

Site Amendments - REGIS

How to submit Site Amendments

How to respond to Further Information Requests



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What is a Site Amendment

- A site amendment is a Governance Amendment that needs to be submitted to the RGO office after an Ethics Amendment has been approved by the lead HREC.
- This used to be referred to as an MC Amendment and was processed via email, however this is now done in REGIS.
- SWSLHD requires a copy of all documents approved by the Lead HREC as well as any Site Specific versions of the approved documents for our sites. These are the documents that are submitted in the Site Amendment.



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Site Amendment Flowchart when Lead HREC is NOT SWSLHD



Steps for Submitting when Lead HREC is NOT SWSLHD

- Once the Ethics Amendment has been approved by the lead HREC you will receive an email advising you that a Site Amendment needs to be submitted in REGIS.
- Locate all the documents approved by the Lead HREC as listed on the Approval Letter and combine them into a zip file with the name 'Site Amendment – [Date]' eg *Site Amendment – 25 March 2021*.
- If you have any documents that require Site Specific Versions, please add these into the zip file in a folder titled 'Site Documents'.
- Please ensure that you also complete the Site Amendment Cover letter



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Lead HREC Approval Letter

None
no_reply@f1solutions.com.au
2021/ETH00146: General Amendment (42247) - Approved
To Logan.Lown@health.nsw.gov.au
Cc Logan.Lown@health.nsw.gov.au

Dear Logan Lown,

Thank you for submitting an Amendment for the following study;
2021/ETH00146: Site Amendment Presentation

The Amendment has been reviewed on 23 Mar 2021, by the Executive Officer as delegated by the HREC Chair and has been approved.

Amendment type: General Amendment with form ID 42247

The following documentation is included in this approval:

- Protocol, Version 2.0, 23.03.2021

It is noted that the South Western Sydney Local Health District Human Research Ethics Committee is constituted in accordance with the National Statement on Human Conduct in Research, 2007 (NHMRC).

THIS EMAIL CONSTITUTES ETHICAL APPROVAL ONLY – SITE SPECIFIC AMENDMENT IS REQUIRED BEFORE ANY APPROVED SITE DOCUMENT CAN BE USED AT ANY NSW PUBLIC HEALTH SITE

Condition of approval: Please ensure that the relevant ethics approval and documents are submitted to all relevant Research Governance Offices for site authorisation prior to use at the sites

Conditions of approval:

1. The Principal Investigator will immediately report anything which might warrant review of ethical approval of the project in the specified format, including:
 - any serious or unexpected adverse events; and
 - unforeseen events that might affect continued ethical acceptability of the project.
2. The Principal Investigator will report proposed changes to the research protocol, conduct of the research, or length of HREC approval to the HREC in the specified format, for review. For multi-centre studies, the Chief Investigator should submit to the Lead HREC and then send the amendment approval letter to the investigators at each sites so that they can notify their Research Governance Officer.
3. The Principal Investigator will inform the HREC, giving reasons, if the project is discontinued before the expected date of completion.
4. The Principal Investigator will provide an annual report to the HREC and at completion of the study in the specified format.
5. The Principal Investigator must reassure participants about confidentiality of the data.
6. Proposed changes to the personnel involved in the study are submitted to the HREC accompanied by a CV where applicable.

Please contact us if you would like to discuss any aspects of this process further, as per the contact details below.

