeting.

Submit an Amendment for an Existing Protocol Duck, Donald PI

Protocol Modification Workflow

Protocol Info

Principal Investigator: Duck, Donald
 Protocol Number: 2009-0056
 Protocol Title: Study of the effects of stress on pigs

Protocol Modification Info

Protocol Modification #: 0001
 Protocol Modification Start Date: 01/05/2010
 Current Status: Pending
 Reason/Justification for Protocol Modification: blah

Pages Under Protocol Modification

| Page | Revised by PI | New Page Modified by PI | Page marked by Reviewer |
|---|---------------|-------------------------|-------------------------|
| Pg: 11.16 CCAC Categories of Invasiveness | No | No | No |

Electronic Signature

Password:

Submit to AUS Office Return to Home Page Clear Form Cancel Protocol Modification

Indicates that protocol modification has not yet been approved

Allows you to modify the reason/justification for the protocol modification

Click Page Name to access modification section once protocol has been sent back to you by the AUS Office with Questions/Recommendations

4.2 – PI Submits a Protocol Modification for a Change to Animal Numbers

- a) PI Selects an AUP to Request an Increase in Animal Numbers → eSirius → PI Home Page → Submit Protocol Modification for an Approved AUP → List of Approved Protocols → Choose protocol to be modified from the list:

Submit an Amendment for an Existing Protocol Bear, Yogi PI

List of Approved Protocols

To start a protocol modification, select the desired protocol and click **Continue**. To **View** in its entirety, click the protocol number link.

| Select | PI | Protocol # | Protocol Title |
|----------------------------------|------------|---------------------------|--|
| <input type="radio"/> | Bear, Yogi | 2009-0029 | PI TEST |
| <input type="radio"/> | Bear, Yogi | 2009-0031 | Study of the use of Ibuprofen and its potential relationship to cardiac arrhythmia |
| <input type="radio"/> | Bear, Yogi | 2009-0037 | FILL IN THE BLANKS! |
| <input type="radio"/> | Bear, Yogi | 2009-0052 | Jellystone Park |
| <input type="radio"/> | Bear, Yogi | 2009-0060 | Study of the effects of stress on pigs for 2010 |
| <input type="radio"/> | Bear, Yogi | 2010-0001 | Protocol for Designated Review |
| <input type="radio"/> | Bear, Yogi | 2010-0002 | Test of the anticoagulant drug Apomoxilan on pigs with immunodeficiencies. |
| <input type="radio"/> | Bear, Yogi | 2010-0007 | Study of the effects of stress on pigs |
| <input type="radio"/> | Bear, Yogi | 2010-0016 | TEST |
| <input type="radio"/> | Bear, Yogi | 2010-008 | TEST |
| <input type="radio"/> | Bear, Yogi | 2010-013 | Study of the use of Ibuprofen and its potential relationship to cardiac arrhythmia |
| <input checked="" type="radio"/> | Bear, Yogi | 2010-015 | Study of the use of Ibuprofen and its potential relationship to cardiac arrhythmia |

Continue Return to Home Page

Click Here!

- b) PI Chooses Protocol Modification Sections → For changes to animal numbers, please select Section 11.1 – Species Information along with associated sections (11.2 and 11.16 – these sections

will automatically appear on the 'Update Protocol Modification Sections' page whether you select them or not):

| | | | |
|---|--|-------------------|--|
| Submit an Amendment for an Existing Protocol | | Bear, Yogi | PI |
| Choose Protocol Modification Sections | | | |
| Protocol Info | | | |
| PI_FULL_NAME | Bear, Yogi | | |
| AUP_NUMBER | 2010-015 | | |
| AUP_TITLE | Study of the use of Ibuprofen and its potential relationship to cardiac arrhythmia | | |
| Protocol Modification > Justification | | | |
| Protocol Modification Number | | | |
| Date Started | / / | | |
| Reason/Justification for Protocol Modification | Additional mice are required for research | | <input type="button" value="↑"/> <input type="button" value="↓"/> |

