

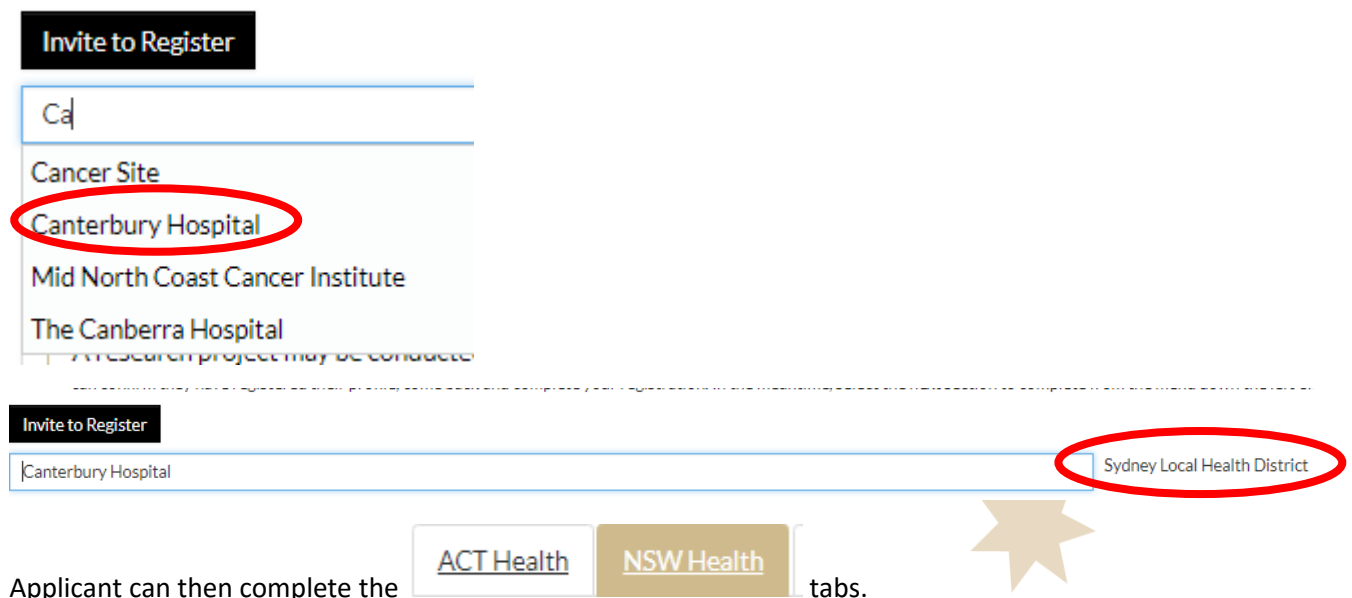
REGIS Operational Webinar (5 February 2019)

External Portal

Project Registration

Part C Research Site/s

A new cell to allow researchers to type in the site name to be given the Project Centre User starts typing in the site name and a searchable drop down field appears.



The screenshot shows the 'Invite to Register' form. A search input field contains 'Ca', and a dropdown menu is open, listing 'Cancer Site', 'Canterbury Hospital' (circled in red), 'Mid North Coast Cancer Institute', and 'The Canberra Hospital'. Below this, another search input field contains 'Canterbury Hospital', and a dropdown menu is open, listing 'Sydney Local Health District' (circled in red). Below the search fields are two tabs: 'ACT Health' and 'NSW Health'.

Applicant can then complete the [ACT Health](#) [NSW Health](#) tabs.

Part F Upload Attachments

The user now selects the Document Type (drop down), Descriptor (20 characters max), Document Version, Document Date.

F2 Document descriptor should be in the following format <short description of doc type>-<brief unique descriptor> (PISCF-Intervention, IB-DrugName)

E2 Other relevant documents, project-wide documents and others required for submission with HREA

This section has been included at Project Registration to ensure consistent naming of frequently required documents. All documents uploaded here will be automatically added to any subsequent ethics and/or site-specific application, as appropriate. For those registrations which require upload of a previously submitted ethics application - please ensure all attachments included with the original application are included in that upload. For projects that will be undertaken at NSW Health sites, site-specific documents are not required to be uploaded here - only project-wide, master documents. Site-specific documents will be requested when completing the relevant SSA.