Yours Sincerely,



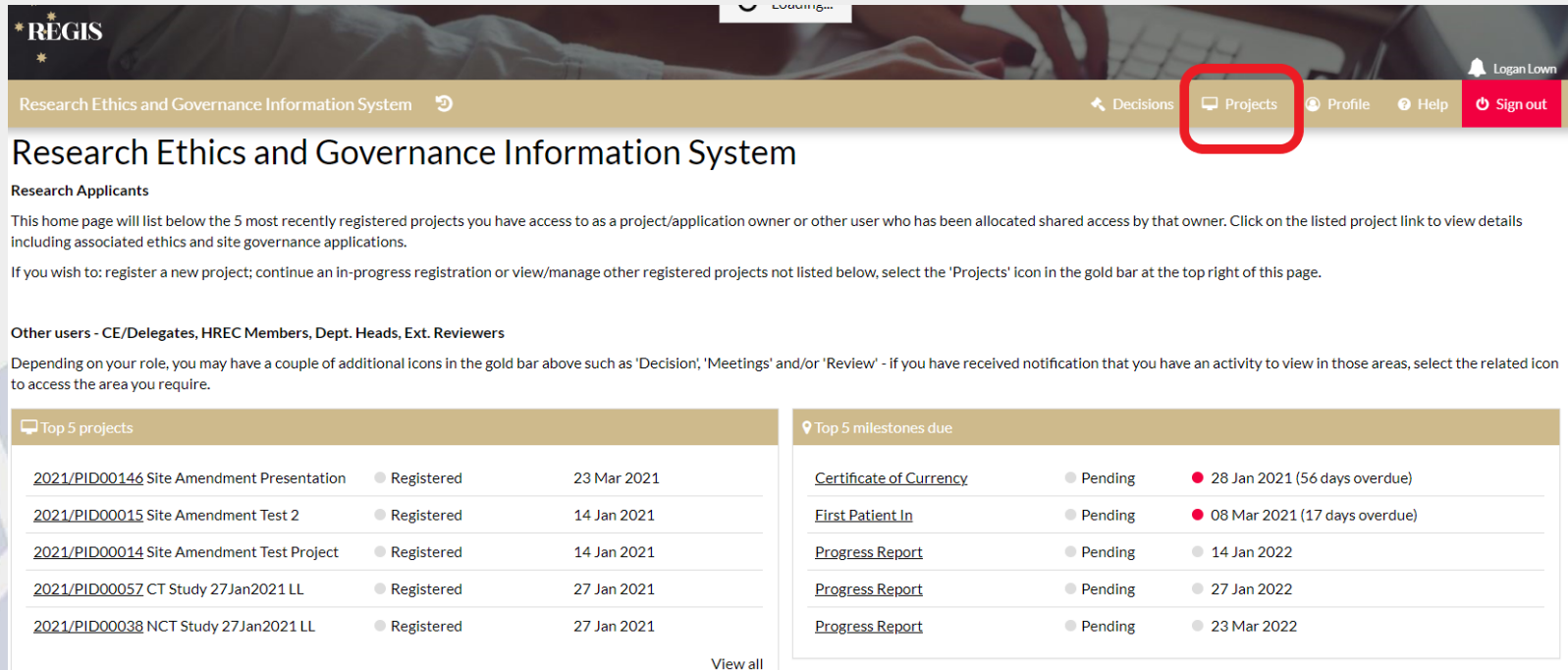
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- The Lead HREC Approval Letter will list two important things required for the Site Amendment, both of which are marked in the previous slide.
- The Amendment Form Number will be used in your submission to link your Site Amendment to the Ethics Amendment which has been approved by the Lead HREC.
- The list of documents will advise you what documents need to be submitted as part of the Site Amendment for review by our office.
- Once you have the Approval Letter and you have combined them into a zip file, you will need to complete the Site Amendment in REGIS.



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Login to REGIS, your home page will show a summary of your Projects.
Click the Projects button as shown below.



*** REGIS ***

Research Ethics and Governance Information System

Decisions Projects Profile Help Sign out

Research Ethics and Governance Information System

Research Applicants

This home page will list below the 5 most recently registered projects you have access to as a project/application owner or other user who has been allocated shared access by that owner. Click on the listed project link to view details including associated ethics and site governance applications.

If you wish to: register a new project; continue an in-progress registration or view/manage other registered projects not listed below, select the 'Projects' icon in the gold bar at the top right of this page.