Indicate that you will be changing animal numbers

Protocol Modification > Choose Applicable Section(s)

| Select | Section | Instruction |
|-------------------------------------|---|--|
| <input type="checkbox"/> | 15. Protocol Personnel List | Add, remove or change personnel information, including their live animal activities associated with this AUP. |
| <input type="checkbox"/> | 1. Investigator Contact Information | PI contact information changes |
| <input type="checkbox"/> | 2. Protocol Title & Project Type | Protocol Title, Project Type & Start Date changes |
| <input type="checkbox"/> | 3. Lay Summary & Glossary | Lay Summary or Glossary of Scientific Terms updates |
| <input type="checkbox"/> | 4. CCAC Animal Procedural Outline | CCAC Procedural Outline updates. May require update if new live animal procedures are added to web pages 10.2 and 11.1-11.16 |
| <input type="checkbox"/> | 5.1 Funding Source List | Funding Source information updates, including funding name, title, type, grant number, contact information (commercial/contract), etc. |
| <input type="checkbox"/> | 5.1.1 Funding Source Detail: Cancer Research Society Inc. | |
| <input type="checkbox"/> | 6. Scientific Peer Review Requirements | Scientific Peer Review requirements, including publications, background, rationale, hypothesis, objectives, and experimental procedures for scientific peer reviewers if requested or required |
| <input type="checkbox"/> | 8. Acute & Chronic Studies | Acute and other. Required for this Protocol |
| <input type="checkbox"/> | 9. Purpose of Study | Part. ALSO, select 10.2 details AND 11.1 numbers have changed |
| <input type="checkbox"/> | 10.1 Animal Numbers | update 11.15 other species-specific |
| <input type="checkbox"/> | 10.2 Procedural Consequences | e.g. if new surgery is added, also complete 11.12.5 Surgery List |
| <input type="checkbox"/> | 11. Species List | Species type change |
| <input checked="" type="checkbox"/> | Mouse: 11.1 Species Information | Change in species activities: If Animal Number change, ALSO complete 11.2 AND 11.16, YES/NO Questions re. Non-Haz &/or Haz Materials, Breeding, Restraint, Surgery (ALSO complete individual information pages for these elements, see 11.12 sections below) |
| <input checked="" type="checkbox"/> | Mouse: 11.2 Justification for Species Choice & Number | Change in justification for CHOICE and/or NUMBER of species. If NUMBER change, also complete 11.1 Species Information page |
| <input type="checkbox"/> | Mouse: 11.3 Species Source | Change in species source, e.g. commercial, non-commercial sources |
| <input type="checkbox"/> | Mouse: 11.4 Species Strains | Change in species strains |
| <input type="checkbox"/> | Mouse: 11.5 Animal Holding/Housing Locations List | Change in animal holding or housing locations. If NEW animal facility, also complete 11.8 Caging, Dietary Requirements and Environmental Enrichment (view facility specific E.E. SOPs) |
| <input type="checkbox"/> | Mouse: 11.5.1. Animal Holding/Housing Location Information: THAMES HALL | |
| <input type="checkbox"/> | Mouse: 11.6 Non-Managed Holding/Housing | Change in non-managed holding or housing location |
| <input type="checkbox"/> | Mouse: 11.7 Holding Period & Quarantine | Change in holding period or quarantine requirements |
| <input type="checkbox"/> | Mouse: 11.8 Caging, Dietary Requirements & Environmental Enrichment | Change in caging, dietary or environmental enrichment requirements and if NEW animal holding facility is chosen within 11.5 Animal Holding/Housing location |
| <input type="checkbox"/> | Mouse: 11.9 Animal Procedure Locations List | Change in animal procedure locations |
| <input type="checkbox"/> | Mouse: 11.9.1 Procedure Location Information: THAMES HALL | |
| <input type="checkbox"/> | Mouse: 11.10 Animal Movement Between Sites | Change in animal movement between sites |
| <input type="checkbox"/> | Mouse: 11.11 Monitoring & Early Euthanasia Endpoints | Change in monitoring or criteria for early euthanasia |
| <input type="checkbox"/> | Mouse: 11.13 Euthanasia Methods List | Change to euthanasia method used |
| <input type="checkbox"/> | Mouse: 11.13.1 Euthanasia Method Information: Exsanguination Under Anesthesia | |
| <input type="checkbox"/> | Mouse: 11.14 CCAC Reporting Checklist | Change in other procedures requiring CCAC training. If personnel are involved, also modify 15. Personnel Information - Protocol Activities section. |
| <input type="checkbox"/> | Mouse: 11.15 Procedural Consequences | Changes to procedural consequences to animals for ANY and ALL procedural changes (e.g. monitoring, surgery, agents use, restraints, injections, etc.) to this AUP |
| <input checked="" type="checkbox"/> | Mouse: 11.16 CCAC Categories of Invasiveness | Change to CCAC Category of Invasiveness and update 11.15 Procedural Consequences. Complete if change in ANIMAL NUMBERS on 11.1 |
| <input type="checkbox"/> | 12. Field/Wildlife Animal Research | Changes to field or wildlife research |
| <input type="checkbox"/> | 14.1 Teaching Information | Change in teaching elements |

