Human Ethics FAQ

I can’t find my legacy (pre-iRECS) project on iRECS?

**Scenario: You are NOT the Coordinating CI**
For the migrated (legacy/pre-iRECS approved) projects, only the Coordinating CI will have outright access to their migrated project upon logging into iRECS.

If you need to have collaborator access to the project, you need to ask the Coordinating CI to grant you ‘Collaborator’ access to the project. Please see the “Collaborator assignment” instructions below on how you can be assigned as a collaborator against a project.

**Scenario: You ARE the Coordinating CI**
This could be because the email that your legacy project is registered under is different from your iRECS login email. Please contact the Human Ethics team for support. We will link the legacy project to your iRECS login email if the case.

How can I gain access to a legacy (pre-iRECS) project that I am part of?

If you need to have collaborator access to the project, you need to ask the Coordinating CI to grant you ‘Collaborator’ access to the project. Please see the “Collaborator assignment” instructions below on how you can be assigned as a collaborator against a project.

How can I be assigned as a Collaborator?

**Collaborator Assignment Instructions:**

1. Please have the Coordinating CI log into his/her iRECS account and navigate to the relevant project (it should appear in the project list as she logged in).

2. Once he/she is on the Project's overview page, click on the “Roles” side panel button.

![Roles Side Panel](image)

3. When the pop-up appears, enter your name into the search field, and have the CI assign you with the appropriate access (note you cannot submit with Read & Write access, you need Read, Write & Submit access for that), then click the Share Role button.

![Share Role Button](image)

4. You will receive an email once you have been assigned as a collaborator – you can click on the hyperlink specified in the email to directly navigate to the project.

I’m an external researcher, how can I gain access to iRECS?

Note that affiliated MRI researchers/personnel with a valid UNSW zID can log in to iRECS via the “University Login”. The login via University Login will be done via the UNSW SSO/MFA process. If you have any issues with the UNSW SSO/MFA login, please contact UNSW IT Services for support.

If you are an affiliated MRI researcher/personnel with no valid UNSW zID, please contact the RECS Human Ethics humanethics@unsw.edu.au team to lodge a request to have your external account created.
How do I complete a modification request on iRECS?

Please see “2.6 Modifying an approved application - Human Ethics” for instructions. Pasted below for your convenience.

**Modifying an iRECS-Approved Project**

**Notes:**
- Modifications must be **submitted** and **approved** by the relevant Committee **prior to implementation**.
- Modifications are made **directly to the application form** 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:**
1. 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 humanethics@unsw.edu.au. 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**

   ![iRECS Project Page](image)

   **Email Notification**

   

   **NR-HREAP-2023-0744 Legacy negligible risk modification - Modifications**

   From:
   
   donotreply@infonetica.net

   To:
   
   Subject: Project Approval

   Dear [Name],

   Reference Number: NR-HREAP-2023-0744

   Your review reference may differ in format from the one shown here

   Project Title: [Title]

   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 donotreply@infonetica.net** 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/mdw/1158](https://irecs.unsw.edu.au/project/mdw/1158).

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

   ![New Application / Modification Request](image)
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.

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**

**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:**

1. 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 humanethics@unsw.edu.au. 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:*
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 donotreply@infonetica.net 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/INDP/1158](https://irecs.unsw.edu.au/Project/INDP/1158).

5. On the project overview page, click on the **Project Details** section and populate any missing fields on this page. Click Next and do the same for the **Research Personnel** section.

   For legacy (pre-iRECS approved) project, 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.

   **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.

6. 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**).
7. Proceed to amend relevant sections of the legacy modification form. You need to populate any missing fields too.

8. Once you have made all necessary modifications (make sure the Declaration section is checked). Click Submit to submit your legacy modification for review.

