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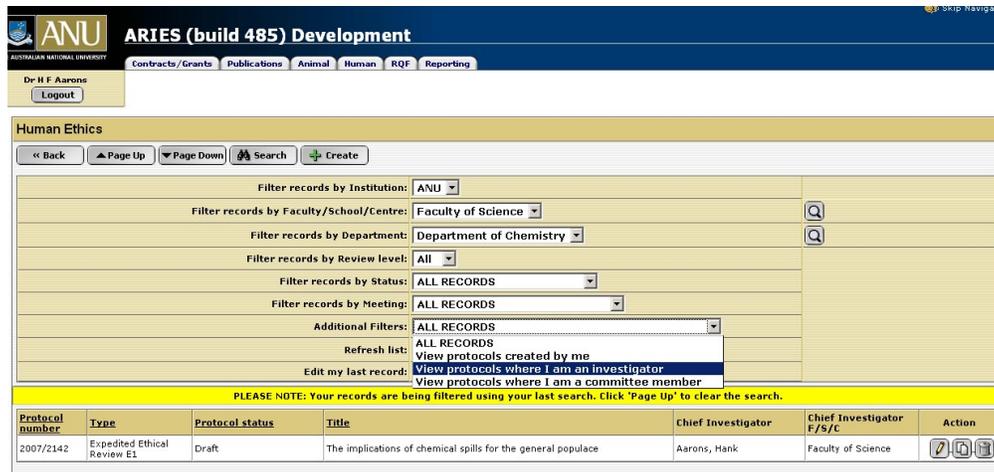
Office of Research Integrity

ARIES Research Management System

Human Ethics User Guide

Version: 4.0

Date: March 2012

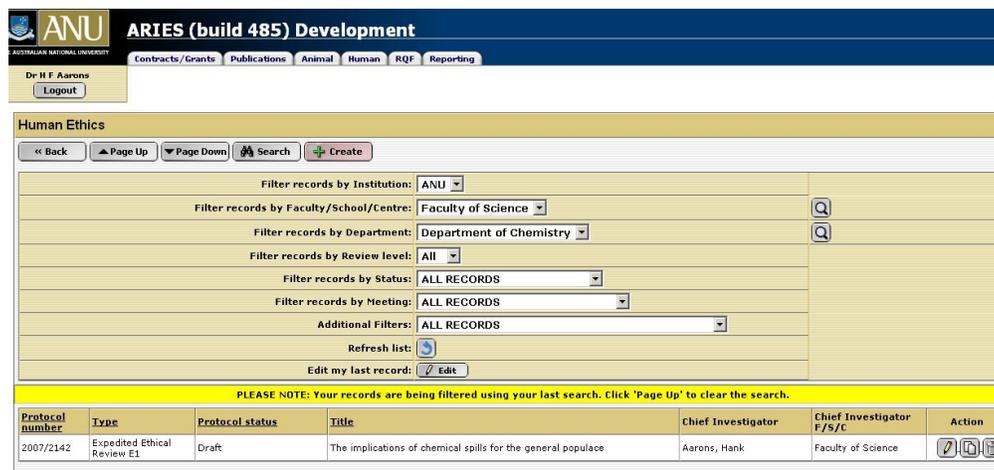


The display will include all protocols where you are named irrespective of whether you are the Primary investigator, supervisor or co-investigator.

If you want to edit one of these protocols click the icon with the pencil . You cannot edit a record that has been submitted, but you may view it and you may add monitoring and variation data.

Creating a Protocol

To add a new protocol from the main screen, click .



You will then choose the option which best suits your sense of the risk of the protocol, where Expedited is low or medium and Full is high.

Unless you know that your research is HIGH RISK, choose the Expedited Review option. As the system is designed to assess the risk level from the answers (yes or no) that you give, if it does prove to be High Risk, your data will be transferred over to a Full Review application without you losing any data that you have entered.

Protocol Data Entry

ARIES is a system where the data is contained in a series of tabs. Fields which must have data contain an asterisk. You may save your protocol and exit Aries **ONLY AFTER YOU HAVE** entered the name of the primary investigator. You then have the option to return to it at any time and make changes and/or submit it.

Enter data against all fields in the **Header** screen and ensure that you choose the appropriate Ethics program type. Dates are entered in the form dd/m/yy, though they will store and display as dd/mm/yyyy. You may enter in this full form if you choose.