Other users - CE/Delegates, HREC Members, Dept. Heads, Ext. Reviewers

Depending on your role, you may have a couple of additional icons in the gold bar above such as 'Decision', 'Meetings' and/or 'Review' - if you have received notification that you have an activity to view in those areas, select the related icon to access the area you require.

Top 5 projects

2021/PID00146 Site Amendment Presentation	Registered	23 Mar 2021
2021/PID00015 Site Amendment Test 2	Registered	14 Jan 2021
2021/PID00014 Site Amendment Test Project	Registered	14 Jan 2021
2021/PID00057 CT Study 27Jan2021 LL	Registered	27 Jan 2021
2021/PID00038 NCT Study 27Jan2021 LL	Registered	27 Jan 2021

[View all](#)

Top 5 milestones due

Certificate of Currency	Pending	28 Jan 2021 (56 days overdue)
First Patient In	Pending	08 Mar 2021 (17 days overdue)
Progress Report	Pending	14 Jan 2022
Progress Report	Pending	27 Jan 2022
Progress Report	Pending	23 Mar 2022

Once you can see your full list of projects, click on the correct Project for the submission that you need to make.

Research Ethics and Governance Information System

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Projects

REGIS is structured with the following hierarchy: Project>>>Applications>>>Post-approval/authorisation Amendments, Reports and Safety Notifications - listed below are all the projects you currently have access to.

In order to submit an application (ethics and/or site-governance), you must first register the project - you can do that here by selecting the [+New Project](#) button below.

Project Registration will determine whether a new HREA is required for consideration by a HREC operating within ACT or NSW health services and if SSA will need to be generated for research to be undertaken at sites with NSW Health. The details entered at registration pre-populate those subsequent applications.

Below are your projects. Click the link to open and manage your project.

[+ New Project](#)

Export CSV

Show 10 entries

Search:

Title	Identifier	Status	Ethics approved	Expiry date	Principal organisation	Overdue milestones	Revision milestones	Total milestones
CT Study 10 November 2020 LL	2020/PID02975	Registered	10 Nov 2020	11 Nov 2020	REGIS	0	0	0
Site Amendment Test Project	2021/PID00014	Registered	14 Jan 2021	15 Jan 2021	REGIS	0	0	0
Site Amendment Test 2	2021/PID00015	Registered	14 Jan 2021	14 Jan 2026	REGIS	0	0	0
NCT Study 27 Jan 2021 LL	2021/PID00038	Registered	27 Jan 2021	28 Jan 2021	REGIS	0	0	0
CT Study 27 Jan 2021 LL	2021/PID00057	Registered	27 Jan 2021	27 Jan 2026	REGIS	0	0	0
Site Amendment Presentation	2021/PID00146	Registered	23 Mar 2021	23 Mar 2026	REGIS	0	0	0

Click on the 3 Dot Icon to the left of the SSA that you are submitting the Site Amendment for. This will load a sub menu for that SSA.

Research Ethics and Governance Information System

DecisionsProjectsProfileHelpSign out

Project

Project details

Applications

Contacts

Details

Documents

History

2021/PID00146 - SITE AMENDMENT PRESENTATION

Project details are on this page.

New sites can only be added if the Ethics application has not been approved and is in the In Progress status.

+ New Site

Applications

Export CSV Show 10 entries Search:

Identifier	Title	Comments	Version	Status	Owner	Created date
2021/ETH00146	Site Amendment Presentation		1.00	Approved	Logan Lown	23/03/2021 03:44:44 PM
2021/STE00207	Site Amendment Presentation		1.00	Authorised	Logan Lown	23/03/2021 03:52:31 PM
2021/STE00208	Site Amendment Presentation		1.00	Authorised	Logan Lown	23/03/2021 03:52:37 PM

Showing 1 to 3 of 3 entries

Previous 1 Next

In the sub menu, select the Project Information option.

