

## Section 3 – AUP Review & Committee Approval – Workflow Process

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## 3.1 – PI Submits a New AUP to the AUS Office

- a) **PI Views the AUP Workflow Page Once an Application Has Been Submitted to the AUS Office** → PI → eSirius Login → Home Page → Alerts – New Protocols section → To view the status of your *Animal Use Protocol* within the review process, click the protocol number link appearing in the ‘Alerts-New Protocols’ section on your Home Page → The **Animal Use Protocol Review Workflow** page will open.

**Home Page**

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

Animal Use Protocol Options  
[Change Password](#)

**ALERTS - UN-FINISHED PROTOCOLS**

AUP_NUMBER	FORM TYPE	AUP_TITLE	UPDATED
<a href="#">2010-0010</a>	New		//
<a href="#">2010-0013</a>	New	Emily's Protocol	01/22/2010

**ALERTS - NEW PROTOCOLS**

AUP_NUMBER	AUP_YR	PI_FULL_NAME	SUBMITTED	FORM TYPE	FROM	TO	WORKFLOW DATE	ACTION
<a href="#">2009-059</a>	1	Bear, Yogi	11/09/2009	New	PI	AUS	01/27/2010	Requests Review
<a href="#">2010-0015</a>	1	Bear, Yogi	01/22/2010	New - Under Revision	AUS	PI	01/22/2010	Changes Requested
<a href="#">2010-0007</a>	1	Bear, Yogi	01/16/2010	New - Under Revision	AUS	Reviewer	03/19/2010	Review

**ALERTS - UN-FINISHED PROTOCOL MODIFICATIONS**

AUP_NUMBER	AUP_YR	PROT MOD #	AUP_TITLE	ProtMod Date	REASON_JUSTIFICATION
<a href="#">2010-0001</a>	1	0001	Protocol for Designated Review	01/21/2010	
<a href="#">2010-0016</a>	1	0001	TEST	01/26/2010	

**ANIMAL USE PROTOCOL OPTIONS**

- [Submit - Animal Use Protocol - AUP Form](#)
- [Submit - Animal Use Protocol \(AUP\) Form FROM an Existing AUP](#)
- [Submit - Protocol Modification Form for an Approved AUP](#)
- [Transfer Ownership of Protocol to Another Researcher](#)
- [Search - Animal Use Protocol](#)
- [Search - AUP Species Usage Register](#)
- [Search - Protocol Modification](#)
- [Reports - Protocol](#)
- [Reports - Regulatory Compliance](#)
- [Reports - Protocol Contacts](#)

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Submit an Application for a New Protocol      Bear, Yogi      PI      SIGN OUT      HOME

## Animal Use Protocol Review Workflow

### Protocol Information

Principal Investigator	Bear, Yogi
Protocol Number	<a href="#">2009-0059</a>
Protocol Title	Study of the effects of stress on pigs
Document Status	New
Submit Date	12/23/2009
Anticipated Research Start Date	12/31/2009
Anticipated Research End Date	//

Click Protocol # Link to View/Print Protocol

### Revision Information

Revision Number	0000000001
Revision Date	12/23/2009
Revision Status	OPEN
Work Flow Status	AUS

Location of protocol within the Review Process (Protocol is still with AUS Office)

### Pages Under Review

List expands as reviewers return recommendations for revision

PI Instructions - Please click on each 'Page' column link to respond to Reviewer recommendations. Once all reviewer recommendations have been addressed, please click 'Submit to AUS Office' button.

Page	Description	AUS Recommendation	Revised by PI	PI Rev. Date	PI Page Added
<a href="#">Return to Home Page</a>					

Click Here to return to your Home Page

- b) **PI Receives a Notification that an AUP Has Been Sent for Review** → Once protocol has been sent for review by the AUS Office, you will receive the following notification within the 'Alerts-New Protocols' section when you sign in to your Home Page:

ALERTS - NEW PROTOCOLS									
Protocol #	Protocol Yr	PI	Submitted	Document Type	From	To	Work Flow Status	Date	Request
<a href="#">2009-0029</a>	1	Bear, Yogi	11/09/2009	New	IACUC	AUS	11/10/2009		Workflow Cancelled
<a href="#">2009-0054</a>	1	Bear, Yogi	12/16/2009	New - Under Revision		AUS	12/23/2009		
<a href="#">2009-0058</a>	1	Bear, Yogi	12/21/2009	New - Under Revision	AUS	Committee	12/21/2009		Review
<a href="#">2009-0031</a>	1	Bear, Yogi	11/25/2009	New - Under Revision	AUS	Reviewer	12/21/2009		Review
<a href="#">2009-0035</a>	1	Bear, Yogi	11/25/2009	New	AUS	Reviewer	11/25/2009		Review
<a href="#">2009-0037</a>	1	Bear, Yogi	11/19/2009	New - Under Revision	AUS	Reviewer	12/21/2009		Review
<a href="#">2009-0052</a>	1	Bear, Yogi	12/16/2009	New - Under Revision	AUS	Reviewer	12/23/2009		Review
<a href="#">2009-0059</a>	1	Bear, Yogi	12/23/2009	New - Under Revision	AUS	Reviewer	12/23/2009		Review

Click Link to View AUP Review Workflow page

Indicates that protocol has been sent by AUS Office to Reviewers

Indicates that the protocol is now under review

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- c) **PI Views AUS Recommendation Notes While AUP is Under Review** → Click **Protocol # Link** → **AUP Review Workflow** page → Allows you to view AUS Office recommendation notes, however you are unable to make any changes to your protocol application at this point in the process:

Submit an Application for a New Protocol      Bear, Yogi      PI

### Animal Use Protocol Review Workflow

#### Protocol Information

Principal Investigator	Bear, Yogi
Protocol Number	2009-0059
Protocol Title	Study of the effects of stress on pigs
Document Status	New - Under Revision
Submit Date	12/23/2009
Anticipated Research Start Date	12/31/2009
Anticipated Research End Date	//

#### Revision Information

Revision Number	0000000001
Revision Date	12/23/2009
Revision Status	OPEN
Work Flow Status	Reviewer

PI's view of the protocol once the AUS Office has sent request to Reviewers: PI can see AUS Office recommendations, but is unable to make any changes at this point

#### Pages Under Review

PI Instructions - Please click on the 'Recommend' button to provide your recommendations. Once you have provided your recommendations, click the 'Submit to AUS Office' button.

Page	Description	AUS Recommendation	Revised by PI	PI Rev. Date	PI Page Added
3. Lay Summary & Glossary		Further detail is required for this section	No	//	No
15. Protocol Personnel List		Update Email ID for Yogi Bear	No	//	No

The Revision # refers to the number of times that a round of recommendations/questions have been submitted for an AUP by assigned reviewers then compiled by the AUS Office and sent to you for revision

Return to Home Page      Click Here to return to your Home Page

### 3.2 – AUS Office Returns AUP to the PI for Revision

- a) **PI Receives an email notification to request revisions to the AUP application** → PI Home Page → Alerts-New Protocols section → Click **Protocol # Link** → **AUP Review Workflow** page → **Pages Under Review** section → Click **'Page'** link to access each section under review.
- b) **Definition of 'Revision'** → A 'Revision' refers to a round of recommendations/questions/comments that have been submitted for an AUP by assigned reviewers and then compiled by the AUS Office

## Section 3 – AUP Review & Committee Approval – Workflow Process

and sent to you for revision. Once you have made the requested changes and answered all associated questions, you will then send the current Revision back to the AUS Office. At this time, you will either be sent another round of recommendations (a second Revision) or your AUP will be sent to the Agenda to be approved by the full AUS.

### Animal Use Protocol Review Workflow

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#### Protocol Information

Principal Investigator	Bear, Yogi
Protocol Number	2009-0059
Protocol Title	Study of the effects of stress on pigs
Document Status	New - Under Revision
Submit Date	12/23/2009
Anticipated Research Start Date	12/31/2009
Anticipated Research End Date	//

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#### Revision Information

Revision Number	0000000001
Revision Date	12/23/2009
Revision Status	OPEN
Work Flow Status	PI

Click on each 'Page' column link to respond to all AUS Recommendations

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#### Pages Under Review

PI Instructions - Please click on each 'Page' column link to respond to Reviewer recommendations. Once all reviewer recommendations have been addressed, please click 'Submit to AUS Office' button.

