

REGIS
CE/Delegate Decision

QUICK REFERENCE GUIDE

FOR CHIEF EXECUTIVES/DELEGATES

Authorising Human Research Projects

All human research that takes place in a Public Health Organisation (PHO) must be reviewed through site specific assessment and authorised by the Chief Executive or their delegate before commencement.

Prior to making the CE/Delegate Decision.

The Research Governance Officer (RGO) will have conducted an assessment of the application following submission by the Principal Investigator.

Following the assessment, the RGO will make a recommendation in REGIS to the Chief Executive or delegate regarding authorisation of the project and indicate whether authorisation:

- ❖ is recommended
- ❖ is not recommended (RGO will provide reasons)
- ❖ requires consideration by the Chief Executive or delegate (RGO will provide reasons).

The RGO should add any project monitoring by the site, requested by the reviewing HREC.

CE/Delegate Decision.

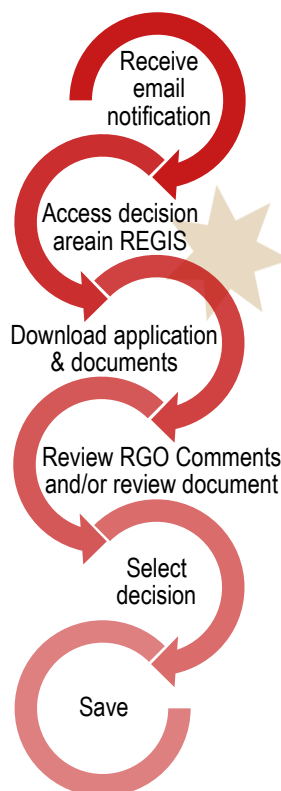
Providing authorisation to commence human research is an important component of research governance. A final authorisation decision is required before the research can commence at the PHO.

This process is completed electronically in REGIS and replaces the former manual signatory collection process (wet signatures). Authorisation of the application constitutes authorisation of the SSA. The CE will select either:

- ❖ Authorised
- ❖ Authorised with conditions
- ❖ Not authorised

How does it work in REGIS?

The following diagram is an overview of the Declaration of Support process in REGIS.



Decisions

AUTHORISED (STANDARD CONDITIONS)

If an application is Authorised (standard conditions) the research project can occur at this site indicated in the application.

There are no additional conditions to conducting this study.

AUTHORISED WITH CONDITIONS

If an application is Authorised with conditions the research project can occur at this site indicated in the application.

However, conditions are imposed. For example:

- ❖ Participants cannot be enrolled prior to the NCAT decision being received and noted by the Research Office.
- ❖ In line with HREC additional requirements the PI must provide additional site reporting.

Note: This option is not used if the CE/Delegate is seeking more information prior to an application being authorised. See [Requesting More Information](#)

NOT AUTHORISED

If an application is Not Authorised the research project cannot occur at the site indicated in the application.

When authorisation is not granted the CE/Delegate is required to provide the reasons in REGIS. These will be provided

to the investigator in the decision outcome communication.

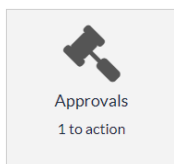
How to provide the CE/Delegate Decision for research projects in REGIS.

Step 1

You should receive an email which will provide you with a direct link into the decision section of the SSA that you have been asked to provide a decision. If you are accessing via the email, after logging in you can jump to Step 4.

Step 2

If you are logging into REGIS home page, you will see the approvals icon under the "Your activities" section on the home page.



This will take you to the approvals page.

Step 3

Click on the Application that you intend to review.



You can click on the Type or the Identifier.

Step 4:

You are now in the Decision Details page.

You are presented with the application details such as the Title, Application identifier and Application Type. This section also includes the CE/Delegate decision dropdown and comments section as discussed in step 6.

Step 5

To download the application form and related documents click the 'Download Documents' button

The documents will download as a temporary .zip file.

If a briefing document was uploaded by the RGO this is available to be downloaded in the 'Documents' section.

Step 6

Predecessor decisions is the RGO decision and comments. This can be seen on the left-hand menu.

RGO decisions discussed on page one 'Prior to making the CE/Delegate Decision'.

Click on the menu item to see the predecessor decision.

This can also be located on the 'Decision Details' page, under 'Recommendation by RGO'.

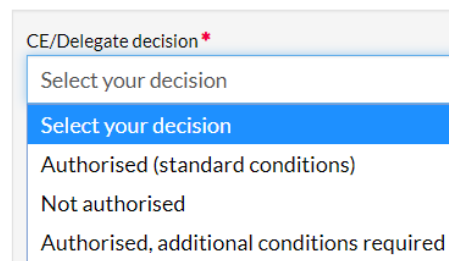
Step 7

Make the CE/Delegate decision by clicking on the Decision Details menu item on the left-hand menu.

Decision Details

Select your decision from the dropdown and provide your conditions and/or reasons for your decision in the free text field below.

Decision



Step 9

Once you have selected your decision and added your comments, click on Save.



The RGO or RO will send the final decision communication.

Requesting More Information

If you require more information before making the final decision you should communicate with the RGO outside of REGIS (e.g. email or phone). The RGO is listed in the Predecessor Decisions. **DO NOT SELECT AUTHORISED WITH CONDITIONS**

The RGO will seek the further information from PI and will let the CE/Delegate know when the information is available in REGIS.

Once the information is available the CE/Delegate can log in using the steps provided in the QRG and finalise their review/decision.

When the RGO has delegated authority.

The RGO can make the CE/Delegate decision from the internal portal.



Select the View User Decision icon next to the CE/Delegate decision type.

Select the User Decision and complete the Decision and Comments cells.

Click Save.

For technical assistance, contact
REGIS HELP DESK

support.f1solutions.com.au
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