After you have entered the data in the **Header** screen click the tab labelled **Investigators**. You now choose the relevant investigators by selecting the **+ Add** button, searching on their names and selecting them.

Please be aware that at a minimum, the first time a researcher starts a protocol, the researcher should enter a title, the start and end dates, ethics program type and the ANU investigators. If this information is NOT ENTERED on initial data entry, the protocol will NOT BE VISIBLE for the user on the ARIES human ethics screen.

Throughout ARIES, searches will work with at least two characters anywhere in the word you are seeking. So for example if you are looking for the name Cardew-Smith you could type “card” or “dew” and it would be retrieved.

If an ANU staff member or student is not on the list, contact the Office of Research Integrity (ORI) on 6125 3427 or human.ethics.officer@anu.edu.au

In selecting investigators you will almost always click yes to “Add their Department”.

For Postgraduate and Undergraduate protocols you must select at least one person with the role of supervisor. Please note that the supervisor must be at ANU

It is recommended that researchers supply at least 1-2 paragraphs when answering the Experience/Expertise/Qualifications question. i.e. “PhD Candidate” is not sufficient for committee members to evaluate your qualifications and experience in relation to what you propose to do.

You should select any external investigators as well as internal investigators.

The text below is largely the same for Expedited and Full protocols, while you are free to read both, it is suggested that you read the section appropriate to the protocol you are entering.

Expedited Protocol Entry

When you have finished adding your Investigators, click on the **High Risk One** tab. The next three tabs have questions that need to be considered.

If your answers are *all* 'No', click on the **High Risk Two** tab.

If any questions are answered 'YES', click on the **Next >>** button, then click on the **Edit** button and answer the questions that are displayed.

Protocol title: The implications of chemical spills for the general populace
Ethics programme type: Staff **Chief Investigator:** Aarons, Hank **Protocol number:** 2007/2142
Approval date: **Anticipated end date:** **Expiry date:**
Submission date: 09/06/2007 **Current clearance status:** Draft
 Review level: Expedited Ethical Review E1 System ID: 2142

High Risk One Questions - Expedited Ethical Review

Next >>

Information	Edit	Question
x	Edit	Is this a clinical trial?

Each question in Aries has an information bubble and an external link that provides helpful information to assist in answering the question.

Please note, the information bubble does not display correctly in Internet Explorer version 6.

Protocol title: The implications of chemical spills for the general populace
Ethics programme type: Staff **Chief Investigator:** Aarons, Hank **Protocol number:** 2007/2142
Approval date: **Anticipated end date:** **Expiry date:**
Submission date: 09/06/2007 **Current clearance status:** Draft
 Review level: Expedited Ethical Review E1 System ID: 2142

Expedited Ethical Review - High Risk Clearance

<< Back Save

Does this research involve the intentional recruitment or issues involving Aboriginal and Torres Strait Islander Peoples?

Cleared by another HREC, listed procedure or renewal application?:
 Yes

Provide details:
 Sydney University 2006/2007.

Once this layer of questions have been answered, click Save.

This same process is followed for the **High Risk Two** tab. When you have finished with each tab, click on the next tab header. Please note that the Next >> button will NOT take you on to the next tab.

You must click on each of High Risk One, High Risk Two and Questions tabs even if you do not answer yes to any of the questions. This is to ensure that you have considered all questions. You will not be able to submit your protocol until you have done this.

Once you have considered the **High Risk One** and **High Risk Two** tabs, click on **Questions** tab.

Protocol title: XXXXXXXXXXXXXXXX Ethics programme type: XXX Chief Investigator: Protocol number: 200X/XXX Approval date: Anticipated end date: Expiry date: XX/XX/XXXX Submission date: Current clearance status: XXXXX Review level: Review XXX System ID: XXXXX		
Questions - Expedited Ethical Review		
Next >>		
Help	Answer	Question
	<input type="text" value="No"/>	Third Party Identification
	<input checked="" type="text" value="Yes"/>	Children or Young People
	<input checked="" type="text" value="Yes"/>	Dependent or Unequal Relationship
	<input type="text" value="No"/>	Membership of a Group, or Related Issues
	<input type="text" value="No"/>	Physical Harm
	<input type="text" value="No"/>	Psychological Harm (includes Devaluation of Personal Worth)
	<input type="text" value="No"/>	Social Harm
	<input type="text" value="No"/>	Economic Harm
	<input type="text" value="No"/>	Legal Harm
	<input type="text" value="No"/>	Covert Observation
	<input checked="" type="text" value="Yes"/>	Deception
	<input type="text" value="No"/>	Sensitive Personal Information
	<input type="text" value="No"/>	Overseas Research
Help	Answer	Question
	<input type="text" value="No"/>	Collection, use or disclosure of personal information WITHOUT the consent of the participant

