

REGIS Operational Webinar (Tuesday 22 January)

Known Bugs

No known new or outstanding bugs.

All new applications in REGIS

What is a new application?

New Ethic applications where the HREC is from NSW/ACT

New Site applications where the HREC is from a NMA jurisdiction (VIC, QLD, SA, WA)

What is NOT a new application?

A Site application where the NSW/ACT Ethics approval was completed in AU RED.

In this scenario the Site Application HAS to be completed in Online Forms/AU RED.

Why can't applications straddle the two platforms?

Data migration - There is no way to merge an application in REGIS with an application that will be data migrated. There are a number of system processes that will not occur.

What if a Site application is submitted across the two platforms?

We are placing announcements on both of the log in portals instructing researchers on what to do.



The image is a composite of three parts. On the left is a screenshot of the REGIS login page with fields for Username (kyllie.becker@health.nsw.gov.au) and Password. In the center is a text box for technical support: 'For technical support, call the REGIS Help Desk: 1300 073 447. The REGIS Help Desk is open Monday to Friday from 7 am to 7 pm (excluding public holidays) to assist with technical issues. If you have questions about your research project or application, please contact your local research office.' On the right is a 'USER LOGIN' form with fields for email and password, a 'Login' button, and links for 'CAN'T ACCESS YOUR ACCOUNT?' (Reset your password) and 'DON'T HAVE AN ACCOUNT YET?' (Register).

It is recommended that the approval letter or email include details of where to submit the site application if it hasn't already been submitted.

What if an applicant doesn't submit a site application before data migration?

If the Ethics application was approved in AU RED but the applicant hasn't started the Site application prior to Data Migration (1 March) the applicant will have to use the Ethics amendment process in REGIS to create the new site. It is not anticipated that the HREC would have to review these applications but this is the only technical mechanism to create the new Site application in REGIS.

It is recommended that the Research Office stops accepting AU RED applications after their March closing date, earlier if possible.

Formal guidance from the REGIS team will be released this week.

Research Offices using Helpdesk

Using phone number v email

Research Offices use the helpdesk phone number 1300 073 447 (1300 0 REGIS) when something is stopping you from doing your job.

The email address (support@f1solutions.com.au) should only be used for general or non-urgent support calls. Emails are taking approximately 3-4 days to get a response.

Generic email accounts in REGIS

Question/Scenario

“We have a query from the XX Department Clinical Trial Co-ordinators who are setting up their REGIS account.

They are wondering if they can set up their REGIS account with a generic department email instead of individual emails for each clinical trial co-ordinator.

If they have one email account registered to REGIS will this cause any issues down the track?

When they used Online Forms they only had the one account which was registered under the generic department email.”

Response 1

The only user accounts we’ve mandated cannot use generic/group emails are Research Office Staff and Heads of Department. Our preference is that they are not used by other user accounts either.

The key reason for this is the need for an individual to be accountable for the actions linked to their user account, while in the main the CTCs may not be named as PIs or CPIs responsible for submission of an application, it is possible that they might be named as administrative contacts or have other roles on the project. If a generic account is used by a number of people, who will be responsible for it?

At this point in time, we have no way to prevent it, but we would advise against it.

Response 2

Team members should have their own individual account that they are able to log into and manage BUT they make the preferred email can be the generic email address. This could be used for CPI’s/PI’s, HOD’s, Trial Teams and Sponsors.

This is the preferred option. The QRG [Creating and managing your REGIS Account](#)

60-day system withdrawal of ineligible applications

When an application is marked as Ineligible the applicant has 60 days to provide a response to the research office otherwise the application is ‘Withdrawn’.

What does this mean for the Research Office?

This application will not be counted in metrics.

What does this mean for the Applicant?

The applicant receives a notification at 29 days reminding them of the ineligible application.

From	no_reply@regis.health.nsw.gov.au
To	\$(ApplicationPrincipalInvestigatorEmail); SinclairPavel@example.com
Reply To	
Cc	EulaMcLune@example.com; \$(ApplicationAdministrationEmail);
Bcc	
Subject	Application identifier: SSA Ineligible 21 Days - 39 Days to Reply
Body	<p>Dear Sinclair Pavel,</p> <p>Thank you for submitting the following SSA for review; Application identifier: Application title</p> <p>The application was assessed to determine whether it could progress to review and was deemed <u>ineligible</u>. The application has now been pending re-submission for 21 Days.</p> <p>The reasons for this are as follows: Feedback comment will appear here.</p> <p>Please address the above criteria, then resubmit your application.</p> <p>How to resubmit the application in REGIS: Please refer to the quick reference guide for 'Resubmitting an application after an ineligible notification.'</p> <p>Following re-submission the application will be re-assessed to determine whether it can progress to review If the application is not resubmitted in 39 days (60 days from original notification) the application will be deemed withdrawn in REGIS and will require re-submission. You will be able to track the progress of your application via updates to its status in REGIS. Please click http://example.com or visit \$(ApplicationUri) to access this. Please do not hesitate to contact us on the details below if you have any questions.</p> <p>Regards,</p>

If the application has not been resubmitted at 60 days the applicant will receive the following notification email.