9. You will receive periodic updates on your legacy modification request as it progresses through the review cycle.

Other Questions we received

System & Access
Is it possible for all email correspondence to be changed to my Kirby email rather than ZID@ad.unsw.edu.au? iRECS will send notifications to the email that is associated with your login. I.e. if you log in using your ZID@ad.unsw.edu.au, all iRECS notifications will be sent to that email account. If you prefer to receive emails in your Kirby email account, you can set up automatic forwarding in your ZID@ad.unsw.edu.au to auto-forward/divert emails to your Kirby email address (instructions here). Just make sure to check the spam/junk mailbox of your Kirby email account in case the forwarded emails get sent to junk by mistake.

I am in the Education school, when I try to create a human ethics application, I just get two options and the Human Ethics Application is not one of them! How can I create one?
Only Gene Technology and Radiation Safety modules can be accessed at the moment. The Human Ethics module is not yet accessible/released on iRECS. We will advise you all via email when the Human Ethics module is released on iRECS. After that, you may log in (using your standard UNSW login) and prepare your submissions on the portal.

Does the system have the capacity for people/applicants to jointly work on/access an application, without transferring it back and forth i.e. do all named applicants have view/read/write access?
Yes, the system can support multiple collaborators working on a submission simultaneously. You just need to either assign relevant Investigators as a collaborator via the blue "Assign Role" button or the Roles button in the side panel. To avoid the need to transfer the application form from one person to another, we strongly recommend that the Coordinating CI create the initial application (via the "Create Project" button on the side panel button of the Work Area) and proceed to assign relevant investigators as collaborators via aforementioned Assign Role/Roles button. By following the above steps, there will be no need for the application to be transferred to the Coordinating CI before submission.

Can the Collaborator's tab (Roles+ button) handle the fact that some collaborators may be external to UNSW?
Yes, but the caveat is that the external collaborator will need to first have an iRECS External User account created before you can assign them as a collaborator. They need an external account to be created to access/log into iRECS too. You can contact the Human Ethics team for any external user account creation requests.

I want to emphasise that external investigators can be listed as an investigator against a Human Ethics application without an external account created (you can manually populate their details in the Personnel field). It is only when the external investigator needs access to iRECS to contribute to an application that you need to request for their external user account to be created.

Can you please repeat what you said about the 'Signatures' tab?
The Signature tab/tile is not relevant (not used) for HE submissions, so it is a tab/tile that you can disregard.

Will there be a link to the iRECS portal from the MyUNSW page?
It is unlikely that we will be able to include an iRECS link on the MyUNSW page, we will look into this and will add iRECS to the page if permissible.

Timeline
What if I can't submit in August, will there be a new timeline in the future?
The August timeline that we mentioned is just the transition period that we outlined. The deadlines for submissions via the existing (PDF/email) process is outlined on the iRECS Information Page. After 22 August* (i.e. after the full launch of iRECS), all submissions will need to be raised via iRECS.

*subject to system readiness

Should I wait till 14 August to create an application?
Yes if you can, that would be great. This means you can view your full Human Ethics application/project on iRECS, rather than an abridged version. This also makes modifications easier to track down the line.

**Does the timeline mean that there are no modifications on existing projects permitted at all between now and August 22nd?**

To clarify, for modifications, no **new modifications** will be accepted via the existing (email) process between Wed 16 Aug – Mon 21 Aug. We will continue to process any **in-progress/pending** modification requests via the existing (email) process until the review cycle is complete. After which, our team will work with you to manually migrate the approved modification request onto iRECS.

**HoS**

Can there be a monthly list of submitted applications in case the HoS details are not included appropriately on the application?

This is something that we will consider on an ad-hoc basis. Should this be something that the HoS is keen on, please have the HoS contact the Director of RECS, Ted Rohr to discuss this reporting request further.

So just to clarify, the head of school (or delegate) no longer has to sign off on applications and send in a letter saying they approve which the applicant submits with their application? It is rather that the HoS is simply notified that an application has been submitted. // **is a letter of support from HoS still required, given you are notifying HoS in the application?**

That is correct. Due to varying levels of oversight required across various Schools, there is no single mechanism that is applicable to all Schools. Therefore, iRECS will not request for HoS sign-off nor is a letter of support from HoS required to be attached against submitted Human Ethics applications.