Page	Description	AUS Recommendation	Revised by PI	PI Rev. Date	PI Page Added
<a href="#">3. Lay Summary &amp; Glossary</a>		Further detail is required for this section	No	//	No
<a href="#">4. CCAC Animal Procedural Outline</a>		Please provide further detail in this section - perhaps you could elaborate on the ingredients within the Christmas pudding and gingerbread men as well as provide the exact volume at which the Christmas carols will be played (along with the names of the carols that have been chosen).  PI could also add the quantity of gingerbread men and Christmas pudding to be fed to the pigs daily.	No	//	No
<a href="#">7. Use of Hazardous Materials Question</a>		Confirmed	No	//	No
<a href="#">11.4 Species Strains</a>	Pig	A minimum of three strains is required to explore the similarities/differences in reaction that may occur within the same species when exposed to a similar stimulus.  Please resubmit application to include additional pig strain to be used for research.	No	//	No
<a href="#">11.12.2 Hazardous Agents, Materials &amp; Devices List</a>	Pig	Confirmed	No	//	No
<a href="#">11.12.3A Physical Restraint Information</a>	Pig; Collar	Please give more detail for Q.5 - answer does to elaborate as to HOW collars will eliminate other possible causes of stress for the pigs.	No	//	No
<a href="#">15. Protocol Personnel List</a>		Please verify the updated email contact information	No	//	No
<a href="#">15.1 Personnel Information</a>	Duck, Donald	Confirmed	No	//	No
<a href="#">15.1 Personnel Information</a>	Bear, Yogi	Confirmed	No	//	No
<a href="#">15.2 Personnel Protocol Related Activities</a>	Duck, Donald	Donald Duck has not yet been trained to administer injectable anaesthetics. A training session will be available on January 4, 2010. Donald Duck MUST receive the training before he can begin to work with the pigs.	No	//	No

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#### Electronic Signature

Password	<input style="width: 95%;" type="password"/>
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Submit to AUS Office

Return to Home Page

Clear Form

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- c) **PI Makes Changes to AUP Sections Marked for Revision by the AUS** → PI must view/edit each section marked for review by AUS Office → Your original answers will appear for your reference → Make all of the requested changes to each section and then click **'Save & Continue'** button:

The screenshot shows a web application interface for submitting a new protocol application. At the top, it says "Submit an Application for a New Protocol" and "Bear, Yogi". Below this is a "Recommendation Notes" section with a red bar indicating "Further detail is required for this section". The main section is titled "3. Lay Summary & Glossary". It contains instructions for writing a "Protocol Lay Summary" and a "Glossary of Terms". Below the instructions is a table with the following data:

Principal Investigator	Bear, Yogi
Protocol Application Number	2009-0059
Document Type	New - Under Revision
Protocol Year	1

Below the table is a section titled "1. Provide a brief lay summary, including the project's purpose and expected benefit of this Animal Use Protocol." The original text is highlighted in yellow: "The purpose of this project is to prove that pigs experience the same levels of stress as humans do when subjected to the Christmas season." Below this is a text area where the user has revised the text: "The purpose of this project is to prove that pigs experience the same levels of stress as humans do when subjected to the Christmas season. Pigs are very intelligent and also anatomically similar to humans so they should provide an accurate comparison in both physical and mental behaviours in response to certain stimuli. Three strains have been selected for research to perform a broader study of animal behaviour."

Callouts explain the workflow: "Recommended changes appear at the top of the section to be revised" (pointing to the red bar), "The original text from the protocol application is displayed above the current editable text for reference (highlighted)" (pointing to the yellow highlight), and "You can revised/add to the original information within this field" (pointing to the text area).

Save & Continue    Clear Page Revisions    Save & Return Home

Click Here to save changes & continue with revisions

Click Here to delete all changes you have made on current page

Click Here to save changes and finish the revisions later

# Section 3 – AUP Review & Committee Approval – Workflow Process

## Pages Under Review

PI Instructions - Please click on each 'Page' column link to respond to Reviewer recommendations. Once all reviewer recommendations have been addressed, please click 'Submit to AUS Office' button.

Page	Description	AUS Recommendation	Revised by PI	PI Rev. Date	PI Page Added
<a href="#">3. Lay Summary &amp; Glossary</a>		Further detail is required for this section	Yes	12/28/2009	No
<a href="#">4. CCAC Animal Procedural Outline</a>		Please provide further detail in this section - perhaps you could elaborate on the ingredients within the Christmas pudding and gingerbread men as well as provide the exact volume at which the Christmas carols will be played (along with the names of the carols that have been chosen).  PI could also add the quantity of gingerbread men and Christmas pudding to be fed to the pigs daily.	No	//	No

Once each section is revised & saved, the 'Revised by PI' status on your AUP Review Workflow page will be updated to 'Yes'.

