NAVIGATING iRECS

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Modifying an iRECS-Approved Project

Notes:

- Modifications must be submitted and approved by the relevant Committee prior to implementation.
- Modifications are <u>made directly to the application form</u> within iRECS by the Project Owner, or by anyone who has been granted read & write" or "read, write & submit" access by the Project Owner.

Modification Instructions:

 To make modifications to an approved project on iRECS, you must request for your application to be unlocked for modification by emailing the Human Ethics team <u>humanethics@unsw.edu.au</u>. Include the review reference of your project (see below), along with a summary of the modification(s) you wish to make in your email.

Note: You can find the review reference in the following sections of iRECS or in your email notification:

iRECS Project Page

HE_New App_EE_Approve

Project Tree	ort		
Action Required on Form	No. Status	te that the reference format may differ Review Reference	<mark>for your project</mark> Application Type
No	Noted (Monitoring Due)	EAR-HREC-2023-0766	External approval registration
Email Notification NR-HREAP-2023-0744 Le donotreply@infonetica To O	gacy negligible risk r ^{a.net}	nodification - Modificatio	(- -
Dear Reference Number <mark>NR-HREAP-202</mark> Project Title:	Your review refe	erence may differ in format from	the one shown here

- 2. The Human Ethics team will review your request and unlock the approved application in iRECS.
- 3. Once your application is unlocked, you will receive a **notification from** <u>donotreply@infonetica.net</u> advising that your application is ready for modification on iRECS.
- 4. Click on the **hyperlink** listed in the email to navigate to your project.

Your Low risk application application has been unlocked and you can now submit your modification in iRECS.

You can access your application modification via https://irecs.unsw.edu.au/Project/Index/1158.

5. On the project overview page, click on the New Application / Modification Request section.

Human Ethics Application

Section	Questions
Before you start	Before you start
New Application / Modification Request	New Application / Modification Request
Submission Type	Submission Type Minimising the Duplication of Ethical Review

6. Select the **Modification** option and provide (i) a **brief summary** of the modifications to the approved application and (ii) a **list of documents that have been amended or revised** ensuring that the version number and date are included for each document.

New Application / Modification Request



If this is the first time you are completing this form or if it has not been reviewed and approved please select 'New Application'. To modify the application after approval select 'Modification' and provide a brief summary of the requested modifications. 'Legacy Project Modification' should be used for modification of preiRECS approved project/application.

O New Application

Select this option if you are lodging a new application OR if you are revising an unapproved application.

Modification

Select this option if you are modifying OR revising an approved application.

O Legacy Project Modification (only applicable for pre-iRECS approved projects)

Select this option if you are modifying or revising a project that is approved prior to iRECS rollout.

Please provide (i) a brief summary of the modifications to the approved application and (ii) a list of documents that have been amended or revised ensuring that the version number and date are included for each document.

Add Another

7. Once this is done, navigate to relevant sections of the Human Ethics form to make the changes you wish to make. For any changes that you've made to a document/attachment, please make sure you upload a clean and track-change version (along with the new date and version number).

Note: All changes (except for content within an attachment/document) will be tracked by iRECS.

- 8. Once you have **made all necessary modifications** (make sure the Declaration section is checked). Click **Submit** to submit your modification for review.
- 9. You will receive periodic updates on your modification request as it progresses through the review cycle.

Modifying a Legacy/Pre-iRECS Approved Project

HE New App EE Approve

Notes:

- Modifications must be submitted and approved by the relevant Committee prior to implementation.
- Although your initial ethics application/project was initially submitted and approved outside of iRECS, a legacy
 record has been created on iRECS for your pre-iRECS approved project. Therefore, any subsequent changes to
 your project will need to be lodged and approved through iRECS.

Modification Instructions:

 To make modifications to an approved legacy project on iRECS, you must request for your application to be unlocked for modification by emailing the Human Ethics team <u>humanethics@unsw.edu.au</u>. Include the review reference of your project (see below), along with a summary of the modification(s) you wish to make in your email.

