



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).

THIS STUDY HAS AN OVERDUE MILESTONE/ANNUAL REPORT. Submitting an annual report is a requirement of your HREC approval. You will need For guidance please see: [Submitting Annual Progress or Final Report \(Milestone\)](#)

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.

Study Type
Clinical trial

Is the study type correct?

Yes: disregard message and progress
No: please contact the research office and request the study type classification be changed.
Click on the helptext icon above for a list of study types and definitions.

Seeing this message will not stop the submission of this form, however forms submitted with incorrect study types may cause the form to be unsubmitted.

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.

Show Detailed Description of Amendment Types

General Amendment

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

General Amendment

Summary of main changes proposed*

For each change proposed, please provide a summary of and rationale for the change, and a summary of any related ethical issues. Briefly summarise:

- 1) the main changes proposed in this amendment using language comprehensible to a lay person.
- 2) the rationale/justification for each change including any change in the overall risk profile or safety information for the study.
- 3) Any ethical implications of the amendment. Consider the risk/benefit profile per National Statement section 2, ethical considerations specific to research methods or fields (Section 3), and ethical considerations specific to participants (section 4).

Summary of modification *	Rationale *	Ethical Issues *

Any other relevant information?

e.g. how changes affecting existing participants who have already consented will be communicated to them; how new participant groups will be recruited/consented

Document Upload

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

Document upload

This section allows the applicant to submit either amended versions of documents already approved by the HREC or to submit new documents.

Submitting a "New Version" means to submit a new version of an approved document that is already physically located in REGIS.

e.g. Studies that have been migrated from a legacy system will have HREC approved documents but they will not yet be available to update in REGIS.

User should select "No" the first time a document is being entered into REGIS.

If you are unsure if the document exists in REGIS select "yes" if the document does not appear in the Document Title/Descriptor drop down change the response to "no" and follow the prompts.

Please upload one tracked-changed copy and one clean copy of each amended document with this form. Tracked copies of the form must have a unique filename.

Only upload documents to be reviewed by the HREC. Site Specific documents that relate to this amendment, should be submitted directly to the RGO.

If there are no documents to be uploaded select the checkbox and the icon and progress to the next section.

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.

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.

Please describe the reasons for the extension*

Include a summary to date and what needs to be achieved to complete the study.

Addition of a new site

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

Is an HREC only indemnity required? *
 Required for Commercially Sponsored Clinical Trials that do not have a site within the same jurisdiction as the HREC (and for which a standard form of indemnity has not been submitted)

☒ Yes ☐ No

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.

Change of Coordinating Principal Investigator (CPI) or Principal Investigator (PI)

[Preview](#) [Save](#) [Previous](#) [Next](#)

- You are only required to notify the HREC of changes to the Coordinating Principal Investigator and/or site Principal Investigators. Changes of site staff, other than the CPI/PI should be notified to the relevant site REGD using other form.
- The HREC will assess the suitability of the incoming CPI or PI, taking into account their professional qualifications, knowledge of the research field, expertise in the procedures involved, previous research experience and training and ability to take professional responsibility for the study as a whole (if CPI changing) or the local research team (if PI changing).
- Clinical trials should update the CTIA, indemnity form, and local Patient Information Sheet/Informed Consent Form (PICF), where relevant, with the new investigator's name and contact information.

Type of Investigator Changing *

Only select one type of investigator for this form. If multiple changes are required please submit a form for each change.

☐ CPI ☐ PI (NSW Health) ☐ PI (All Other)

Reason for change of CPI or PI *

Describe the research activities this person will be responsible for *

Describe the person's expertise relevant to this research activity *

CPI Declaration

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

Coordinating Principal Investigator Declaration

I declare that:

- I am the CPI of this study
- The information provided is true and accurate.

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.

Top 5 milestones due

[Progress Report](#) Pending 09 Apr 2020 (6 days overdue)

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.

Progress Report

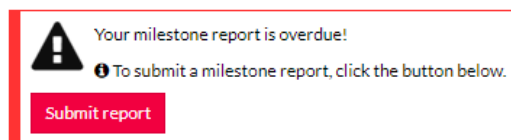
Project details are on this page.

Details

Type	Progress Report	Due date	09 Apr 2020
Detail	Progress Report		

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

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 enter 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 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 Milestones

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


Step 2.

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


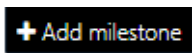
Creating Milestone Progress Reports

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 

Step 2.

Select edit  and then select  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

Title *	<input type="text"/>
Type *	Please select...
Organisation *	Sydney Children's Hospitals Network Human Research Ethics Committee (Principal)
Current due date *	dd/mm/yyyy
<input type="button" value="✓ Ok"/> <input type="button" value="✗ Cancel"/>	

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 

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.

Study type
<input checked="" type="checkbox"/> Clinical research
<input type="checkbox"/> Clinical trial
<input type="checkbox"/> Health Research/ Social Science
<input type="checkbox"/> Other (please state, required)

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.

Details	Adding a Contact Select the ETH Project and click Management → Contacts
Management	
Classifications	
Comments	
Contacts	


Step 2.

Select edit  and 

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

Role *	Principal Investigator
Contact *	<input type="text"/>
Approval date *	17/04/2020
Expiry date	dd/mm/yyyy
<input type="button" value="✓ Ok"/> <input type="button" value="✗ Cancel"/>	

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 then 

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.au