The HoS (specified in the Declaration section of the Human Ethics application) will be notified of a **submitted** application.

That said, the HoS/delegate can opt to implement any local-level pre-submission approval requirement(s) as desired. Should the HoS wish to access an iRECS application prior to submission, the Chief Investigator can add the HoS as a Collaborator (via the “Roles” button), allocating the HoS the relevant access function, such as read-only or edit. The HoS can then make comments, or add suggestions via tracked changes depending on access provided. Once the HoS pre-submission approval has been obtained, it is recommended that the Chief Investigator removes the HoS as Collaborator prior to submission. Note that all local-level pre-submission requirements will need to be communicated and administered locally.

I approve all ethics applications in my school before they are submitted but am DHoS research not HoS. Will my name pop up in the search? And do I need to look at the entire application or just sign off on it.

Please see above for queries regarding pre-submission review/sign-off by HoS or delegate. This process will need to be done before the application is submitted on iRECS. Please communicate any pre-submissions requirements to your School’s researchers.

**Application/Modification Preparation & Submission**

Does a coordinating investigator need to create the initial ethics application? Or is it ok for any research personnel to create the form?

Both can – if it is the non-Coordinating CI who created the initial ethics application, he/she will need to make sure that the application is transferred to the CI prior to submission. This is to ensure that notifications will be sent to the Coordinating CI.

As mentioned prior, to avoid the need to transfer the application form from one person to another, we **strongly recommend** that the Coordinating CI create the initial application (via the “Create Project” button on the side panel button of the Work Area) and proceed to assign relevant investigators as collaborators via aforementioned Assign Role/Roles button. By following the above steps, there will be no need for the application to be transferred to the Coordinating CI prior to submission.

Can PhD students or HDR students complete the form and then transfer it to their lead CI to submit? // **For HDR projects, supervisors will have to submit the ethics on behalf of the HDR student? (this rule will continue, correct?)**

Yes that is correct. If possible, we recommend that the CI create the initial application and assign you as a Collaborator with read and write access so you can prepare the application without the need to transfer the application to the CI down the line.

If all the boxes only take plain text, does that mean we can no longer add diagrams/figures?
Yes, that is correct. However, we’ve added an “Upload Document” button against the questions that we believe may require the provision of supplementary docs/info (e.g. figures). Should an “Upload Document” button be N/A against a question, you can upload the figures in the Attachments section of the Human Ethics application. You can then reference these docs in your text response.

Will there remain a word template on the website to prepare offline please rather than having to copy/paste each section?
Unfortunately, no. We explored this option, however, due to the extensive network of logic that is embedded within the Human Ethics form (i.e. different form sections or questions will appear based on previous responses), we are not able to provide a word version of the Human Ethics form.

Once an application is almost ready for submission, can it be downloaded as a zip file so it can be reviewed outside of the iRECS system? Including the main body of the application form and all attachments, we may have uploaded.
Yes you can. All you need to do is click on the following “Documents” button on the left-hand panel of your Human Ethics application page and check the files you want to download (note: Submission = your Human Ethics application form) and then click “Download Selected”. The selected files will then be downloaded into a zip folder.

Note that due to the logic that is embedded within the Human Ethics form, the PDF extract of the Human Ethics application form has inconsistent spacing in certain form sections.

Please confirm whether attachments uploaded on applications are automatically labelled by iRECS Attachment 1, Attachment 2 etc. If not automatically labelled, then an applicant should do it in the names of the files uploaded, right?
Yes, iRECS automatically pulls the doc name, i.e. if the doc is labelled *Lumos ABC*, the document will be labelled as such once uploaded. The applicant can also change the doc name on the iRECS Document Upload pop-up if they wish to.

Can you please advise how to submit projects approved by other/external ethics committees for acknowledgement by UNSW HREC?
All you have to do is indicate “New Application” in the New Application / Modification Request and then indicate “External Ethics Submission” in the Submission Type page of the Human Ethics iRECS application form. After which, you shall proceed to fill in the remaining sections of the External Ethics form sections.