Export CSV Show 10 entries

Identifier	Title	Comments	Version	Status
2021/ETH00146	Site Amendment Presentation		1.00	Approved
	Application information		1.00	Authorised
	Project information		1.00	Authorised

Showing 1

- Invite user to register or share application
- Invite user to register or share project
- Download application attachments
- View submitted application

Search Office | Contact a NSW Research Office

When the new screen loads, select forms from the left hand menu.

The screenshot displays the 'Research Ethics and Governance Information System' interface. On the left, a sidebar menu lists several options: Applications, Contacts, Details, Documents, Forms, History, and Milestones. The 'Forms' option is highlighted with a red rectangular border. The main content area on the right is titled '2021/STE00207 - SITE AMEND' and includes a sub-header 'Project details are on this page.' Below this, the text 'Project details' is displayed. A large dark blue circle contains the word 'Authorised' above the word 'Status'. Further down, a section titled 'Details' contains a table with project information.

2021/STE00207 - SITE AMEND	
Project details are on this page.	
Project details	
Authorised Status	
Details	
Parent project	2021/PID00146
Project identifier	2021/STE00207
Principal organisation	Liverpool Hospital
Approval date	23 Mar 2021

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The Site Amendment page will now load. On this page you will start the process to create the Site Amendment. Click on the New Form button.

Research Ethics and Governance Information System

DecisionsProjects

Project

2021/PID00146
Site Amendment Presentation

Applications

Contacts

Details

Documents

Forms

History

Milestones

2021/STE00207 - SITE AMENDMENT PRESENTATION

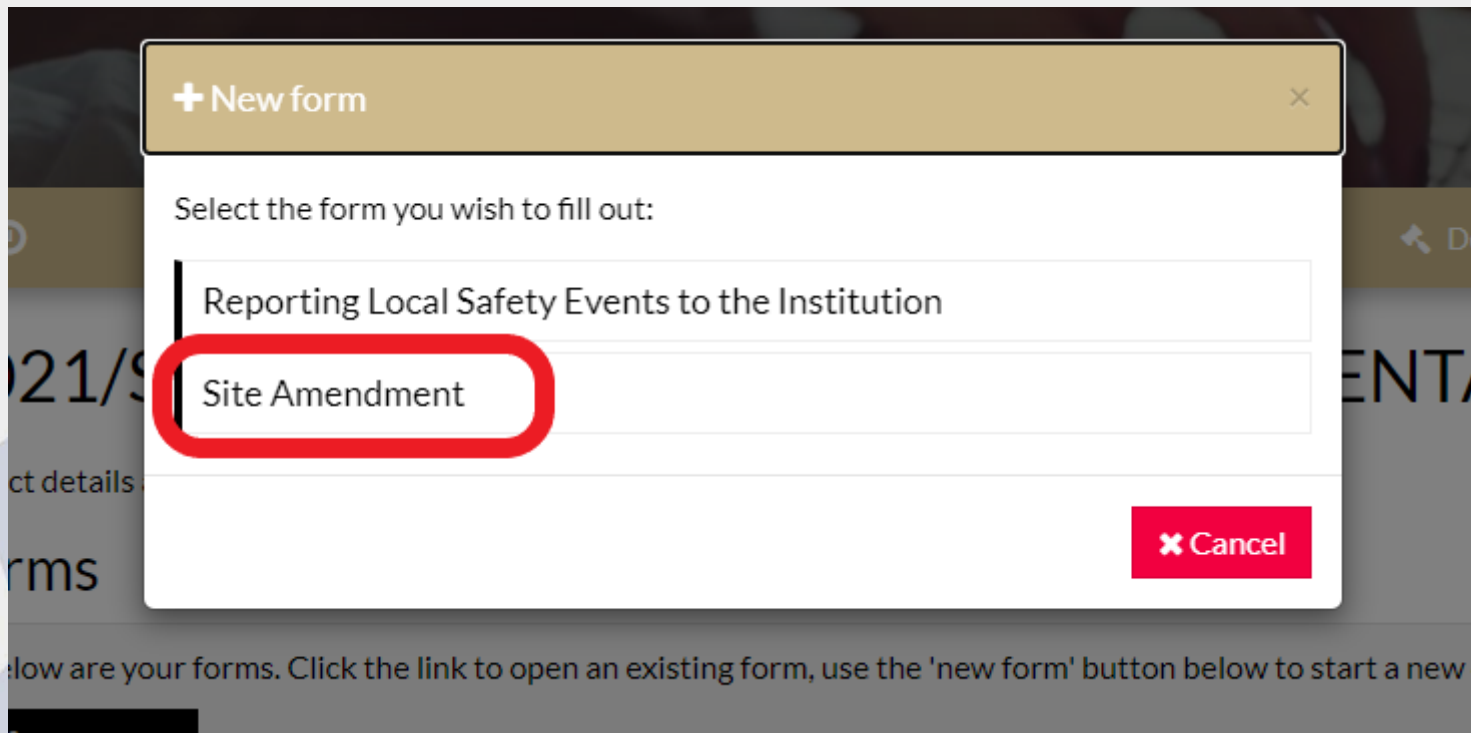
Project details are on this page.