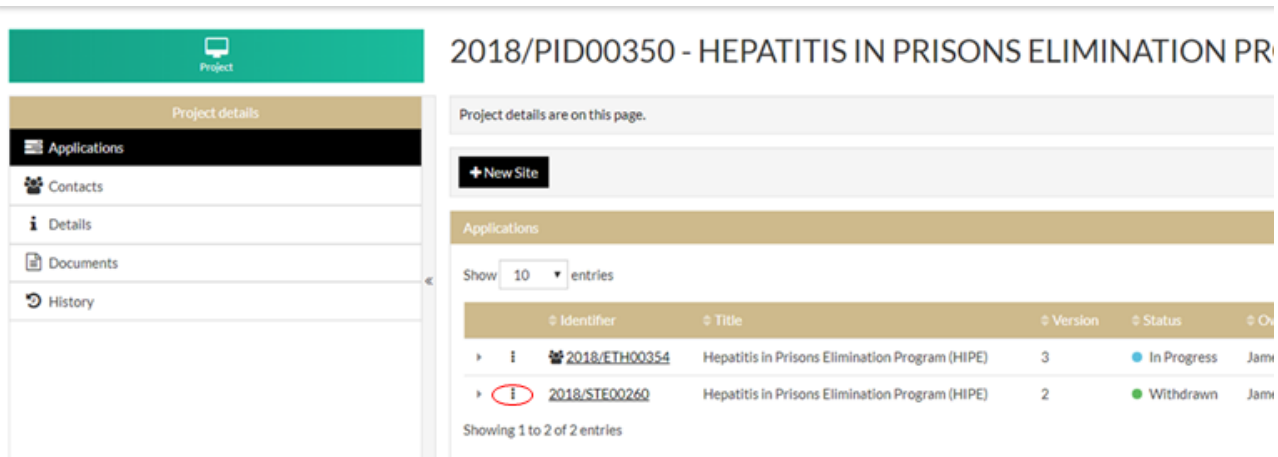
From	no_reply@regis.health.nsw.gov.au
To	\$(PrincipalInvestigatorEmail); SinclairPavel@example.com
Reply To	
Cc	EulaMcLune@example.com; \$(ApplicationAdministrationEmail)
Bcc	
Subject	Application identifier: SSA Ineligibility 60 Days - Application Withdrawn
Body	<p>Dear \$(PrincipalInvestigatorName),</p> <p>Thank you for submitting the following application for governance review; Application identifier: Application title</p> <p>The application was assessed to determine whether it could progress to review and unfortunately was deemed <u>ineligible</u>. A re-submission of this application has now been pending for 60 Days.</p> <p>The status of the application will now be deemed Withdrawn in REGIS and will require resubmission should you wish the application to be assessed.</p> <p>Please do not hesitate to contact us on the details below if you have any questions regarding this process.</p> <p>Please click http://example.com or visit \$(ApplicationUri) to access this.</p> <p>Regards,</p>

The system will set the application to 'Withdrawn'.

