REGIS

What's New 2020

QUICK REFERENCE GUIDE

FOR RESEARCH APPLICANTS AND RESEARCH OFFICES

What's New June 2020 - Milestone Progress Report

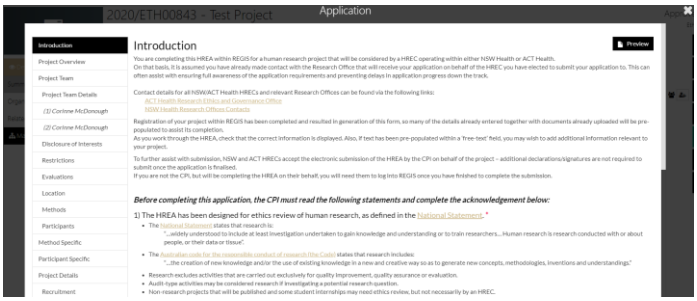
What's New

Changes have been made to the Milestone Progress Report to refine and incorporate additional information based on the review and feedback from a working group of Research Offices, the REGIS user group and a Researcher reference group. This document outlines the changes that the Research Applicant and Research Office will see to the Milestone Progress Annual and Final Report form for Non-Clinical Trials and Clinical Trials.

New Functionality

Research Offices can now access the application form and supporting documents from the 'Summary' page of the Ethics (ETH) and Site (STE) Application, only after initial submission.

On the 'Application Identifier' row, a link has now been inserted. By clicking the ETH or STE application identifier the application form will appear on the screen. This document is view only and allows you to go through each page.



To view the application form and supporting documents as a PDF or word document, click the 'Preview' button Preview and a zip folder will download at the bottom of the screen.

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.

Study Type

The smartform logic identifies the type of study (Clinical Trial/Non-Clinical Trial) and will hide or ask questions to ensure that only relevant questions are asked. If the study type is incorrect, contact the Research Office and request the study type classification to be changed before completing and submitting the Milestone Progress Report.

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 Milestone Progress Report but are warning that you need to review and action appropriately.

Safety Reporting

The smartform logic recognises conflicting answers, the below is an example of when two questions are answered "No" where at least one should be answered "Yes". A red warning message appears advising the applicant that it is assumed that research will involve either recruitment of participants or data/tissue samples and that they need to contact their research office to clarify their study type.

It is assumed that research will will involve either recruitment of participants or data/tissue samples. Please contact the reserach office to clarify your study type.

Compliance, Confidentiality & Storage

This message advises that the CPI/Sponsors should no longer send the HREC the following reports; single case AEs, SAE/SARs and SUSARS or device/non-therapeutic good trial equivalents or six-monthly line listings. If these reports are sent to the HREC then they will not be reviewed. If any of the events above result in an SSI, then this should be reported to the HRECs using the form posted on the OHMR safety reporting webpage.

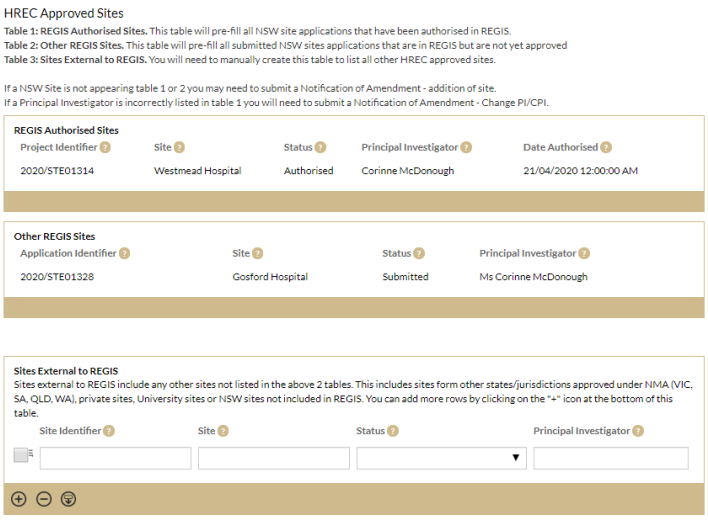
> NSW/ACT Research Offices have adopted the NHMRC Guidance: Safety Monitoring and Reporting in Clinical Trials Involving Therapeutic Goods (November 2016). In accordance with this document, CPI/Sponsors should no longer send to HRECs the following reports: • Single case AEs, SAE/SARs and SUSARs or device/non-therapeutic good trial equivalents or six monthly line listings. Any of these reports sent to HRECs will not be reviewed. If any of the events listed above result in a Signification Safety Issue then this should be reported to the HRECs using the form posted on the OHMR Safety Reporting Webpage.