Forms

Below are your forms. Click the link to open an existing form, use the 'new form' button below to start a new one.

+ New form

In the pop up menu select 'Site Amendment'.



The image shows a 'New form' pop-up menu. The menu has a title bar with a plus icon and the text '+ New form'. Below the title bar, it says 'Select the form you wish to fill out:'. There are two form options listed: 'Reporting Local Safety Events to the Institution' and 'Site Amendment'. The 'Site Amendment' option is highlighted with a red rounded rectangle. At the bottom right of the menu is a red button with a white 'X' icon and the text 'Cancel'.

+ New form

Select the form you wish to fill out:

Reporting Local Safety Events to the Institution

Site Amendment

Cancel

The Site Amendment form will load. At the bottom of the page is a list of Site Amendment types and a drop down menu.

If the Lead HREC is in NSW but is NOT SWSLHD, select the General Amendment type then press Next.

Select Amendment Type*

The types of amendment that can be submitted to the RGO are:

- General amendment
- Addition of a site
- CPI change notification
- PI change notification
- Extension of HREC approval notification
- Change site investigators or site administration contacts
- Change to contracts

Show Detailed Description of Amendment Types

General

→ Next



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The next page of the Site Amendment will ask a couple of yes/no questions and request a summary of the site implications. Answer these as required. If you select Yes, you may be required to add some extra documents to your zip file.

General Site Amendment

Preview

Save

Previous

Next

Does the amendment require changes to contracts?*

Contract amendments may be required, for example, when there are changes to the study visits (investigations/ frequency), or when any of the sponsor details are changing (address, invoicing information)

Yes

No

Does the amendment require changes to study budgets?*

Budget amendments may be required, for example, when there are changes to the study visits (investigations/frequency), or when any of the sponsor details are changing (address, invoicing information).

Yes

No

Please provide a summary of site implications. ?

Related Ethics Amendment Form ID

Below the previous questions will be the document upload section. In this section you will need to add the Ethics Amendment ID number, which you can get from the Approval Letter.

Related Ethics Amendment Form ID

Select the Ethics amendment form ID from the below list to allow the research office to identify the submitted/approved ethics general amendment and supporting documents that already exist in the system. You can locate the ethics form ID from the approval email or the ETH project.

The form type, owner, status and submission date will appear once a selection is made and are provided to assist in confirming the correct form has been selected.

Form ID	Form Type	Owner	Status	Submission Date
42247	Notification of an amendment to a research study	Logan Lown	Approved	23/03/2021 5:26:46 AM

Site Specific Document Upload

Upload only site specific documents here e.g. site PISCF. If there are no site documents select the checkbox and then the minus icon.