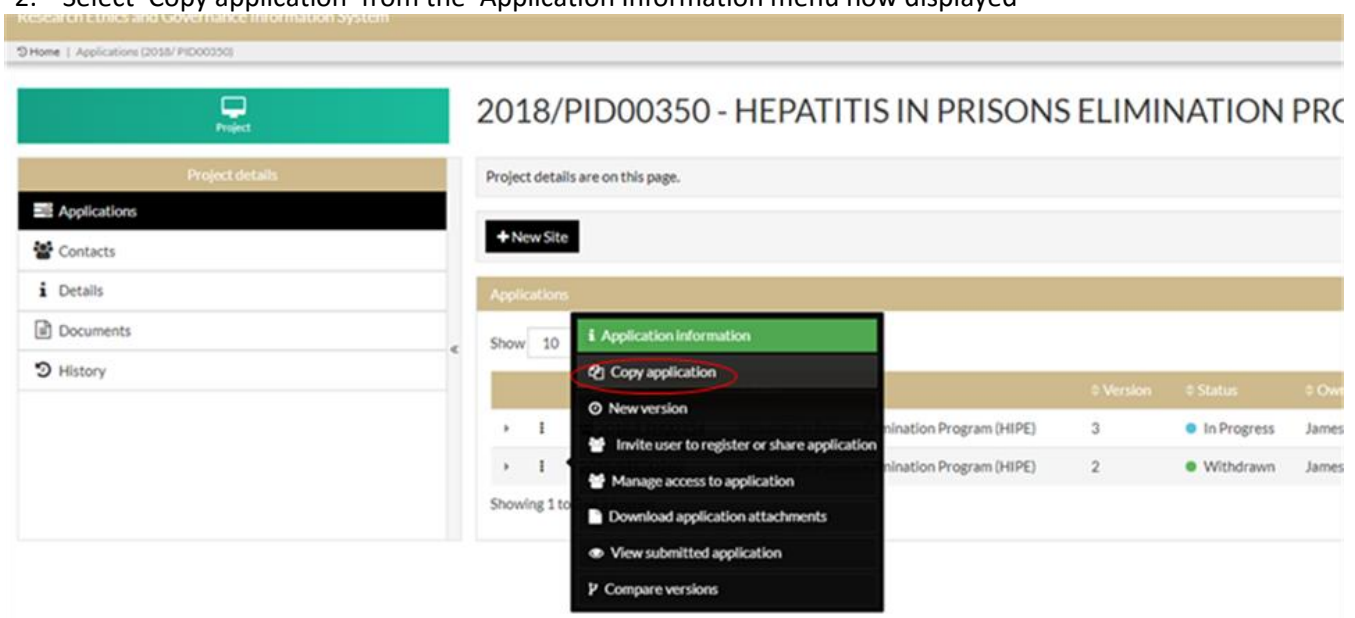
When this occurs, the application is not lost – but rather the status changes to 'Withdrawn' and the applicant will no longer receive reminders to respond to the request.

When the applicant is ready to update the application with the requested detail/documentation they will need to 'Copy' the withdrawn application using the following steps...

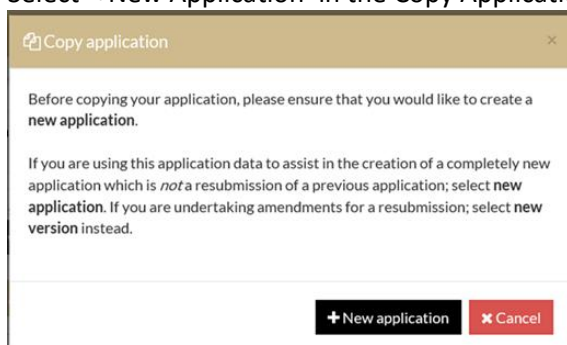
1. Open the Registered project to view the list of applications and select the three vertical dots to the left of the Identifier (201x/STExxxx) – circled below in red:



2. Select 'Copy application' from the 'Application Information' menu now displayed



3. Select '+New Application' in the Copy Application dialogue box:



4. Check the application title and enter comments e.g. 'Copy of application withdrawn at 60d'. Select '+new application' to generate a copy of the withdrawn application which will include all previously entered information and attachments.

Copy application

You are about to copy the selected application. If you would like to continue, click the 'new application' button below. Please provide the new name below.

Application title

Just checking - Copy of 2018/STE05571

Application comments

Back
New application
Cancel

A new Identifier will be assigned to the application (201x/STEXXXXX) and its status will be 'in-progress'.

The applicant can now follow the Quick Reference Guides for Site Specific Application Part 1 and Part 2.

The new submission will required HOD support.

Homepage

Basic Setup ETH (post 1.7/18 release)

Start
Search...

?
kyle.becker@health.nsw.gov.au

Home

New ETH

Identifier	Title
2018/ETH-00069	Nick Test 2 - New Title
2018/ETH-00105	New version of ineligible application
2018/ETH-00159	Leanne - Dietetics Test2
2018/ETH-00160	dgdfg
2018/ETH-00164	PH - Sponsor Organisation Fix Test - ...
2018/ETH-00166	PH - Sponsor Organisation Fix Test - ...
2018/ETH-00170	PH Regression 1.7 - Clinical Trial - 01
2018/ETH-00171	PH Regression 1.7 - 02
2018/ETH-00169	Kylie testing updated email template...
2019/ETH-00003	Document Naming