Select 'Yes' against the questions that apply to your protocol, and then click the **Next >>** button. This will take you to further questions relating to the questions answered 'Yes'. If all boxes are selected 'No', the system will take you directly to Project Details.

Protocol title: XXXXXXXXXXXXXXXX Ethics programme type: XXX Chief Investigator: Protocol number: 200X/XXX Approval date: Anticipated end date: Expiry date: XX/XX/XXXX Submission date: Current clearance status: XXXXX Review level: Review XXX System ID: XXXXX		
Questions - Expedited Ethical Review		
Next >>		
Information	Edit	Question
×	Edit	Children or Young People
×	Edit	Dependent or Unequal Relationship
×	Edit	Deception

When you select the **Edit** button the system will take you to further questions relating to the initial question. For example, when you select the **Edit** button against 'Children or Young People' the below questions will appear.

Protocol title: XXXXXXXXXXXXXXXX Ethics programme type: XXX Chief Investigator: Protocol number: 200X/XXX Approval date: Anticipated end date: Expiry date: XX/XX/XXXX Submission date: Current clearance status: XXXXX Review level: Review XXX System ID: XXXXX		
Questions - Expedited Ethical Review		
<input type="button" value="Next »"/>		
Information	Edit	Question
✓	<input type="button" value="Edit"/>	Children or Young People
✓	<input type="button" value="Edit"/>	Dependent or Unequal Relationship
✓	<input type="button" value="Edit"/>	Deception

Remember that you must click all  **Edit** buttons that present themselves and keep answering until you get a green tick ✓ instead of a red cross ✗. You will not be able to submit your protocol within ARIES until each Question has a green tick ✓.

Depending on your answers in the three questions tabs your protocol will now be:

E1: if you have answered all questions as no, or if your protocol has been previously approved by another HREC.

E2: if you have answered yes to any question on the questions tab but your subsequent answers make it clear that the risks have been minimized.

You will have had your protocol converted to **Full** if you have answered yes to any of the questions in the three tabs and you do not have prior approval or if you have not been able to demonstrate that you can minimize risk. For further instructions please refer to the Full Protocol Entry.

Protocol title: XXXXXXXXXXXXXXXX Ethics programme type: XXX Chief Investigator: Protocol number: 200X/XXX Approval date: Anticipated end date: Expiry date: XX/XX/XXXX Submission date: Current clearance status: XXXXX Review level: Review XXX System ID: XXXXX		
Questions - Expedited Ethical Review		
<input type="button" value="Next »"/>		
Help	Answer	Question
	No	Third Party Identification
	Yes	Children or Young People
	Yes	Dependent or Unequal Relationship
	No	Membership of a Group, or Related Issues
	No	Physical Harm
	No	Psychological Harm (includes Devaluation of Personal Worth)
	No	Social Harm
	No	Economic Harm
	No	Legal Harm
	No	Covert Observation
	Yes	Deception
	No	Sensitive Personal Information
	No	Overseas Research
Help	Answer	Question
	No	Collection, use or disclosure of personal information WITHOUT the consent of the participant

In all of these tabs you will be returned to the main menu when you have answered all questions.

The next section will address risk assessment of protocols that require Full Review – **if your protocol is not Full Review, please go to the bottom of page 12** to continue the guide to completing your protocol.

Full Protocol Entry

When you have finished adding your ‘Investigators’ click on the  tab. This will show additional risk assessment questions to be considered.

Questions - Full Ethical Review

[Next >>](#)

1. Additional approval requirements

Help	Answer	Question
------	--------	----------

If this proposal has been reviewed and approved by any other Human Research Ethics Committee, please complete the Expedited Review.