Annual/Final Report

Project Details

Under the heading "HREC Approved Sites" there are three tables, Table 1 is for NSW sites authorised in REGIS, Table 2 is for NSW sites submitted in REGIS but not yet approved and Table 3 is for HREC approved external sites. Tables 1 and 2 will pre-fill these sites and external sites will need to be manually added to Table 3.

There is also a message above Table 1 that advises if a NSW site is not appearing in table 1 or 2 you may need to submit a Notification of Amendment – addition of site and also if a Principal Investigator is incorrectly listed in table 1 you will need to submit a Notification of Amendment – Change CPI/PI.



Status

The status' Terminated/Abandoned are now standalone statuses, when either status is selected you will be advised to complete the final progress report form. This advice also appears when selecting the status Closed (post analysis).

The smartform logic identifies if the report is an annual progress report or final report and asks or hides questions to ensure only relevant questions are asked.

Recruitment/Data/Samples

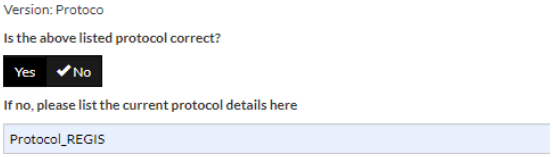
A Study Wide Recruitment section has been inserted, this allows for the overall study information and total recruitment data to be entered alongside the NSW site specific recruitment information. Questions regarding participants ongoing/active treatment and currently in follow up have also been added. Additional questions are asked for clinical trials in the recruitment section.

For any questions answered "No" on this page, a free text box will appear asking for an explanation.

Progress Summary

Details of publications or conference attended in relation to the study and what actions are planned in the next 12 months should be listed in this section.

The current version of the protocol will pre-fill, if it is incorrect select "No" and manually list the correct protocol.



Safety Reporting

The annual safety report can now be submitted with the submission of the progress/final report.

Compliance, Confidentiality & Storage

The research applicant is asked to confirm that the project has been conducted in accordance with the NHMRC national statement on ethical conduct in human research, conducted in accordance with the approved protocol and study amendments and that the data collected and stored is in accordance with the protocol. If any of these questions are answered "No", they are asked to explain why.

Document Upload

The form now allows the research applicant to upload relevant documents with the progress report i.e. audit report, annual safety report, other etc.

Final Report

If a final report is being completed, additional questions will be asked in the Recruitment section and based on those answers further additional question may be asked as well as the Final Report sections becoming available.

Questions are shown or hidden based off the study type and smart form logic of questions above. It is important the study type is correct as it ensures the appropriate questions are asked.

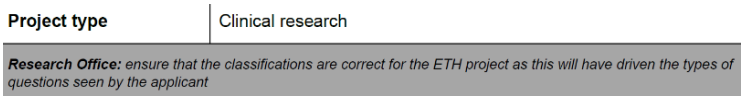
Research Office

Annual/Final Report

Processing progress reports has not changed for the Research Office. You will notice the differences on the submitted form are the extra questions asked and grey sections. These grey sections are directed at the research office for information or action as appropriate.

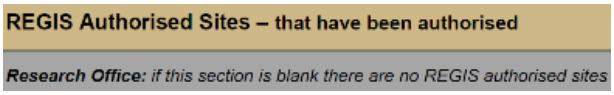
Study Type Classification

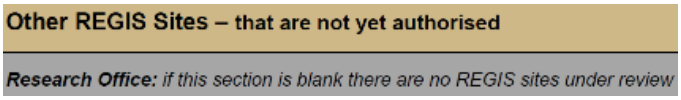
The research office is asked to ensure that the study type classification is correct as this will drive the types of questions seen by the research applicant.

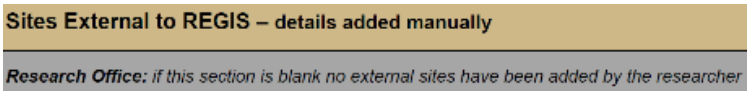


HREC Approved Sites

Only HREC approved sites will be listed under these sections.





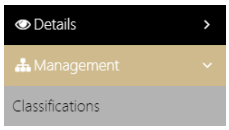


How to Change the Study Classification

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.