ETH Eligible

Identifier	Title
2018/ETH00158	Leanne - Dietetics test
2018/ETH00167	PR test

Review submitted

No data found

RFI In

2018/ETH00104 - Ethics

Approved - send out email/letter

2018/ETH00042 - Ethics
2018/ETH00103 - Ethics
2018/ETH00123 - Ethics
2018/ETH00137 - Ethics
2019/ETH00004 - Ethics

New Amendment

1099 - Notification of an amendment to a research
1112 - Notification of an amendment to a research
1113 - Notification of an amendment to a research
2171 - Notification of an amendment to a research
2161 - Notification of an amendment to a research
2269 - Notification of an amendment to a research
2273 - Notification of an amendment to a research
2270 - Notification of an amendment to a research
2289 - Notification of an amendment to a research
an amendment to a research
an amendment to a research

Amnd RFI In

Identifier	Title
001099	Notification of an amendment to a r...
001112	Notification of an amendment to a r...
001113	Notification of an amendment to a r...
002171	Notification of an amendment to a r...
002161	Notification of an amendment to a r...
002270	Notification of an amendment to a r...
002369	Notification of an amendment to a r...
002390	Notification of an amendment to a r...
002392	Notification of an amendment to a r...
002393	Notification of an amendment to a r...

Safety Reporting to HREC

2472 - Significant Safety Issue Notification

Annual/Progress Report

Identifier	Milestone type	Date received
2018/ETH00035	Progress Report	2018-09-13

Task

Name	Due date
Eligibility Appr...	2018-09-05
Eligibility Appr...	2018-09-15
Eligibility Appr...	2018-09-20
Eligibility Appr...	2018-10-31
Eligibility Appr...	2018-10-31
Eligibility Appr...	2018-11-02
Eligibility Appr...	2018-12-01
Eligibility Appr...	2018-12-01

Basic Setup STE

Home

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	Kyiles testing the email templates an...
2018/STE00267	Shishir 25 sep -test 1
2018/STE00299	Testing Document Management KB
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HOD done - Pending PI Submit

Identifier	Title
2018/STE00065	HREC TEST for NEW SSA
2018/STE00077	Electronic filename
2018/STE00086	shishir - test project 20July - test 1
2018/STE00101	Shishir - 23July - test 3
2018/STE00102	Shishir - Approved ethics test SSA
2018/STE00087	shishir - test project 20July - test 1
2018/STE00135	Kyiles testing the email templates an...
2018/STE00138	Testing Valid when status in moved t...
2018/STE00147	Shishir - 15 Aug test project
2018/STE00158	PH Regression Version 1_6 004
<div><div><<</div><div><</div><div>1</div><div>2</div><div>3</div><div>></div><div>>></div></div>	

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

Valid (pending ethics)

Identifier	Title
2018/STE00339	PH Regression 1.6 - 020
2018/STE00340	PH Regression 1.6 - 020

Eligible

Identifier	Title
2018/STE00010	Kylie Admin email testing
2018/STE00013	Cup of Tea
2018/STE00016	Shishir New project title 0406
2018/STE00027	shishir project for testing 0706
2018/STE00050	B1 Project Title
2018/STE00082	NMA Study - Functionality Review
2018/STE00108	Shishir - Site and ethics together test...
2018/STE00111	Release 1.5 - Full Regression Multi St...
2018/STE00119	Shishir - test project 15 July - test 5
2018/STE00114	Release 1.5 - Full Regression Multi St...
<div><div><<</div><div><</div><div>1</div><div>2</div><div>3</div><div>></div><div>>></div></div>	

Response In

Identifier	Title
2018/STE00117	Shishir - test project 15 July - test 5
2018/STE00120	Shishir - test project 15 July - test 5
2018/STE00150	.
2018/STE00164	shishir 20 aug - test 6
2018/STE00183	Shishir 27 aug test 3
2018/STE00148	Shishir - 15 Aug test project - resub
2018/STE00207	PH Regression 1_6 006
2018/STE00129	1.5 Full Regression 002
2018/STE00130	1.5 Full Regression 002
<div>This page can be edited.</div> <div>SaveAdd<div><div><<</div><div><</div><div>1</div><div>2</div><div>></div><div>>></div></div></div>	

Auth pending email

Identifier	Title
2018/STE00076	Electronic filename
2018/STE00085	Metrics/Reports Meeting with Hilal
2018/STE00092	Application001TD