Upload as a new version*	Title / Descriptor*	Document Filename*	Document Type	Version *	Date *	Upload File *
<input type="checkbox"/> <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/> <input type="button" value="Upload New"/>


Maximum file size is 20MB

Upload your Zip File containing the Ethics Approved documents and any Site Specific documents. Click 'No' for Uploading as a New Version. The Document type should be 'User Submitted Documents', Version Number 1, and the date is the date you are submitting the Site Amendment. The Title is the same title as the Zip File name, eg *Site Amendment – 25 March 2021*. Click next to move to the next page.

Form ID	Form type	Owner	Status	Submission Date
42247	Notification of an amendment to a research study	Logan Lown	Approved	23/03/2021 5:26:46 AM

Site Specific Document Upload

Upload only site specific documents here e.g. site PISCF. If there are no site documents select the checkbox and then the minus icon.

Upload as a new version*	Title / Descriptor*	Document Type	Version *	Date *	Upload File *
<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Site Amendme	User Submitted Documents	1	25/03/2021	 Upload New

Maximum file size is 20MB

+ - ⌵

Next

The Principal Investigator will need to press the Submit button, which will submit the Site Amendment to the SWSLHD Research Directorate. The Principal Investigator will receive an email advising them that the Site Amendment has been submitted. REGIS unfortunately does not consistently CC coordinators into these emails, however we will try to manually CC coordinators in when we can.

dment

Declaration

I declare that:

- I am the CPI/PI of this study
- The information provided is true and accurate.

Logan Lown

Thursday, 25 March 2021

Clicking the SUBMIT button below will submit your completed Amendment Notification form to the Site/s RGO/s for consideration.

Submit

Once the Site Amendment has been submitted, the Forms section of the SSA will show a new line entry for the Site Amendment, and the status will be 'Submitted'. At this stage there is no further action required as the Site Amendment will be reviewed by the SWSLHD Research Directorate.

2021/STE00207 - SITE AMENDMENT PRESENTATION

Project details are on this page.

Forms

Below are your forms. Click the link to open an existing form, use the 'new form' button below to start a new one.

[+ New form](#)

[Export CSV](#) Show entries

Search:

◆ Title	◆ Status	◆ Owner	◆ Created date	◆ Modified date	◆ Submitted date
⋮ 042253 - Site Amendment	● Submitted	Logan Lown	25/03/2021 09:32:07 AM	25/03/2021 10:03:59 AM	25/03/2021 10:03:58 AM