Page	Description	AUS Recommendation	Revised by PI	PI Rev. Date	PI Page Added
<a href="#">3. Lay Summary &amp; Glossary</a>		Further detail is required for this section	Yes	12/28/2009	No
<a href="#">4. CCAC Animal Procedural Outline</a>		Please provide further detail in this section - perhaps you could elaborate on the ingredients within the Christmas pudding and gingerbread men as well as provide the exact volume at which the Christmas carols will be played (along with the names of the carols that have been chosen).  PI could also add the quantity of gingerbread men and Christmas pudding to be fed to the pigs daily.	Yes	12/28/2009	No
<a href="#">7. Use of Hazardous Materials Question</a>		Confirmed	Yes	12/28/2009	No
<a href="#">11.4 Species Strains</a>	Pig	A minimum of three strains is required to explore the similarities/differences in reaction that may occur within the same species when exposed to a similar stimulus.	Yes	12/28/2009	No
<a href="#">11.12.2 Hazardous Agents, Materials &amp; Devices List</a>			Yes	12/28/2009	No
<a href="#">11.12.3A Physical Restraint Information</a>			Yes	12/28/2009	No
<a href="#">15. Protocol Personnel List</a>			Yes	12/28/2009	No
<a href="#">15.1 Personnel Information</a>			Yes	12/28/2009	No
<a href="#">15.1 Personnel Information</a>	Bear, Yogi	Confirmed	Yes	12/28/2009	No
<a href="#">15.2 Personnel Protocol Related Activities</a>	{DELETED} Duck, Donald	Donald Duck has not yet been trained to administer injectable anaesthetics. A training session will be available on January 4, 2010. Donald Duck MUST receive the training before he can begin to work with the pigs.	Yes	12/28/2009	No

When information is removed from a page (e.g. Donald Duck is no longer permitted to administer Anaesthetics, so this activity has been removed from page '15.2 Personnel Protocol Related Activities' as per AUS Recommendations), the word 'Deleted' will appear under the description for that selected page.

## Electronic Signature

Password

Once you have viewed/revised all listed pages, you may enter your password into the Electronic Signature field and then click 'Submit to AUS Office' button

## Section 3 – AUP Review & Committee Approval – Workflow Process

ALERTS - NEW PROTOCOLS		Bear, Yogi		PI		SIGN OUT		REFRESH		12/28/2009	
Protocol #	Protocol Yr	PI	Submitted	Document Type	From	To	Work Flow Status	Date	Request		
2009-0029	1	Bear, Yogi	11/09/2009	New	IACUC	AUS	11/10/2009		Workflow Cancelled		
2009-0054	1	Bear, Yogi	12/16/2009	New - Under Revision		AUS	12/23/2009				
2009-0059	1	Bear, Yogi	12/23/2009	New - Under Revision	PI	AUS	12/28/2009		Requests Review		

Indicates that you have sent protocol back to AUS Office

Indicates that protocol will be reviewed by the AUS office and will either be approved or sent back for more changes

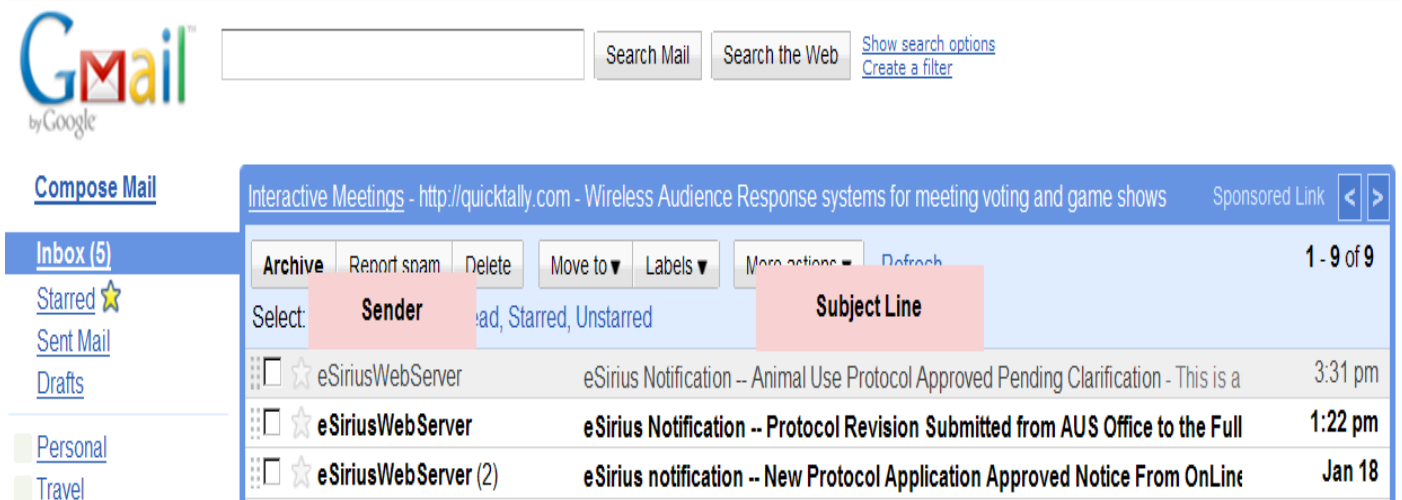
### 3.3 – AUP is Assigned a New Status During an AUS Meeting