The screenshot shows the document upload form. It has four main fields: 'Document type - please select from the list' (a dropdown menu), 'Document descriptor - your name for the file' (a text input field), 'Document version' (a text input field), and 'Document date' (a text input field). There is an 'Upload New' button and a note 'Maximum file size is 20.00 MB'.

There will be changes in the instruction text to encourage applicants to register ALL the documents they intend submitting with the ethics application now even if draft.

The Document descriptor, version and date will become the Document Title in the internal portal and the document title when downloaded by external users (HREC, Reviewers etc). The details will prefill the HREA in the standard format.

HREA

Upload

Documents that were uploaded during PR and available to update. They are displayed in Q4.2.2 based on how they were entered in at project registration and this is how they will appear in the approval letter.

The advantage to the applicant uploading at PR is that they will only need to change the version and date in the description when updating. Can update the document by clearing content and updating new document.

Attach any other relevant documents associated with conducting your research project.

- Ensure that you give meaningful and unique names to your files before uploading them. Also provide a meaningful description for each file at Q4.2.2.

Q4.2.1 Upload attachment*	Q4.2.2 Description of attachment*
<input type="checkbox"/> Clear content selection (IB_REGIS.doc) [Open]	IB-DrugName-1.5-01-FEB-2019
<input type="checkbox"/> Clear content selection (Master_PISCF_Interventional_REGIS.doc) [Open]	Investigation-7-04-FEB-2019
<input type="checkbox"/> Clear content selection (Master_PISCF_THIRD_REGIS.doc) [Open]	Carer-5-04-FEB-2019
<input type="checkbox"/> Clear content selection (smmse-tool-v2.pdf) [Open]	QUES-SMMSE-1-15-JUL-2003

Project Registration is no longer able to be deleted.



- Press the '+' button to add another row for additional documents to attach.
- Tick the grey box and press the '-' button to remove an attached document.
- Click and drag the grey bars to reorder the attached documents.

Q4.3 Attached Project Registration form.

[005685_Registration.pdf.zip] [\[Open\]](#)

Site Application

Part F

Mimics project registration

Document Title 2019/ETH00018	Document Type Ethics application (HREA or other)	Clear content selection (2019/ETH00018.zip) [Open]		
<input type="checkbox"/> Document Type *	Document Descriptor *	Document version *	Document date *	<input type="button" value="Upload New"/>
Maximum file size is 20.00 MB				

Internal Portal

Loading Page

Loading bar

Look and feel changes to loading page.



Loading...

Ethics Homepage

Status

Ethics homepages will be able to use the application status tiles to better track application movement

The screenshot shows a dashboard with a search bar at the top and a user profile on the right. The main content area is divided into several tiles:

- New ETH**: A table with columns 'Identifier' and 'Title'. It lists various research applications with their identifiers and titles.
- ETH Eligible**: A table with columns 'Identifier' and 'Title'. It lists applications that are eligible for review.
- Review submitted**: A tile indicating 'No data found'.
- RFI In**: A tile with a red border, containing a table with one entry: '2018/ETH-00104 - Ethics'.
- Approved - send out email/letter**: A table with columns 'Identifier' and 'Title'. It lists approved applications.
- New Amendment**: A list of amendment notifications with their identifiers and titles.
- Amnd RFI In**: A table with columns 'Identifier' and 'Title'. It lists amendment notifications that are eligible for review.
- Safety Reporting to HREC**: A tile indicating '2472 - Significant Safety Issue Notification'.
- Annual/Progress Report**: A table with columns 'Identifier', 'Milestone type', and 'Date received'. It lists progress reports.
- Task**: A table with columns 'Name' and 'Due date'. It lists tasks with their due dates and status indicators (exclamation marks).

Homepage

Start Icon

No more 'Start' Hamburger, now an infinity design.



Homepage Tiles

Tile Pagination in Table view

When Table view is the selection option for the homepage tile you will now see if there is more than one page of search items. List view remains the same.