Just to confirm, for any kind of amendment for approved research, we need to email the ethics/iRECS team to unlock?
Yes, that is correct. Steps to follow:

1. You have to contact the Human Ethics team first to unlock the approved project for modification. Make sure to quote your review reference – found within your project page, see screenshot below – so that the HE team can unlock the correct project.

   ![HE_New App EE_Approve](image)

   **Note that the reference format may differ for your project**

<table>
<thead>
<tr>
<th>Action Required on Form</th>
<th>Status</th>
<th>Review Reference</th>
<th>Application Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>No</td>
<td>Noted (Monitoring Due)</td>
<td>EAR-HREC-2023-0766</td>
<td>External approval registration</td>
</tr>
</tbody>
</table>

2. Once the form is unlocked by the Human Ethics team, you will receive an email from the iRECS system (donotreply@infonetica.net) informing you that your project has been unlocked for modification.

3. Log into iRECS and update the New Application / Modification Request field to “Modification”.


Important note: If you are modifying a legacy (pre-iRECS approved) project, please leave the Legacy Project Modification option checked as it is. Changing the field to “Modification” will lead to a loss of migrated data.

4. Provide a modification summary and a summary list of the docs you have amended. Then, proceed to amend relevant sections of the Human Ethics form.

5. Once done, check the Declaration section and submit your modification request.

For modifications, apart from stating the purpose of the modification, do we need to provide a (sometimes long) list of submitted documents with filenames etc. or does the system indicate when new docs are submitted?

Yes, we have asked for researchers to list all the amended docs in the modification summary response field. Although iRECS does track when a new document has been uploaded, it doesn’t provide the Human Ethics team with a summary list of documents that have been updated. The Human Ethics team needs to accurately relay what documents have been amended in your modification approval email, therefore providing them with this info will help aid in this process.

Am I correct that (after August 22) we modify "Legacy Projects" in pretty much the same way we do now, expect we just type the list of modifications into a box in the system (instead of the modification Word document), and attach the track-changes and clean documents in iRECS (instead of to an email)? What was the bit about contacting you to unlock the form?

Yes that is correct, to be clear, the following are the steps to follow to modify a legacy (pre-iRECS approved) project:

1. Contact the Human Ethics team first to unlock the approved legacy project for modification. Make sure to quote your review reference – found within your project page, see screenshot below – so that the HE team can unlock the correct project.

2. Once the form is unlocked by the Human Ethics team, you will receive an email from the iRECS system (donotreply@infonetica.net) informing you that your legacy project has been unlocked for modification.

3. Log into iRECS. Navigate directly to the Project Details page and populate any missing fields in the Project Details page. Do the same for the Research Personnel section.

   Important note: If you are modifying a legacy (pre-iRECS approved) project, please leave the Legacy Project Modification option and the specified Submission Type as it is. Changing these fields will lead to a loss of migrated data.

   Note 1: This 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.

4. On the Legacy Modification page, provide the Legacy Modification Summary and upload the clean and track changes version of any documents you have amended.

5. Proceed to amend relevant sections of the legacy modification form. You may be required to populate any missing fields too.

6. Once done, check the Declaration section and submit your legacy modification request.

So to make an amendment for approved/legacy research, we also will likely have to fill in a range of fields that aren’t dragged from infoed?

Yes that is correct – see my response above.
For modification of legacy projects, as no attachments from the previous ethics app migrate to iRECS, do we attach all of the attachments or only the ones which have changed?

Only the ones you have changed. That said, feel free to attach your initial application in the Attachments section (before Declaration) of the legacy modification form, if you wish to have easier access to your approved application for subsequent modification requests.

What if we have a research project that is going to be an extension of an already approved ethics application? Do we need to submit a modification adding a section of 2nd experiment or do we need to submit the new application? // Are you able to repeat what do we do for an extension of ethics approval for an already approved ethics pre-iRECS?

Yes, you’ll have to submit a modification request. Please follow the following steps to follow to request for an extension to a legacy (pre-iRECS approved) project:

1. Contact the Human Ethics team first to unlock the approved legacy project for modification. Make sure to quote your review reference – found within your project page, see screenshot below – so that the HE team can unlock the correct project.