- Protocol has been sent to the AUS Meeting**→ Once your protocol has been sent by the AUS Office to the Online Agenda for the next AUS Committee meeting, it will no longer appear under the ‘Alerts-New protocols’ section of your Home Page. At this point, the AUS Committee may choose to **Approve** your protocol, approve your protocol **Pending Clarification** or, if your protocol is **Not Approved**, forward it to the Full Review workflow process.
- Protocol is APPROVED**→ You will receive an email notification from eSirius informing you that your protocol has been approved by the AUS→ Animal use may begin at this time.
- Protocol is APPROVED PENDING CLARIFICATION**→ You will receive an email notification from eSirius informing you that your protocol has been ‘*Approved Pending Clarification*’→ Your protocol will appear in the **Alerts-New Protocols** section of your Home Page→ The AUS Office will inform you via eSirius of the outstanding issues to be addressed before the protocol can receive approval→Make all necessary changes→Send the protocol back to the AUS Office (as described in **Section 3.2 - AUS Office Returns Protocol for Revision**)→If changes are satisfactory, the AUS Office will approve your protocol and you will be sent an email confirmation of the approval→ Once AUP is ‘Approved’, animal use may begin.
- Protocol is NOT APPROVED**→ You will receive an email notification from eSirius informing you that your protocol has NOT been approved→ Your protocol will appear in the **Alerts-New Protocols** section of your Home Page→The AUS AO will forward the protocol to the **Full Review Workflow process**→Protocol will need to be revised (as per the AUS Office) and resubmitted for full review in order to gain approval→**Animal use may NOT begin at this time.**

# Section 3 – AUP Review & Committee Approval – Workflow Process

## 3.4 – Email Notifications

- a) **Email Notification is Sent to the PI Indicating the Status/Location of an AUP →The following is an example of the email notifications sent automatically by eSirius indicating the status/location of your Animal Use Protocol application:**



The screenshot shows a Gmail interface with a search bar at the top. Below the search bar, there is a navigation menu on the left with options like 'Compose Mail', 'Inbox (5)', 'Starred', 'Sent Mail', 'Drafts', 'Personal', and 'Travel'. The main content area displays a list of emails. The first email is from 'eSiriusWebServer' with the subject 'eSirius Notification -- Animal Use Protocol Approved Pending Clarification - This is a' and a timestamp of '3:31 pm'. The second email is from 'eSiriusWebServer' with the subject 'eSirius Notification -- Protocol Revision Submitted from AUS Office to the Full' and a timestamp of '1:22 pm'. The third email is from 'eSiriusWebServer (2)' with the subject 'eSirius notification -- New Protocol Application Approved Notice From OnLine' and a timestamp of 'Jan 18'. The email list has a table-like structure with columns for 'Sender' and 'Subject Line' highlighted in pink.

Select	Sender	Subject Line	
<input type="checkbox"/>	eSiriusWebServer	eSirius Notification -- Animal Use Protocol Approved Pending Clarification - This is a	3:31 pm
<input type="checkbox"/>	eSiriusWebServer	eSirius Notification -- Protocol Revision Submitted from AUS Office to the Full	1:22 pm
<input type="checkbox"/>	eSiriusWebServer (2)	eSirius notification -- New Protocol Application Approved Notice From OnLine	Jan 18

### Email Body Example

**From:** eSiriusWebServer  
**To:** Principalnvtgtr62  
**Date:** Jan 21  
**Subj:** eSirius Notification -- Animal Use Protocol Approved Pending Clarification

This is an electronic notification that your Animal Use Protocol has been approved by the AUS Committee PENDING CLARIFICATION. Follow-up questions will be sent via eSirius. :

Sent by OnlineAgenda  
Protocol Number: 2010-0009.  
Title: title