REGIS

What's New 2020

QUICK REFERENCE GUIDE

FOR RESEARCH APPLICANTS AND RESEARCH OFFICES

What's New April 2020 - Ethics Amendment

What's New

Changes have been made to the amendment form to reduce the amount of 'clicks' and create a more streamlined submission process. This document outlines the changes that the Research Applicant and Research Office will see to the amendment form, how to identify overdue milestones and how Research Offices can delete and create milestone progress reports.

Research Applicant

System Generated Warnings and Compliance

Form warnings are now used to indicate important messages to the applicant.

HREC Expiry Warning

This message will only appear if your Ethics approval is due in the next 6 months or has expired.

> **HREC expiry within 6 months or has expired.** Consider if a Request for extension of HREC approval is required.
> This is for information only: seeing this message will not stop the submission of this form.

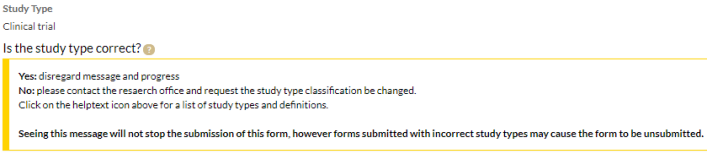
Overdue Milestones – to be enabled 1 June 2020

From 1 June 2020 researchers will not be able to submit an amendment on a project if it has an overdue milestone (progress report).

Instructions are available in this document for identifying if your studies have overdue milestones and what needs to be done to clear these.

Study Type

This form shows/hides questions based on the Study Type, specifically Clinical Trials. If the study type is incorrect contact the Research Office and request the study type classification to be changed before completing and submitting the amendment.

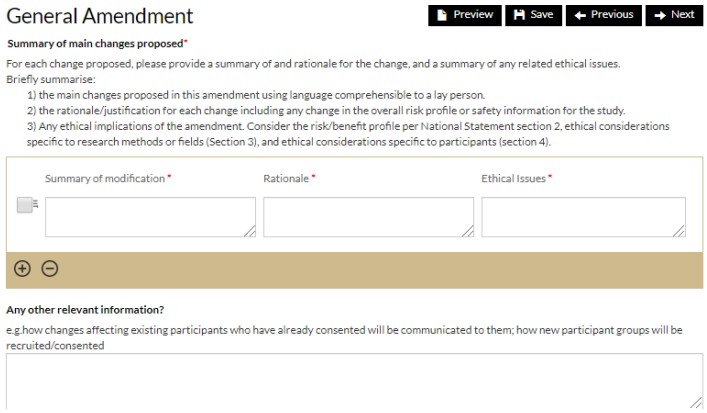


A yellow warning message will not stop the submission of your amendment but are warning that you need to review and action appropriately.

Information has been added on the first page to provide a clear description of what an amendment is and types of amendments that should be submitted using this form. Clicking the button, on the form, will expand to show clear and detailed descriptions of amendment types. Click again for the description to hide.

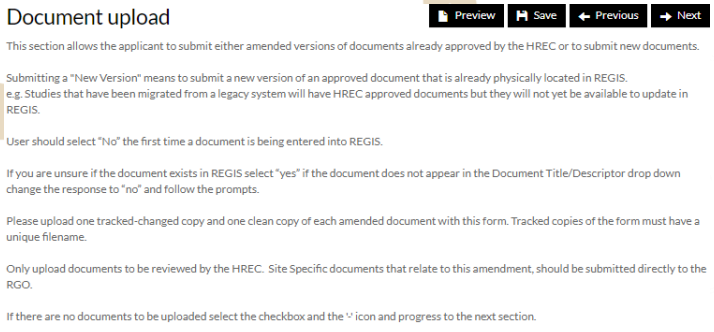
General Amendment

Governance questions have been removed from this form. Further information can be noted in the "Any other relevant information" section.



