

## Head of Department - Not Supported

For guidance on how to complete and submit the initial site application in REGIS please refer to **Site Application Completing, Requesting Head of Department Support and Submitting**.

### How does it work in REGIS?

The site application is submitted to the Heads of Department on completion of the site application by the Principal Investigator. If all HODs indicate support, the application will be automatically submitted to the research office.

If one or more HODs indicate they are unable to support the application the status will indicate, ● HOD Not Supported the applicant may need to take the following action:

- ❖ have further discussions with one or more HODs
- ❖ make changes to the application, or
- ❖ discuss issues with the Research Office.

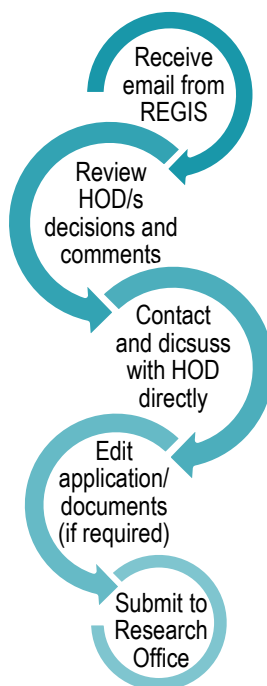
### Accessing the STE/SSA

#### Step 1: Access the Site application

##### Accessing application from email link

Click on the link from the system generated email.

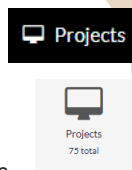
Progress to **Step 2b: Review HOD declarations - View Individual decision outcomes and comments**



OR

#### Accessing from REGIS homepage

Click on the 'Projects' icon to view a list of all the projects you have access.



Select the project from the list and click anywhere on the STE study row to expand it and select Application Information.

#### Step 2: Review HOD declarations

##### 2a. Locate HOD declaration(s)

Select Decisions

Application Details   Decisions   Forms   Applications

Click the decision row to view individual decisions and comments.

TITLE
Head of Department Support for Site Specific Assessment

- ❖ User = HOD
- ❖ Decision = Outcome
- ❖ Comment
- ❖ Overridden = when Research Office has made a manual change
- ❖ Overridden Decision = when Research Office has made a manual change
- ❖ Assigned Date = date request was sent to HOD

#### HOD is 'unable to undertake...'

Decision
unable to undertake the investigations/services indicated, on the following grounds

If after discussion with the HOD if there is agreement that they will support the study, evidence will need to be uploaded into a new version of the application.

### Submit a new version of the application.

To make any changes to the application (changing details, adding or removing HOD) or supporting documents you will need to create a new version.

Return to the **Application Details** page showing a list of the applications.



Then select the New version button in the top right-hand corner of the screen.

A warning message will appear. Click 'New version' again. You will now be asked to confirm a new version and add application comments, e.g. 'new version to include HOD support requirements'.

The status of the application will now appear as **In Progress** indicating it can be edited/completed.

Update the application. Add, update or delete attachments as needed.

## Updating an existing document

To update an existing site document with a new version, click on the **x** to remove the old document.

File Name	Size
<b>x</b> Site PICF v 2.docx	16.40 kB

Then drag and drop or browse your local files for the new document.

Ensure to update the description of the attachment including the version and date

**Upload attachment:** Drag and drop or browse your local files for the new document.

*Note: The document Type and Description is what the Research Office will see and how the document will appear on the approval notification.*

*e.g. Participant Information Sheet Site PICF version 2 dated 13 January 2022*

## To add a new document on the SSA

To add a new site-specific document, select the + Add another button

+ Add Another

**Document Type:** Select from dropdown.

**Document Descriptor:** List exactly as you need the document to appear on the approval letter including the version and date if it exists. Usually this corresponds with the footer of the document.

**Upload attachment:** Drag and drop or browse your local files for the new document.

## Submitting to the Research Office

Once the application is ready to be re-submitted, the PI will be able to select 'Complete SSA' under Part G: Declaration.

The application will be submitted to the Research Office and the status will show as **Submitted**

If a new Head of Department was added, the application the status of the application will change from 'In Progress' to **Completed pending HOD**

Only the **NEW** HOD will receive a notification from REGIS that a site application is ready for their decision.

You will receive an email from REGIS when all HODs have made their decision. If all decisions are supported or supported with conditions the application will be automatically submitted to the Research Office.

## Submitting without HOD support

Only select this option on discussion with the Research Office otherwise the application will be made ineligible.

### Step 1. Locate HOD Decisions

Follow steps to Access the SSA/STE and HOD decisions on page 1.

### Step 2.

Select Submit to RGO.

Once selected you must provide a justification to proceed, once completed select save.

**Submitted**

## Once your site application has been submitted:

- ❖ Your application will be assessed for eligibility to be reviewed by the RGO. If you have any questions, contact the Research Office at the site relevant to the application.
- ❖ If your ethics application is yet to be approved after you have submitted your site application, the final decision made by the Chief Executive/Delegate can only be made once ethics approval for the project has been received from the nominated Human Research Ethics Committee. Your application will be in the status of 'Valid' and will automatically update upon ethics approval being recognised in the system to 'Eligible'.

For technical assistance, contact  
REGIS HELP DESK

support@f1solutions.com.au  
1300 073 447