REGIS

| QUICK REFERENCE GUIDE | FOR RESEARCH OFFICES |

Processing a Governance Milestone (External HREC Progress Report, Certificate of Currency)

The following Governance milestones are submitted and processed via REGIS

- ❖ **First Patient In:** First Patient In data is collected for NSW metrics 5. *Milestone is automatically 'Achieved' upon submission, the Research Office does not need to review or process this milestone.*
- ❖ **Certificate of Currency:** For Commercial and Collaborative Group sponsored Clinical trials. *Process via Project Decisions section.*
- ❖ **Progress Report – External HREC:** HREC approved progress reports from a HREC external to REGIS must be submitted to the RGO. *Milestone is automatically 'Achieved', process via Project Decisions section.*

Processing a milestone from the STE Project Decisions section

Step 1
Select the milestone to be processed from the Decision homepage tile. You are taken directly to the 'Decisions' section of the Project.

Note: 'RGO review of Certificate of Currency' and 'RGO review of a Progress Report' decisions are automatically created upon submission of these type of milestones.

Step 2
Locate the 'RGO review of Certificate of Currency' or 'RGO review of a Progress

Report' decision as appropriate. Select 'Edit' from the bottom of the screen.

Step 3
Select the 'Edit' icon on the row of the decision you are processing.

Note: Research Governance Officers will be automatically listed as the 'User' against the decision, this is dependent on who your Research Office has listed as a 'Research Governance Officer' in the system.

Select 'View User Decision' and the 'User Decisions' pop-out box appears on the right-hand side of the screen. If your name appears, proceed to **Step 4** if not, follow the steps below.

Select the 3 horizontal dots at the end of the 'User' row. The 'Add Users' pop-out box appears, use the search bar to find the person who has the authority to review the milestone.

Select the checkbox against their name and then select the tick at the bottom of the pop-out box to save your selection.

Step 3
In the 'Notes' section, add any notes as necessary and then click 'Save'.

Step 4
Select 'View User Decision' and the 'User Decisions' pop-out box appears on the right-hand side of the screen.

Select your name and the decision drop-down menu will appear.

Choose from the following decisions:

- ❖ Approved – No further action is required
- ❖ More Information Required – Action is required from the applicant.

A comment needs to be added when 'More Information Required' is selected, this will pull through to the email. Once necessary comments have been added, click 'Save'.

Step 5
The milestone will now be in the status of 'Revision' and is with the applicant for editing.

Automatically Shared with Authorised Sites in REGIS

When the milestone is 'Achieved', PI's listed in REGIS will receive a copy of the decision notification and the Progress Report – External HREC will be automatically shared with all sites in REGIS.

Navigate to 'Related documents' and using the aggregate view, identify the 'Milestone Report' and 'System Generated Email'.

Change the Status of the Project

When an external progress report has a status of Completed, Closed (post analysis), Terminated or Abandoned the Research Office should change the status of the Site Project.

Step 1.

In the Site 'Project', select 'Management' from the left-hand menu and 'Status'. Make the page editable and select '+ Add status'. Once completed, select 'Ok' and 'Save'. Repeat these steps in the Site 'Application'.

Manually creating a Milestone

Research Office can create any type of milestone as required.

Step 1

Select the STE Project and click 'Milestones'

Step 2

Select 'Edit' from the bottom of the screen and then select '+ Add milestone' under 'Milestone summary'.

Step 3

Fill in the details as per below;

Title: Normally the same name as the type of milestone being created but you can add additional detail here i.e. reference number etc.

Type: Select from dropdown

Organisation: Auto populates

Current due date: Add due date

Step 4

Click 'Ok' and then 'Save' on the right-hand side menu.

The new milestone will now appear in the Milestones list for the researcher.