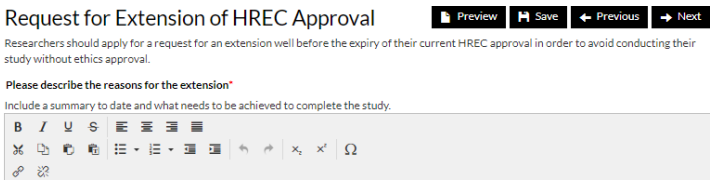
Document Upload

More information has been provided to assist you with correctly checking and uploading a document.



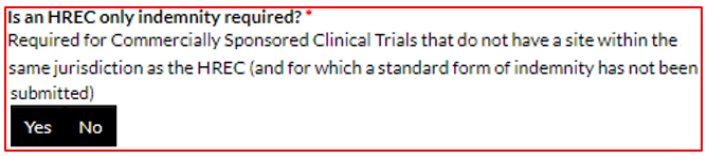
Request for Extension of HREC Approval

Study budget and changes to contract questions have been removed and a larger free text field added in order to provide more information for the extension request.



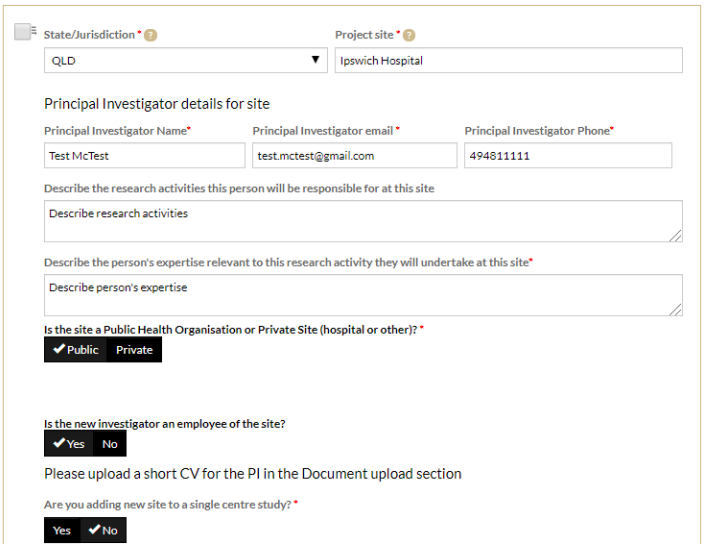
Addition of a new site

For Clinical Trial studies, clinical trial specific questions will be asked. *Note: below image cropped to fit on document.*



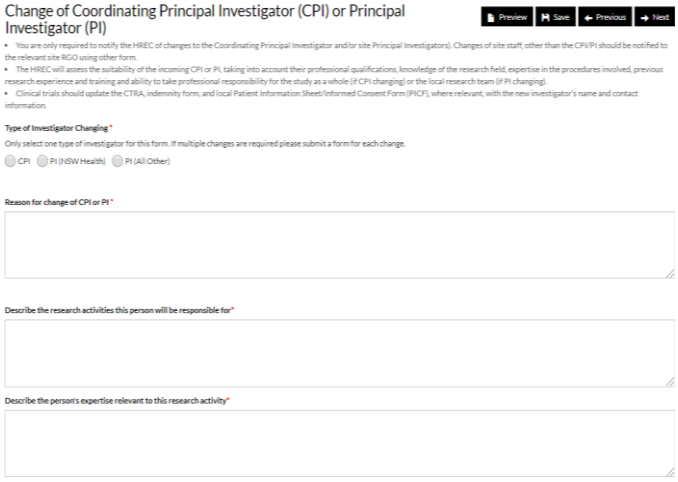
When a site falls under "Other health jurisdiction or organisation" the PI is no longer required to have a REGIS account.

This form also allows for the site to be easily listed as well as the site PIs details, responsibilities and expertise.



Change of CPI/PI

The form now delineates between NSW Health PIs and Other PIs. PIs that fall under the "PI (All Other)" category are not required to have a REGIS account. This form also allows for the CPI/PI selection, reason for the change, CPI/PI responsibilities and expertise to be listed on the one page.