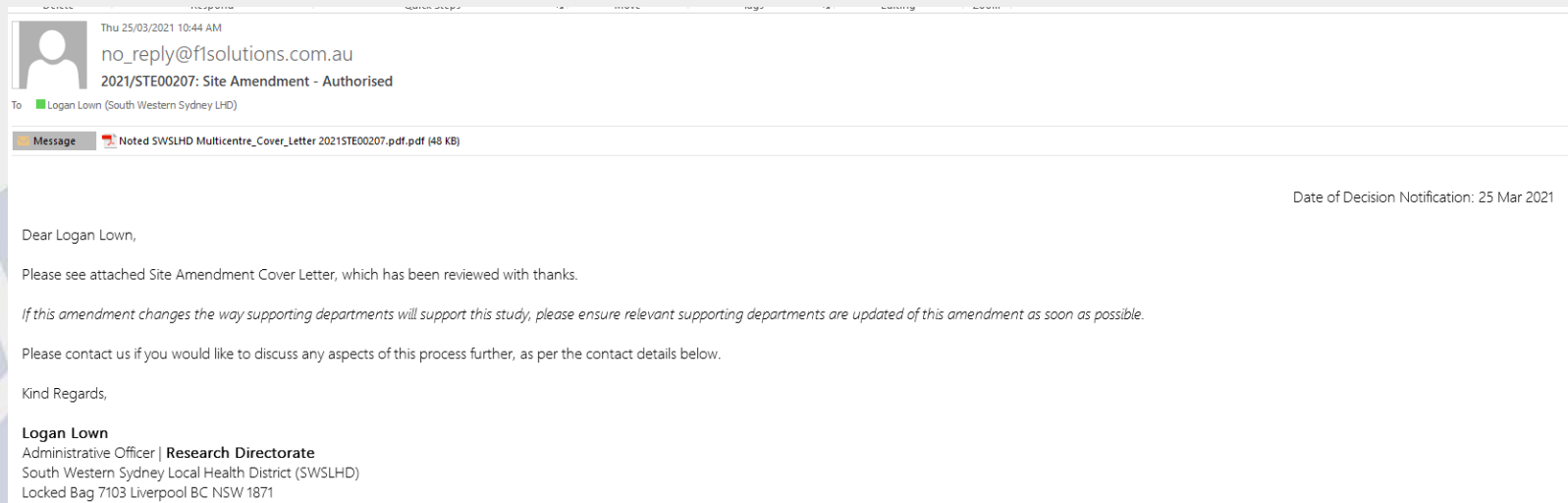
Showing 1 to 1 of 1 entries

[< Previous](#) **1** [Next >](#)



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Once the Site Amendment has been reviewed, if there are no further queries to be raised, the Principal Investigator will receive an RGO Approval Email. The email will have the Site Amendment Cover Letter attached to it, which will have been signed and dated.



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On the Forms page of the SSA, the status of the Site Amendment will change from 'Submitted' to 'Approved'. There will be no further action required from you once the status has changed to Approved.

Project details are on this page.

Forms

Below are your forms. Click the link to open an existing form, use the 'new form' button below to start a new one.

[+ New form](#)

[Download CSV](#)

Show entries

Search:

	◆ Title	◆ Status	◆ Owner	◆ Created date	◆ Modified date	◆ Submitted date
⋮	042253 - Site Amendment	● Approved	Logan Lown	25/03/2021 09:32:07 AM	25/03/2021 10:12:56 AM	25/03/2021 10:03:58 AM

Showing 1 to 1 of 1 entries

[< Previous](#) **1** [Next >](#)

[Use GOOGLE to search REGIS](#)

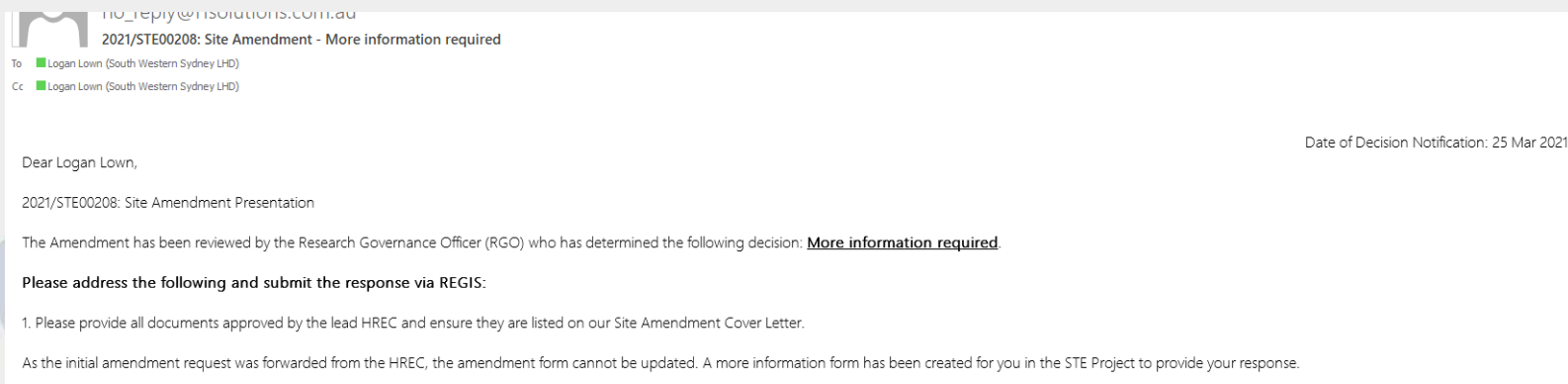
[Contact an ACT Research Office](#)

[Contact a NSW Research Office](#)



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Once the Site Amendment has been reviewed and if there are further queries to be raised, the Principal Investigator will receive an RGO More Information required Email.