Table View

Currently with HOD

Identifier	Title
2018/STE00118	Shishir - test project 15 july - test 5
2018/STE00145	Shishir - 15 Aug test project
2018/STE00146	Shishir - 15 Aug test project
2018/STE00144	Shishir - 15 Aug test project
2018/STE00149	Kylie Admin email testing
2018/STE00190	shishir - previous ethics - email test
2018/STE00195	PHNMA_16_001
2018/STE00230	Kylie's testing the email templates an...
2018/STE00267	Shishir 25 sep -test 1
2018/STE00299	Testing Document Management KB

« < 1 2 > »

List View

New STE App

2018/STE00014 - Site
2018/STE00032 - Site
2018/STE00075 - Site
2018/STE00080 - Site
2018/STE00133 - Site
2018/STE00143 - Site
2018/STE00154 - Site
2018/STE00260 - Site
2018/STE00236 - Site
2018/STE00294 - Site
2018/STE00342 - Site
2018/STE00351 - Site

Tile edit sort orders

User can now manage the order in which the applications/items appear in the tile

Sort by Date Modified or Identifier, Sort Ascending or Descending

Search by dashboard tile

Title	Currently with HOD
Template type	Table
Program	Site
Submitted only	No
Status	Completed pending HOD
With tags	
Without tags	
Classification	
Decision status	
Sort by	Date modified
Sort order	Ascending

Tags

System generated tag

Based off the applicant's response to Q4.5 in the HREA the system will create either the "Greater than low risk review pathway" or "Low risk review pathway" Tag.

If the applicant submits a new version with a different response the tag will change. However changing the tag will not change the response in the HREA.

2019/ETH00012 - Checking 2019/ETH00002 -

2019/PID00012
Tags **Greater than low risk review pathway**

2019/PID00003
Tags **Low risk review pathway**

Tags will remain on submission of a new version

If a RO adds a tag to an application/project it will remain on submission of a new version.

Related Documents

Document Format Icon

The document format icon appears to easily determine the format of the document.

<input type="checkbox"/>	Title ^
<input type="checkbox"/>	HREA
<input type="checkbox"/>	HREA
<input type="checkbox"/>	SSA
<input type="checkbox"/>	SSA
<input type="checkbox"/>	Submission_Original

Document Title includes version and date

Based off the entry at PR, HREA and/or Site application the Title will comprise of the Document Descriptor, Document Version and Document Date.

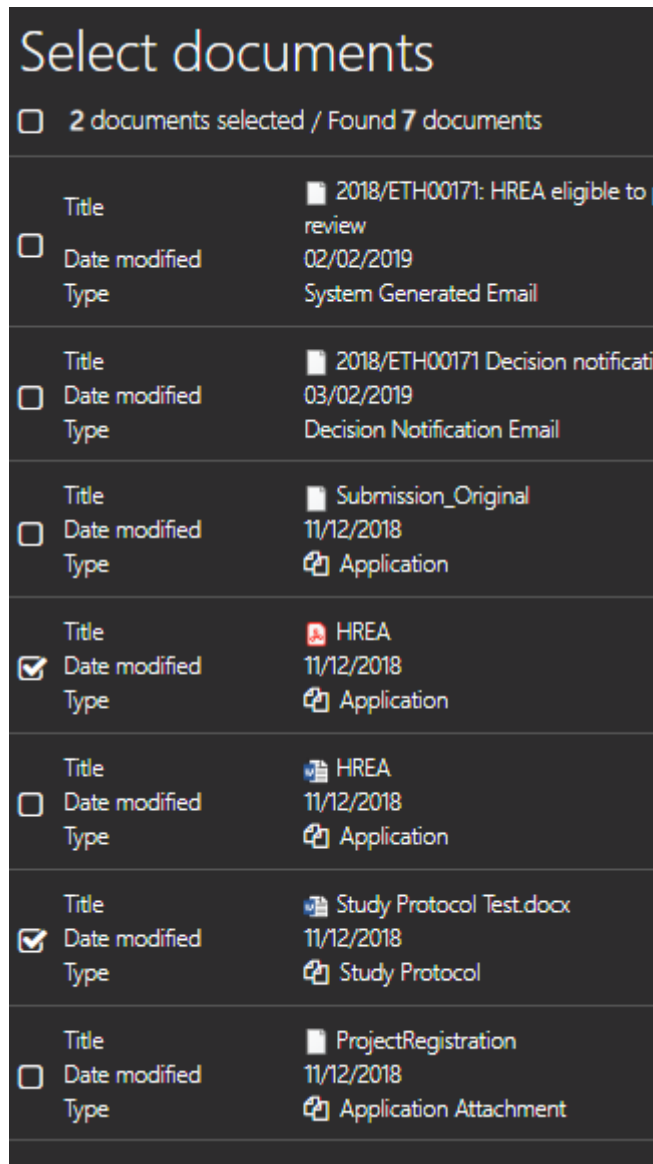
Version has been renamed to System Version.