A. Participants

Help	Answer	Question
------	--------	----------

	No	Healthy members of the community
	No	University students
	No	Employees or officers of a specific company or organisation
	No	Members of a specific community group, club or association
	No	Clients of a service provider
	Yes	Children and young people
	No	Members of a socially disadvantaged group
	No	People who belong to a group
	No	People who may be involved in illegal activities
	No	People whose primary language is other than English
	No	People in other countries
	Yes	Aboriginal or Torres Strait Islander Peoples
	No	People in a dependent or unequal relationship

If the questions here are all answered ‘No’ then you should probably be using the Expedited Review rather than Full Review. Contact the Ethics Office (ext 53427 or ext 53931) and they will be able to reset your protocol at this level without losing any of the data you have entered.

If you do answer ‘Yes’ to any of the questions then click the  button. This will bring you to a summary screen of further questions relating to the questions to which you answered ‘Yes’.

Protocol title: XXXXXXXXXXXXX

Ethics programme type: XXX Chief Investigator: Protocol number: 200X/XXX

Approval date: Anticipated end date: Expiry date: XX/XX/XXXX

Submission date: Current clearance status: XXXXX

Review level: Review XXX System ID: XXXXX

Questions - Full Ethical Review

[Next >>](#)

Information	Edit	Question
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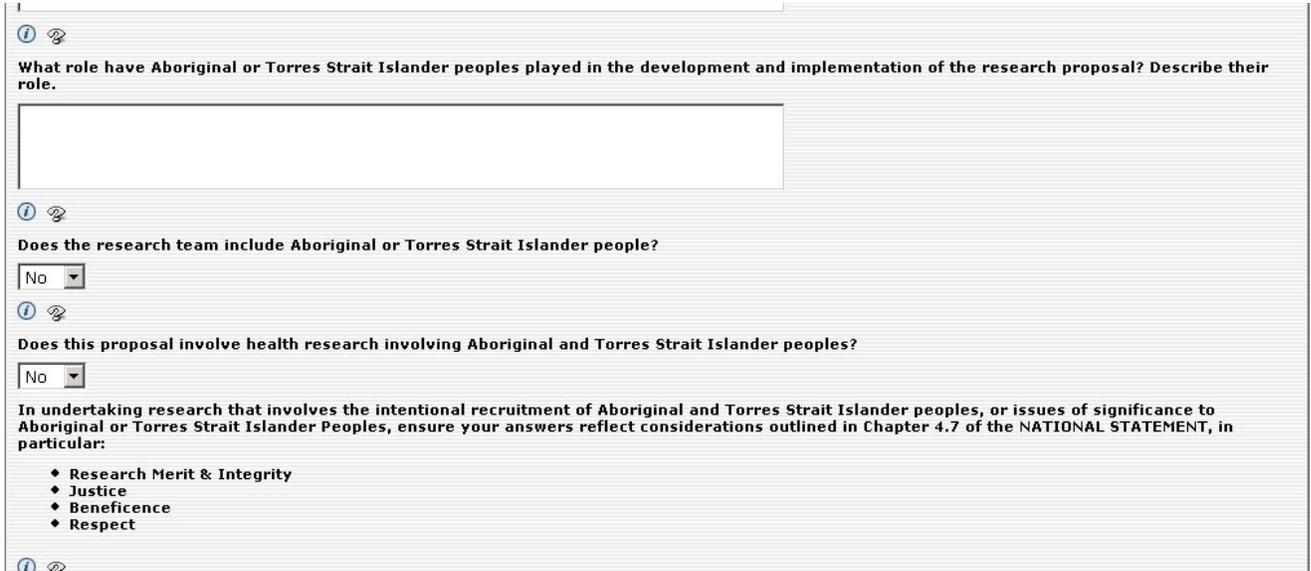
x		Children and young people
x		Aboriginal or Torres Strait Islander Peoples

Page 12

TEQSA Provider ID: PRV12002 (Australian University) | CRICOS Provider Code: 00120C

Click the  button against each question in turn and you will be taken to a new range of questions.