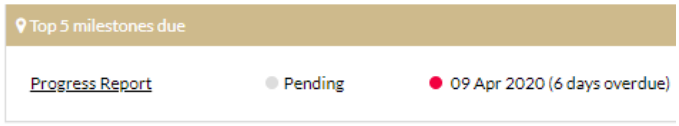
CPI Declaration

It is clearly stated that the person submitting the amendment is the Coordinating Principal Investigator of the study.

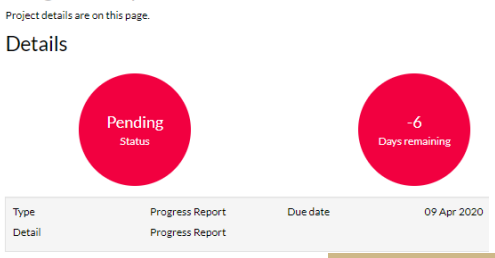
Research Applicant

Identifying & Managing Overdue Milestones

On your homepage under "Top 5 Milestones due", overdue milestones are easily identified by the red dot. The amount of days overdue is also indicated in brackets.

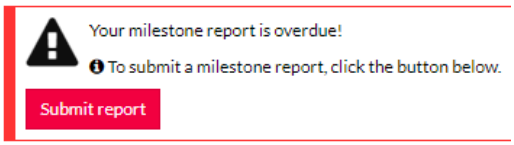


When clicking on the Progress Report two large red circles indicate your progress report's status and how many days are remaining. Any days showing a minus symbol are overdue.



For technical assistance, contact
REGIS HELP DESK
1300 073 447
support@f1solutions.com.a

The below warning also flashes at the bottom of the progress report page, advising you to submit your overdue report.



If you have already submitted your annual progress report outside of REGIS to your Research Office and have an overdue milestone showing for that submitted period then you will need to contact the Research Office to have it removed from REGIS.

Research Office

Amendment Output Form

The output form has been updated to reflect the actual form that is completed by the researcher. Grey sections below are specifically for Research Offices to check and action appropriately when reviewing amendments.

Sections Appearing on All Forms

The researcher is presented with a warning to check that the study type listed is correct and if it is incorrect they need to get in contact with the Research Office to have it corrected.

A classification can be updated prior to a researcher contacting the research office if it is found to be incorrect.

Notification of an amendment to a research study
Amendment type - General Amendment

HREC Reference No.	2020/ETH00810
Project title	CJM_Test_Study
Lead HREC	Sydney Children's Hospitals Network Human Research Ethics Committee
Coordinating Principal Investigator	Albert Kerfien
Study Type	Clinical research

Research Office: *This form shows/hides questions based on the Study Type classification in the ETH project, specifically clinical trials.*
If the form is submitted with the incorrect study type please update the classification. If the form is for the Addition of a new site the RO may also want to un-submit the form so the clinical trial questions can be answered.

COVID-19 Data

COVID-19 details need to be manually entered in the ETH Project. See COVID-19 Data Collection – Research Office Guidance

COVID-19

Research Office: *If the response is "Yes" please entre the following details into the COVID-19 menu option in the Project (post-approval folder).*
Form id, response to each of the below questions

Document Upload

The document title is a combination of the document descriptor/title the version number and date completed by the applicant. e.g *KCTP_Protocol_REGIS.docx (descriptor)-2(version)-25-DEC-2019(date)*

Note to Research Office: *If no documents appear below, no documents were submitted with the amendment.*

Request for HREC Extension

A new milestone may need to be created or a date may need to be manually updated. See Creating Milestone Progress Reports.

Request for extension of HREC approval

Researchers should apply for a request for an extension well before the expiry of their current HREC approval in order to avoid conducting their study without ethics approval.

Note to Research Office: *On approval a new milestone may need to be created in the ETH project.*
If the HREC approves a date that is different to the one requested below the approval date will need to be manually updated.

Addition of Site

Outgoing correspondence needs to be manually updated to include the external site details. The site can be added to the Project organisation details if in REGIS. If not and this site is frequently used by the Research Office, a request to add the site can be submitted to EHNSW-Regis@health.nsw.gov.au following the new HOD process email circulated 9 April 2020.