<input type="checkbox"/>	Title ^	Filename	Size	External document type	System Version	Tags	Date modified	
<input type="checkbox"/>		IB-UATDRUG-13-30-JAN-2019	IB_REGIS.doc	95.5 KB	Investigator Brochure	4	(None)	30/01/2019

Meetings/Reviews

Document Management/Select Documents

The document format icon appears to easily distinguish between documents with the same title but different formats.



Select documents	
<input type="checkbox"/>	2 documents selected / Found 7 documents
<input type="checkbox"/>	Title: 2018/ETH00171: HREA eligible to review
<input type="checkbox"/>	Date modified: 02/02/2019
<input type="checkbox"/>	Type: System Generated Email
<input type="checkbox"/>	Title: 2018/ETH00171 Decision notificati
<input type="checkbox"/>	Date modified: 03/02/2019
<input type="checkbox"/>	Type: Decision Notification Email
<input type="checkbox"/>	Title: Submission_Original
<input type="checkbox"/>	Date modified: 11/12/2018
<input type="checkbox"/>	Type: Application
<input checked="" type="checkbox"/>	Title: HREA
<input checked="" type="checkbox"/>	Date modified: 11/12/2018
<input checked="" type="checkbox"/>	Type: Application
<input type="checkbox"/>	Title: HREA
<input type="checkbox"/>	Date modified: 11/12/2018
<input type="checkbox"/>	Type: Application
<input checked="" type="checkbox"/>	Title: Study Protocol Test.docx
<input checked="" type="checkbox"/>	Date modified: 11/12/2018
<input checked="" type="checkbox"/>	Type: Study Protocol
<input type="checkbox"/>	Title: ProjectRegistration
<input type="checkbox"/>	Date modified: 11/12/2018
<input type="checkbox"/>	Type: Application Attachment

Process Decision (approval/authorisation email)

Send Letter no longer an option

When an application has been approved/authorised and the RO is sending the decision notification communication (approval/authorisation email) the only option is send email.

Send letter was removed as the system requires the send email process to be completed to create the project (post approval folder) and is the stopping point for metrics.

Start 2019/ETH00006

Process decision Send email

Application identifier: 2019/ETH00004
 Owner: Kylie Becker
 Organisation: Northern Sydney Local Health District Human Research Ethics Committee

Document selection to appear in approval/authorising email

Research Office can delete any document they DON'T want to appear in the approval letter. These documents should also be automatically shared with other applications/projects (i.e. site applications.)