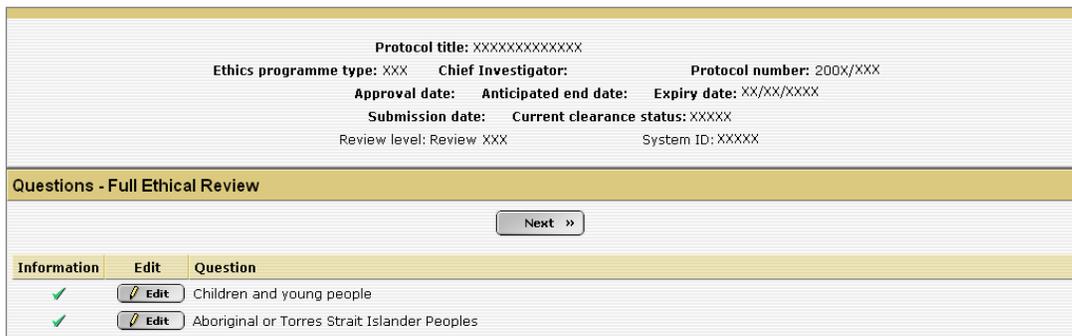
For example if you clicked ‘Yes’ to the question relating to Aboriginal or Torres Strait Islander Peoples, then the screen below displays:



The screenshot shows a series of questions in the ARIES system:

- Question 1: "What role have Aboriginal or Torres Strait Islander peoples played in the development and implementation of the research proposal? Describe their role." (Text input field)
- Question 2: "Does the research team include Aboriginal or Torres Strait Islander people?" (Dropdown menu with "No" selected)
- Question 3: "Does this proposal involve health research involving Aboriginal and Torres Strait Islander peoples?" (Dropdown menu with "No" selected)
- Question 4: "In undertaking research that involves the intentional recruitment of Aboriginal and Torres Strait Islander peoples, or issues of significance to Aboriginal or Torres Strait Islander Peoples, ensure your answers reflect considerations outlined in Chapter 4.7 of the NATIONAL STATEMENT, in particular:"
 - Research Merit & Integrity
 - Justice
 - Beneficence
 - Respect

You must click all  buttons that present themselves and keep answering until you get a green tick ✓ instead of a red cross ✗. You will not be able to submit your protocol within ARIES until each Question has a green tick ✓.



The screenshot shows the protocol summary and a list of questions:

Protocol title: XXXXXXXXXXXXXXXX
Ethics programme type: XXX **Chief Investigator:** **Protocol number:** 200X/XXX
Approval date: **Anticipated end date:** **Expiry date:** XX/XX/XXXX
Submission date: **Current clearance status:** XXXXX
 Review level: Review XXX System ID: XXXXX

Questions - Full Ethical Review

Next »

Information	Edit	Question
✓		Children and young people
✓		Aboriginal or Torres Strait Islander Peoples

Once you have addressed the above, you have entered all the information relating to the risk assessment of the protocol.

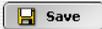
Project Details

Now click on the  tab. You must enter something in the text type questions even if this is N/A. You cannot submit your protocol until these sections contain some text.

Protocol title:		
Ethics programme type: Staff	Chief Investigator:	Protocol number: 2008/
Approval date:	Anticipated end date:	Expiry date:
Submission date:	Current clearance status: Draft	
Review level: Expedited Ethical Review E1		System ID: 2614

Project Details - Expedited Ethical Review

Last auto-saved at 13:44:01 - This page will automatically save every 5 minutes



Description of Project ⓘ

Describe the research project in terms easily understood by a lay reader, using simple and non-technical language. ⓘ

Location of Data Collection ⓘ

Australia ⓘ

Yes

Overseas ⓘ

No

Provide country / area where data collection will be conducted ⓘ

This screen contains a considerable amount of data. In order to prevent you from being timed out of your ARIES session, the system automatically saves every five minutes and consequently prevents the data loss. This saving can be slightly disconcerting but it is preferable to the alternative of data loss.

Last auto-saved at 13:44:01 - This page will automatically save every 5 minutes

Documents

In addition to the basic data entry for protocols, investigators are able to upload documents against each protocol. For example, the Information Sheet and Consent Form required for each protocol will be stored in the 'Documents' tab.

Click on the **Documents** tab, and then the  button. This will bring up a screen where you name the document you are uploading, and then browse and select the document from your hard drive.