Note: You can find the review reference in the following sections of iRECS or in your email notification:

iRECS Project Page

Project Tree 🗸			
HE New App_EE_Approve Human Ethics Application Monitoring Compliance I	Report		
Action Required on Form	N	ote that the reference format may differ Review Reference	for your project Application Type
No	Noted (Monitoring Due)	EAR-HREC-2023-0766	External approval registration
Email Notification			
NR-HREAP-2023-0744	Legacy negligible risk	modification - Modificati	(_
	t: t	○ <>	<

donotreply@infonetica.net To Cc C	
Dear	
Reference Number NR-HREAP-2023-0744 Project Title:	Your review reference may differ in format from the one shown here

- 2. The Human Ethics team will review your request and **unlock** the approved application in iRECS.
- 3. Once your application is unlocked, you will receive a **notification from** <u>donotreply@infonetica.net</u> advising that your application is ready for modification on iRECS.
- 4. Click on the **hyperlink** listed in the email to navigate to your project.

Your Low risk application application has been unlocked and you can now submit your modification in iRECS.

You can access your application modification via <u>https://irecs.unsw.edu.au/Project/Index/1158</u>.

5. On the project overview page, click on the **Completeness Check** to identify any missing fields¹ you need to populate.

Note 1: This step is necessary as we can only migrate a small subset of data that is available on our legacy system (InfoEd). You will also be prompted by iRECS to complete any blank fields prior to submission. All changes (except for content within an attachment/document) will be tracked by iRECS.

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Project	Create Sub Form		Completeness Check the following are missing fields that you need to populate
Completeness Check	Submit	Vie	Incomplete: Please complete the following questions
Correspond			 Legacy Project Number Legacy Project Title Legacy Risk Level Legacy Clinical Trials Legacy Modification Summary Participants & Area of Research: Indicate the type of research that will be conducted Participants & Area of Research: Indicate the target population for this research Research Conducted in Australia: Does this research involve the collection of data from participants located within Australia? Access to Existing Collections: Does the research involve access to existing collections of data or biospecimens?

IMPORTANT NOTE: For legacy (pre-iRECS approved) projects, please DO NOT ATTEMPT to change/modify the Legacy Project Modification option (under "New Application/Modification Request" section) and the pre-selected Submission Type option (under "Submission Type" section). Changing any of the above fields will lead to loss of migrated legacy data.

Show Inactive Section

Human Ethics Application	
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Section	Questions	DO NOT MODIFY DATA IN THESE TWO SECTIONS
Before you start	Before you start	
New Application / Modification Request	New Application / Modification	Request
Submission Type	Submission Type Minimising	the Duplication of Ethical Review

- 6. Navigate to the missing info section to populate relevant data/info as necessary.
- 7. Once you are on the Legacy Modification page, provide the Legacy Modification Summary and upload the clean and track-change version of any documents you have amended (along with the new date and version number.

IMPORTANT NOTE: DO NOT change the Legacy Risk Level specified in the following field:

Legacy Risk Level DO NOT CHANGE THIS (this is the risk level of your initial application)

More than Low Risk	~

- 8. Proceed to update/amend relevant sections of the legacy modification form. You need to populate any missing fields too.
- 9. Once you have made all necessary modifications (make sure the Declaration section is checked). Click Submit to submit your legacy modification for review.
- 10. You will receive periodic updates on your legacy modification request as it progresses through the review cycle.

FURTHER SUPPORT

- If you have any iRECS login or technical issues, please contact UNSW IT Services at itservicecentre@unsw.edu.au or (02) 9385 1333.
- For any queries, regarding the iRECS Human Ethics, Animal Ethics Gene Technology or Radiation Safety application approval and/or review process, please contact:

Human Ethics: <u>humanethics@unsw.edu.au</u> Animal Ethics: <u>animalethics@unsw.edu.au</u> Gene Technology: <u>genetechnology@unsw.edu.au</u> Radiation Safety: <u>radiationsafety@unsw.edu.au</u>