For changes to Animal Numbers, select protocol modification section 11.1 - Species Information (Associated pages: 11.2 and 11.16 will automatically appear for revision on 'Update Protocol Modification Sections' page

Continue Clear Form Return to Home Page

Click Here!

- c) **PI Updates Protocol Modification Sections Related to Animal Numbers** → **Update Protocol Modification Sections** page → Update all sections pertaining to a change in animal numbers (11.1, 11.2 and 11.16), then click 'Continue'

Update Protocol Modification Sections

Protocol Info

| | |
|--------------|--|
| PI_FULL_NAME | Bear, Yogi |
| AUP_NUMBER | 2010-015 |
| AUP_TITLE | Study of the use of Ibuprofen and its potential relationship to cardiac arrhythmia |

Protocol Modification > Justification

| | |
|--|---|
| Protocol Modification Number | 0002 |
| Date Started | 03/03/2010 |
| Reason/Justification for Protocol Modification | Additional mice are required for research |

Protocol Modification > Selected Sections

| Select | Section | Revised |
|----------------------------------|---|---------|
| <input checked="" type="radio"/> | Mouse: 11.1 Species Information | Yes |
| <input type="radio"/> | Mouse: 11.2 Justification for Species Choice & Number | No |
| <input type="radio"/> | Mouse: 11.16 CCAC Categories of Invasiveness | No |

Remove Selected Section

Select each Section link: You must revise all associated pages (they should all read 'Yes') before you can continue

Amendment Info

| | |
|------------------------------------|--|
| Principal Investigator | Bear, Yogi |
| Protocol Number | 2010-015 |
| Protocol Title | Study of the use of Ibuprofen and its potential relationship to cardiac arrhythmia |
| Amendment No. | 0001 |
| Amendment Status | Un-Finished |
| Reason/Justification for Amendment | Additional mice are required |
| Amendment Started Date | 03/02/2010 |

Enter the New **4 Year Total** Numbers for the species rather than entering the number of animals that you would like to add (E.g. If you would like to add 3000 more mice to a protocol that was originally approved for 2000 mice over four years, you must add the 2000 original mice + 3000 additional mice to request a four year total of 5000 mice). *Animal numbers now reflect the total required for the 4 year life of the protocol, NOT the amount required annually.*

11.1 Species Information

Choose the proposed species from the pick list. Enter 2 - 6 for each species. Inform the Administrator if you are not available. See below for details pertaining to animal number determination.