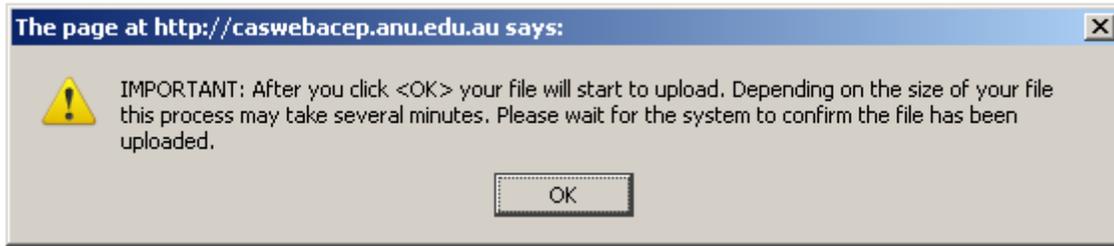
New - Document

Document description*:

File to upload (.pdf .doc) *:

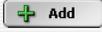
The documents uploaded to the documents tab must be uniquely named. The following convention can be used: Year_ProtocolNo_ Surname_document description.doc / pdf i.e., **2007_123_Smith_InformationSheet.doc**. If you delete a document, both the replacement document name AND the document name in Aries, will need to be given a new name i.e. **2007_123_Smith_InformationSheet1.doc**.

Once you have named and selected your document, click the  button.



The system will then take some time in uploading the document depending on the file size and will alert you with the above message.

Once the file is successfully uploaded, it will be listed on the documents tab of the protocol as shown below.

Protocol title: XXXXXXXXXXXXXXXX Ethics programme type: XXX Chief Investigator: Protocol number: 200X/XXX Approval date: Anticipated end date: Expiry date: XX/XX/XXXX Submission date: Current clearance status: XXXXX Review level: Review XXX System ID: XXXXX			
Documents - Full Ethical Review			
Make your document title unique to you and your application. e.g. 2008_001_surname_nameofdoc			
			
Document	File Size	Type	Action
File Name	137614	pdf	 

Printing Applications

PLEASE NOTE: Submitting your application will lock your application and you will not be able to edit your application online. As the paper form needs to be identical to the electronic form, it is advisable that you **print your application BEFORE submitting**, so that you are able to edit your protocol if you notice an error that needs editing, after printing. If you have submitted and wish to edit your protocol, please contact the Office of Research Integrity (ORI) on 6125 3427 or human.ethics.officer@anu.edu.au

Protocol title: XXXXXXXXXXXXXXXX
Ethics programme type: XXX **Chief Investigator:** **Protocol number:** 200X/XXX
Approval date: **Anticipated end date:** **Expiry date:** XX/XX/XXXX
Submission date: **Current clearance status:** XXXXX
 Review level: Review XXX System ID: XXXXX

PDF and RTF Templates

Report name	External reporting services	Action
Expedited approval form	No	
Full Approval form	No	

To print you application, click the button on the Header tab. Select the magnifying glass that relates to the Review Level of your application.

Submitting

If you are satisfied that the application is now complete go to the screen and click the button.

Remember: You may save your application and exit ARIES at any time after you have entered the names of investigators, and then return to it and make changes and/or submit it.

Created by: XXXXXXXX
Record number: XXXX
Protocol type: Ethical Review
Protocol number: 200X/XXXX

Date entered*:
Ethics program type:

Requested start date*:
Requested end date*:

Protocol title*:

You should now sign the form and get it signed by your supervisor (if appropriate) and the Dean or Director/Head of School. Once your application has been signed by the appropriate person in your area, you are ready to submit your application to the Office of Research Integrity.

NB: If you are a student, your supervisor can sign as supervisor and Head/Dean/Director. However, a Co-Investigator named on the application cannot sign as the Head/Dean/Director as well. In this instance, you will need to seek an alternative signature (Deputy etc)

Submitting the protocol has three effects:

- It locks the protocol and prevents further data entry.
- It sends a message to the Ethics Office that a new application has been submitted online. You will then receive an ARIES email advising you what to do next.
- It allows the final printing of your protocol.