Application documents Found 22 items

<input type="checkbox"/>	<input type="checkbox"/>	Filename	Size	External document type	System version	Tags	Date modified	Modified by		
<input type="checkbox"/>	<input type="checkbox"/>	2019/ETH00004 v1 - v2 Changes	ETH00004 v1 - v2 Changes.pdf	170.4 KB	Change Tracking	1	17/01/2019	Becker, Kylie		
<input type="checkbox"/>	<input type="checkbox"/>	AD-MasterAdBrochure-1-2019-1-1	Master_Brochure_REGIS.docx	11.2 KB	Advertising Material	2	17/01/2019	Becker, Kylie		
<input type="checkbox"/>	<input type="checkbox"/>	AD-MasterAdBrochure-1-2019-1-1	Master_Brochure_REGIS.docx	11.2 KB	Advertising Material	2	18/01/2019	Becker, Kylie		
<input type="checkbox"/>	<input type="checkbox"/>	DATA-DataTool-1-2019-1-1	Data_Tool_Ljun18.docx	11.2 KB	Other: Please specify	2	17/01/2019	Becker, Kylie		
<input type="checkbox"/>	<input type="checkbox"/>	DATA-DataTool-1-2019-1-1	Data_Tool_Ljun18.docx	11.2 KB	Other: Please specify	2	18/01/2019	Becker, Kylie		
<input type="checkbox"/>	<input type="checkbox"/>	HREA	HREA.docx	57.6 KB	Application	2	17/01/2019	Becker, Kylie		
<input type="checkbox"/>	<input type="checkbox"/>	HREA	HREA.pdf	257.7 KB	Application	2	17/01/2019	Becker, Kylie		
<input type="checkbox"/>	<input type="checkbox"/>	IB-IRGchanges-1-2019-1-1	IB_REGIS.doc	326.0 KB	Investigator Brochure	2	17/01/2019	Becker, Kylie		
<input type="checkbox"/>	<input type="checkbox"/>	IB-IRGchanges-2-2019-1-18	IB_REGIS.doc	95.5 KB	Investigator Brochure	2	18/01/2019	Becker, Kylie		
<input type="checkbox"/>	<input type="checkbox"/>	KCTF_Protocol_REGIS.docx	KCTF_Protocol_REGIS.docx	65.2 KB	Study Protocol	2	17/01/2019	Becker, Kylie		
<input type="checkbox"/>	<input type="checkbox"/>	MOP-NewSite-1-2019-1-1	Methods of Payment - New submissions_int...	254.1 KB	Application Attachment	1	17/01/2019	Becker, Kylie		
<input type="checkbox"/>	<input type="checkbox"/>	MOP-NewSite-1-2019-1-1	Methods of Payment - New submissions_int...	254.1 KB	Application Attachment	2	18/01/2019	Becker, Kylie		
<input type="checkbox"/>	<input type="checkbox"/>	PISCF-Genetic-1-2019-1-1	Master_PISCF_GeneticTesting_REGIS.doc	91.5 KB	Participant Information Sheet	2	17/01/2019	Becker, Kylie		
<input type="checkbox"/>	<input type="checkbox"/>	PISCF-Genetic-1-2019-1-1	Master_PISCF_GeneticTesting_REGIS.doc	91.5 KB	Participant Information Sheet	2	18/01/2019	Becker, Kylie		
<input type="checkbox"/>	<input type="checkbox"/>	PISCF-Intervention-1-1-2019	Master_PISCF_interventional_REGIS.doc	96.5 KB	Participant Information Sheet	1	17/01/2019	Becker, Kylie		
<input type="checkbox"/>	<input type="checkbox"/>	PISCF-Intervention-2-1-2019	Master_PISCF_interventional_v1jun18.doc	96.5 KB	Participant Information Sheet	1	17/01/2019	Becker, Kylie		
<input type="checkbox"/>	<input type="checkbox"/>	PISCF-Intervention-2-1-2019	Master_PISCF_interventional_v1jun18.doc	96.5 KB	Participant Information Sheet	1	17/01/2019	Becker, Kylie		
<input type="checkbox"/>	<input type="checkbox"/>	PISCF-Intervention-2-1-1-2019	Master_PISCF_interventional_REGIS.doc	96.5 KB	Participant Information Sheet	1	18/01/2019	Becker, Kylie		
<input type="checkbox"/>	<input type="checkbox"/>	ProjectRegistration	004658_Registration.pdfzip	73.4 KB	Application Attachment	2	17/01/2019	Becker, Kylie		
<input type="checkbox"/>	<input type="checkbox"/>	QUEST-SSME-1-2019-1-1	smmse-tool-v2.pdf	32.6 KB	Questionnaire	2	17/01/2019	Becker, Kylie		
<input type="checkbox"/>	<input type="checkbox"/>	QUEST-SSME-1-2019-1-1	smmse-tool-v2.pdf	32.6 KB	Questionnaire	2	18/01/2019	Becker, Kylie		
<input type="checkbox"/>	<input type="checkbox"/>	Submission_Original	Submission_Original.xml	5.2 KB	Application	2	17/01/2019	Becker, Kylie		

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