New Requested #

| Species Name | To | From |
|--------------|--------|------|
| Mouse | 5000 * | 2000 |

Original Authorized #

To view examples of experimental procedures considered to be representative of each category listed above, link to CCAC's [Categories of Invasive Experiments](#)

Indicates the number change that you requested on section 11.1- Species Information

The following fields pertain to the species listed below.

| Species Name | | Mouse | |
|-------------------------------|-----------------------------------|--------|---------------------------------|
| Total # Requested for Species | 5000 | To | From |
| | | 2000 | 5000 |
| Pain Level | # of Animals | Action | Description |
| E | <input type="text" value="0"/> | | Severe Pain |
| D | <input type="text" value="0"/> | | Mod-Severe Distress/ Discomfort |
| C | <input type="text" value="5000"/> | | Minor Stress or Short-Term Pain |
| B | <input type="text" value="2000"/> | | Little/No Discomfort or Stress |

Enter new #'s/ Category of Invasiveness

Please NOTE: You can only assign ONE Category of Invasiveness to the selected Species; Please assign the highest Category of Invasiveness per species

Indicates original # of animals/Category of Invasiveness

BUTTON USE -

- **SAVE & CONTINUE** - Update information and automatically proceeds to the protocol form page.
- **CLEAR PAGE REVISIONS** - Defaults to previously saved fields. Then click the 'Save & Continue' button, or click the next item on the **Table of Contents** (left margin) to proceed with this *Animal Use Protocol*
- **RETURN TO SPECIES LIST** - Click to return to web page **11. Species List without saving and without completing details** for currently chosen species. **Note:** Completion of this page and subsequent species-specific information are required before form submission.

Save & Continue Clear Page Revisions

Submit an Amendment for an Existing Protocol Bear, Yogi PI

Electronic Signature

By electronically signing this protocol modification, you will confirm that you wish to submit your changes to the AUS Office

| | |
|--|--|
| Investigator Name | Bear, Yogi |
| Protocol Number | 2010-015 |
| Protocol Title | Study of the use of Ibuprofen and its potential relationship to cardiac arrhythmia |
| Protocol Modification Number | 0002 |
| Date Started | 03/03/2010 |
| Reason/Justification for Protocol Modification | Additional mice are required for research |
| PASSWORD | <input type="password" value="....."/> |

Enter Password

Continue Clear Form Finish Later

Animal # Protocol Modification has been submitted for review

| ALERTS - NEW PROTOCOL MODIFICATIONS | | | | | | | | | |
|-------------------------------------|--------|--------------------|------------|--|------|-----|---------------|---|-----------------|
| AUP_NUMBER | AUP_YR | PRINC_INVESTIGATOR | PROT_MOD # | PROTOCOL_TITLE | FROM | TO | WORKFLOW_DATE | REASON_JUSTIFICATION | ACTION |
| 2010-015 | 1 | Bear, Yogi | 0002 | Study of the use of Ibuprofen and its potential relationship to cardiac arrhythmia | PI | AUS | 03/03/2010 | Additional mice are required for research | Requests Review |

- d) **Animal Number Protocol Modification has been Approved by the AUS Office** → Once your change in animal numbers has been approved, you may view the change to the species usage register through the ‘Search – AUP Species Register’ feature on your Home Page (see instructions for **Section 6.3 – AUP Species Register**) → Please see example of an updated register due to an approved animal number protocol modification:

5000 Protocol Species Usage Register Bear, Yogi PI

Protocol Register Summary Results

Results are organized by Category of Invasiveness

| Select | Protocol | PI | Status | Approved | Expires | Species | CCAC CI | Original Auth. | ProtMod Total | Order DB | Order CR | XFR DB | XFR CR | Total |
|-----------------------|----------|------------|----------------------------|------------|------------|---------|---------|----------------|---------------|----------|----------|--------|--------|-------|
| <input type="radio"/> | 2010-015 | Bear, Yogi | Approved (w/o Stipulation) | 03/02/2010 | 03/02/2014 | Mouse B | | 2000 | -2000 | 0 | 0 | 0 | 0 | 0 |
| <input type="radio"/> | 2010-015 | Bear, Yogi | Approved (w/o Stipulation) | 03/02/2010 | 03/02/2014 | Mouse C | | 0 | 5000 | 0 | 0 | 0 | 0 | 5000 |

View Register Detail for Selected Protocol

Indicates total #'s requested within protocol modification

Indicates current Animal #'s total

Indicates total #'s originally authorized during initial approval