Note to Research Office: External site details will have to be manually added to outgoing communications.

Change of CPI/PI

As the "PI (All Other)" no longer needs to have a REGIS account, the PI details need to be manually entered in outgoing correspondence and the new PI added to the Project contacts.

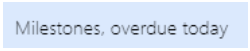
Note to Research Office: Principal Investigator changes for PI (All Other) will have to be manually entered in outgoing communication.

Research Office

Deleting and Creating Milestone Progress Reports

There is a report available to all Research Offices to identify any overdue milestones in the system.

Step 1. Select Reports 

Step 2. Select Milestones, overdue today 

Step 3. Click the Export icon  and choose your preferred document e.g. PDF

Deleting Milestone Progress Reports

Where an external progress report forms has been received the Research Office can delete the milestone showing as overdue.

Step 1.

Select the ETH Project and click 

Step 2.

Select edit and then locate the Progress Report to be deleted, select the delete icon and then click save.

Creating Milestone Progress Reports

Where an extension for HREC approval date has been applied and an additional milestone will be required the Research Office can create a new milestone.

Step 1.

Select the ETH Project and click Milestones

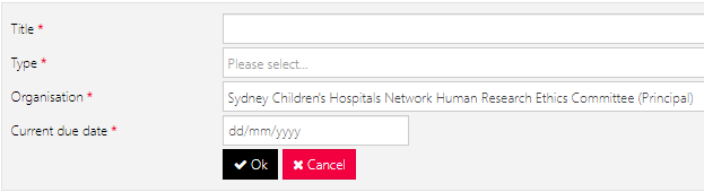
Step 2.

Select edit and then select + Add milestone under "Milestone summary".

Step 3.

Fill in the milestone details as per below, click Ok and then Save;

Title: Progress Report
Type: Progress Report
Organisation: Auto populates
Current due date: Add due date



The new milestone progress report will now appear in the progress report list.

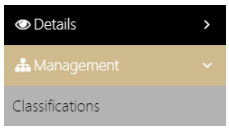
How to Update Study Type Classifications

Study Type Classifications

Where a study type classification has been identified as being incorrect you will need to manually correct it.

Step 1.

Select the ETH Project and click Management → Classifications

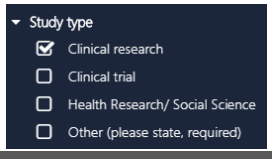


Step 2.

Select edit and add classification + Add classification

Step 3.

In Study type, click the correct study type and then select the tick at the bottom of the page to apply the change.

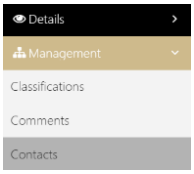


Adding Contacts to the ETH Project

Adding a Contact

There are processes in the system that will send notifications to all contacts, reducing duplication for the Researchers and Research Office e.g. safety reporting notifications.

Step 1.



Adding a Contact

Select the ETH Project and click Management → Contacts

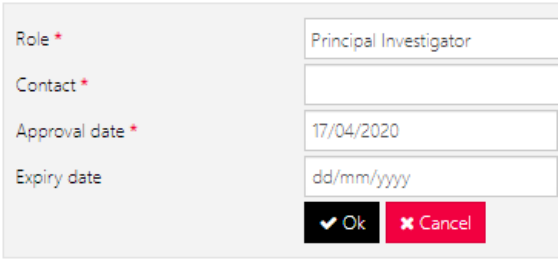
Step 2.

Select edit and + Add contact

Step 3.

Fill in the PI details as per below, click Ok and then save;

Role: Principal Investigator
Contact: Click on the three dots and search for the PI
Approval date: Date amendment was approved



Expiring a Contact

Where the external PI is being replaced you will need to indicate they no longer hold this role by expiring them.

Select the ETH Project and click Management → Contacts

Select page edit and then

Select the date the PI was replaced dd/mm/yyyy then Ok

What you will see;

Approval date	Expiry date
03/04/2020	17/04/2020

For technical assistance, contact
REGIS HELP DESK
1300 073 447
support@f1solutions.com.a