2. Once the form is unlocked by the Human Ethics team, you will receive an email from the iRECS system (donotreply@infonetica.net) informing you that your legacy project has been unlocked for modification.

3. Log into iRECS. Navigate directly to the Project Details page and populate any missing fields in the Project Details page. Do the same for the Research Personnel section.

   **Important note:** If you are modifying a legacy (pre-iRECS approved) project, please leave the Legacy Project Modification option and the specified Submission Type as it is. Changing these fields will lead to a loss of migrated data.

   **Note 1:** This 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.

4. On the Legacy Modification page, specify that you are asking for an extension (+ extension period requested) in the Legacy Modification Summary. Upload the clean and track changed version of any documents you have amended.

5. Proceed to amend relevant sections of the legacy modification form. You may be required to populate any missing fields too.

6. Once done, check the Declaration section and submit your legacy modification request.

Could you please clarify what the process is if you are responding to comments on an application that has been reviewed but not approved? I have an application that requires me to submit a response by Thursday 17 August.

Assuming you have submitted your application via the existing process, we will continue to process any in-progress/pending application via the existing process until the review cycle is complete – this includes your submission above. After that, our team will work with you to manually migrate the approved modification request onto iRECS.

It seems that modification of pre-iRECS projects needs to be approached with care! Can I strongly agree with Cecilia’s comment about needing much clearer and stronger wording on that page about retaining the project
under the legacy setting and not pressing the middle Modification button. This looks like an all-too-easy and costly error to make!

Yes, we agree. We will insert warning text against the relevant legacy response buttons to mitigate any risk of loss of data.

How do I report on the condition(s) that is listed against my project?

How do I complete and submit a Monitoring Compliance Report/Protocol Deviation/Incident and Safety Report for my project?

These reports can be accessed via the "Create Sub-Form" button that appears in the Project overview page.

Instructions

1. Log into iRECS and navigate to the project that you wish to submit the Condition/Monitoring Compliance Report/Protocol Deviation/Incident and Safety Report against.
2. In the left-hand panel, click on the "Create Sub-Form" button.
3. Select the desired sub-form template from the sub-form drop-down list and click "Create".
4. Complete all sections of the form and submit ASAP.

Human Ethics-Specific Queries

Do we need a letter of support for each external collaborator? Even when there are > 5 or 10 collaborators?

This pertains to in-person collection of data at specified sites. Yes, you will be required a letter of support to be provided for each site you specified. FYI- you can specify multiple sites by pressing the Add Another button below.
Where do we find the PISCF templates? Are they accessible in iRECS or do we still go to the HREC webpage?
They will be linked in the Consent section of Human Ethics form, e.g.

Participant Information Statement and Consent Form (PISCF)
Create a PISCF using one of the following templates. If the research involves each group:
- PISCF Template (Implied Consent e.g. Online Surveys)
- PISCF Template (Written Consent e.g. Focus Group, Interview, Survey)
- PISCF Template (Intervention Clinical Trial Clinical Research)
- PISCF Template (Parent Guardian)
- PISCF Template (Easy Read)
- PISCF Verbal Consent Script
- PISCF Template (Low-Risk School of Psychology)

Upload a PISCF relevant to the participant group

In the old ethics from cohort and clinical trials were combined. Will they be separated now?
The old process did not combine cohort and clinical trials. The iRECS form has fields for you to indicate whether your research involves clinical research (incl. cohort studies) and/or clinical trials.

Will data management plans be integrated into iRECS?
We will have included new questions and updated the Human Ethics iRECS questions to meet the requirements of the UNSW Data Management Policy.

Instructions/FAQs
Do you plan to have an iRECS user manual or FAQ document to assist people with using the system?
Yes, we already have standardised (applicable to Human Ethics) instructions available on the Support & Further Information section of the iRECS Information Page and on the iRECS Help Page. Note that we will continue to refine the help instructions as we continue to roll out more Ethics Module on iRECS.