

REGIS
CE/Delegate Decision

FOR CHIEF EXECUTIVES/DELEGAGES

QUICK REFERENCE GUIDE

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.

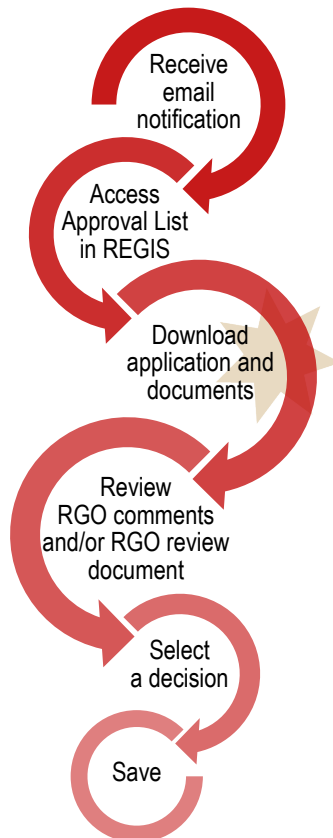
This process is completed electronically in REGIS and replaces the former manual

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.

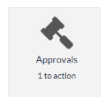
How to provide the CE/Delegate Decision for research projects in REGIS.

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.



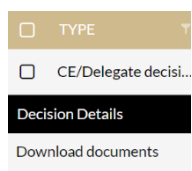
This will take you to the approvals page.

Step 3

Approvals are automatically filtered to 'Pending' so that you will only see approvals that need actioning.

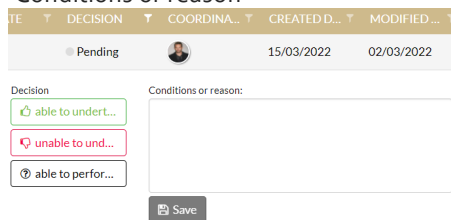
You can review and provide a decision on the Approvals page or from within the decision.

3a Approvals Page: Clicking anywhere on the decision row, except the title, will open a quick view of the application you intend to review.



Select 'Download documents' and a zip folder containing the documents will download at the bottom of the screen.

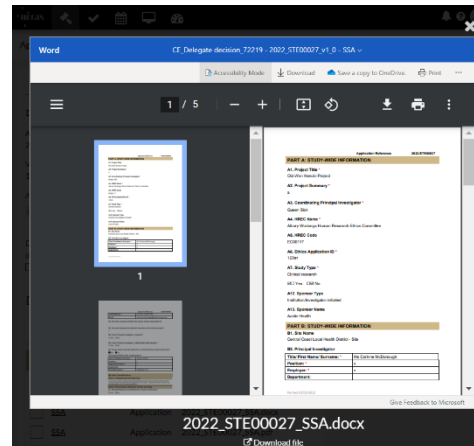
Select your decision from the 'Decision' options to the right of the screen and provide any comments in the free text box 'Conditions or reason'



3b Within Decision: Click on the application title to be taken directly into the decision.

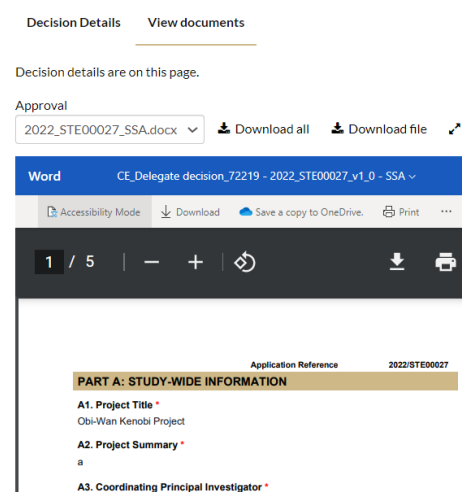
Step 5

To review the documents, you can open documents (except zipfiles) on the page by clicking on the Title from the 'Documents' section at the bottom of the screen.



You can also review the documents via the header 'View documents' at the top of the page. Selecting any document (except zipfiles) will open on the page. You can choose to 'Download all' or 'Download file' from this section.

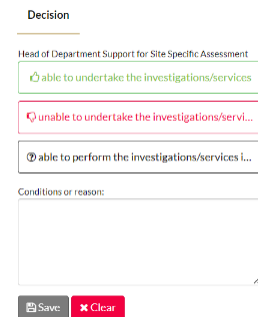
If a briefing document was uploaded by the RGO this is available to be downloaded in the 'Documents' and 'View Documents' sections.



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

Click on the menu item to see the predecessor decision.

Step 7



Make the CE/Delegate decisions selecting your decision from the 'Decision' options to the right of the screen and provide any comments in the free text box

'Conditions or reason'.

Once you have selected your decision and added your comments, click 'Save' and a system notification will appear advising that the decision details have been saved.

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. via email or telephone). The RGO is listed in the Predecessor Decisions.

DO NOT SELECT AUTHORISED WITH CONDITIONS


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

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.

What's next?


You have now submitted your approval decision to the RO, the RGO or RO will send the final decision notification. This approval will now be cleared from your Approval list.

How to find a submitted Approval decision



The decision will now disappear from your Approval List. You can find previously submitted decisions by using the advanced search function.

Under the 'Decision' section, you can filter for decision types i.e. Pending, Authorised (standard conditions), Not Authorised etc.

You can add decisions by clicking the 'Decisions' box and a dropdown menu will appear. To delete the decision, click on the x.

Search: 

Decision

- Pending 
- Authorised (standard conditions) 

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