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Now when you go into the SSA project information – forms section you will have a More Information Required form to be completed.

2021/STE00208 - SITE AMENDMENT PRESENTATION

Project details are on this page.

Forms

Below are your forms. Click the link to open an existing form, use the 'new form' button below to start a new one.

[+ New form](#)

[Export CSV](#) Show entries

Search:

◆ Title	◆ Status	◆ Owner	◆ Created date	◆ Modified date	◆ Submitted date
⋮ 042269 - Site Amendment	● Submitted	Logan Lown	25/03/2021 01:23:00 PM	25/03/2021 01:24:06 PM	25/03/2021 01:24:05 PM
⋮ 042272 - More Information Required - R...	● In Progress	Logan Lown	25/03/2021 01:27:57 PM	25/03/2021 01:27:57 PM	

Showing 1 to 2 of 2 entries

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You can respond to the further information queries in the table below if clarification is required – no response cover letter necessary. Alternatively there is also an upload document section.

More Information Required - RGO Approval

More Information Required

More Information Required

Preview

Save

Please provide the information required

Supporting document upload

Upload as New Version *

Version *

Date *

Upload File *

☐ Yes ☐ No

Upload New

Maximum file size is 20MB

+ - ↺

Submit

Upload relevant documents – ensuring any updated documents are submitted in tracked and clean with updated version number and dates.

Supporting document upload

Upload as New Version *	Document title/ Descriptor*	Document Type *	Version *	Date *	Upload File *
<div><div></div><div>Yes</div><div>✓ No</div></div>	Site Amendm	User Submitted Documents	2	25/03/2021	<div><div></div><div>Clear content selection (Site Amendment Further Information 1 25 March 2021.zip) [Open]</div><div>Maximum file size is 20MB</div></div>

Submit

Upon submission, the status of the 'More Information Required' form will change to submitted.

Forms

Below are your forms. Click the link to open an existing form, use the 'new form' button below to start a new one.

[+ New form](#)

[Export CSV](#) Show entries

Search:

	Title	Status	Owner	Created date	Modified date	Submitted date
	042269 - Site Amendment	Submitted	Logan Lown	25/03/2021 01:23:00 PM	25/03/2021 01:24:06 PM	25/03/2021 01:24:05 PM
	042272 - More Information Required - R...	Submitted	Logan Lown	25/03/2021 01:27:57 PM	25/03/2021 01:38:04 PM	25/03/2021 01:38:04 PM



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This 'More Information Required' form will subsequently change from 'In Progress' (in researchers hands) to 'Submitted' (in research office's hands) depending on the number of further information requested and received respectively until it has ultimately received Approval from the RGO.

Forms

Below are your forms. Click the link to open an existing form, use the 'new form' button below to start a new one.

[+ New form](#)

[Export CSV](#) Show entries

Search:

◆ Title	◆ Status	◆ Owner	◆ Created date	◆ Modified date	◆ Submitted date
⋮ 042269 - Site Amendment	● Approved	Logan Lown	25/03/2021 01:23:00 PM	25/03/2021 01:41:53 PM	25/03/2021 01:24:05 PM
⋮ 042272 - More Information Required - R...	● Approved	Logan Lown	25/03/2021 01:27:57 PM	25/03/2021 01:41:52 PM	25/03/2021 01:38:04 PM

Showing 1 to 2 of 2 entries

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Questions



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