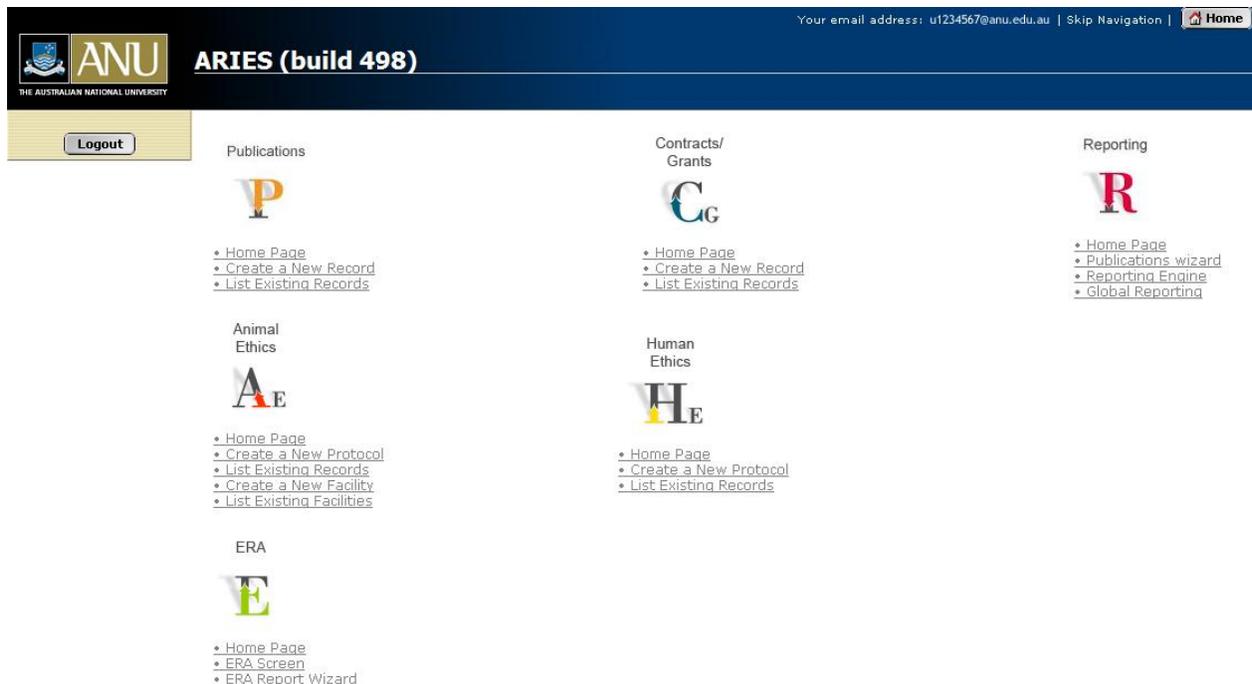
Additional Tips

Selecting the 'Submit' button will take you to the opening summary screen. If you have saved your data and want to return to edit the protocol, the easiest way to get back to your protocol is to click the 'Edit my last record' button on the main screen. Additionally, if you would like to print your protocol after submission, you will need to re-open your protocol by selecting the pencil button .

Navigating the System

Home Menu

ARIES opens to a **Home Menu** displaying the various modules of ARIES. This includes Human Ethics, Animal Ethics, Contracts/Grants, Publications and ERA.



Your email address: u1234567@anu.edu.au | Skip Navigation | [Home](#)

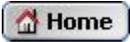
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ARIES (build 498)

[Logout](#)

Module	Links
Publications	<ul style="list-style-type: none">• Home Page• Create a New Record• List Existing Records
Contracts/Grants	<ul style="list-style-type: none">• Home Page• Create a New Record• List Existing Records
Reporting	<ul style="list-style-type: none">• Home Page• Publications wizard• Reporting Engine• Global Reporting
Animal Ethics	<ul style="list-style-type: none">• Home Page• Create a New Protocol• List Existing Records• Create a New Facility• List Existing Facilities
Human Ethics	<ul style="list-style-type: none">• Home Page• Create a New Protocol• List Existing Records
ERA	<ul style="list-style-type: none">• Home Page• ERA Screen• ERA Report Wizard

Once a menu option has been selected, the user will be taken into the system. From here, the user can navigate through the different modules using the tabs that appear at the top of the screen.

Alternatively, the user can select the  button to return to the **Home Menu**, to select the desired menu.

Human Ethics module

The Human Ethics section has three menu options.



‘Home Page’ takes the user to a menu strictly displaying Human Ethics menu options.

‘Create a New Protocol’ commences the process of creating a new protocol.

‘List Existing Records’ takes the user to a summary screen of protocols from the users department. The user will only be able to access protocols that they have created; or they are listed on as an investigator.

Once a menu option has been selected, the user will be taken into the system.



The ‘*Human*’ tab will be highlighted when the user is using the ‘Human Ethics’ module.

Log Out

At the conclusion of your work in the system, please terminate your session to guarantee that unauthorized users do not use your profile. Ensure your session is terminated by selecting the

 button.