Task

Name	Due date
Eligibility Appr...	2018-09-05
Eligibility Appr...	2018-09-15
Eligibility Appr...	2018-09-20
Eligibility Appr...	2018-10-31
Eligibility Appr...	2018-10-31
Eligibility Appr...	2018-11-02
Eligibility Appr...	2018-12-01
Eligibility Appr...	2018-12-01

See QRG: Setting up a Home Page (update pending) and REGIS User Manual Homepage tile (update pending)

Office Specific Setups

SCHN Ethics

<p>Home</p> <p>New Application</p> <p>No data found.</p>	<p>Information Provided</p> <p>No data found.</p>	<p>SAC and / or HREC</p> <p>No data found.</p>	<p>Executive Committee</p> <p>2018/ETH00690 - Ethics</p>
<p>Executive Officer</p> <p>2018/ETH00556 - Ethics</p> <p>2018/ETH00628 - Ethics</p>	<p>Out of Session</p> <p>No data found.</p>	<p>Invalid Applications</p> <p>2018/ETH00560 - Ethics</p> <p>2018/ETH00637 - Ethics</p> <p>2018/ETH00650 - Ethics</p> <p>2018/ETH00677 - Ethics</p> <p>2018/ETH00699 - Ethics</p> <p>2019/ETH00008 - Ethics</p> <p>2019/ETH00022 - Ethics</p> <p>2019/ETH00048 - Ethics</p> <p>2019/ETH00055 - Ethics</p>	

SCHN Gov

Home

New Application 2018/STE00500 - Site	Pending submission 2018/STE00403 - Site 2018/STE00417 - Site 2018/STE00422 - Site 2018/STE00425 - Site 2018/STE00428 - Site 2018/STE00429 - Site 2018/STE00431 - Site 2018/STE00440 - Site 2018/STE00470 - Site	Ineligible No data found.	Jessa New Applications No data found.
Recall back with researcher No data found.	Information Provided 2018/STE00440 - Site 2018/STE00483 - Site	Eligible No data found.	Authorised 2018/STE00470 - Site 2018/STE00471 - Site
Completed pending HOD 2018/STE00403 - Site 2018/STE00431 - Site			

SESLHD Ethics

Home

New Applications (Submitted Only)

Identifier	Title
2018/ETH00487	Assessing residual cone function in R...
2018/ETH00552	Reasons for patients with persistent ...
2018/ETH00589	Sexual health consumers' use of Dr ...
2019/ETH00045	Exploring patients' concerns around ...
2019/ETH00086	An audit of coding accuracy and fun...

Application

Identifier	Title
2018/ETH00063	Developing a deep learning based ...
2018/ETH00080	Emergency Nurse Practitioner Ultra...
2018/ETH00089	Radiotherapeutic outcomes in pleu...
2018/ETH00138	Tumour infiltrating lymphocytes in t...
2018/ETH00151	An analysis of outcomes following ...
2018/ETH00178	CLINICAL CHARACTERISTICS AND ...
2018/ETH00179	A program of universal blood-born...
2018/ETH00187	An observational study of periper...

Applications Eligible

Identifier	Title
2018/ETH00487	Assessing residual cone function in R...
2018/ETH00552	Reasons for patients with persistent ...
2018/ETH00589	Sexual health consumers' use of Dr ...
2019/ETH00045	Exploring patients' concerns around ...
2019/ETH00086	An audit of coding accuracy and fun...

Assigned to meeting

Identifier	Title
2018/ETH00474	Mobile Phones in Youth Mental Heal...
2018/ETH00476	General Practitioners' (GP) perspect...
2018/ETH00529	Ambulance Use of Patients with Acut...
2018/ETH00577	Arteriovenous Fistula Maturation an...
2018/ETH00665	Retrospective analysis of a Bi-Nation...
2018/ETH00684	Trends in Carotid Revascularisation P...
2019/ETH00041	OUTCOMES OF NEOADJUVANT TH...

Forms

42 - Project Registration
93 - Project Registration
205 - Project Registration
247 - Project Registration
283 - Project Registration
296 - Project Registration
309 - Project Registration
318 - Project Registration
324 - Project Registration

Applications back with researcher

2018/ETH00127 - Ethics
2018/ETH00401 - Ethics
2018/ETH00404 - Ethics
2018/ETH00535 - Ethics
2018/ETH00591 - Ethics
2018/ETH00630 - Ethics
2018/ETH00657 - Ethics
2018/ETH00669 - Ethics
2018/ETH00727 - Ethics

Approval pending email

No data found.

Approved

2018/ETH00063 - Ethics
2018/ETH00080 - Ethics
2018/ETH00089 - Ethics
2018/ETH00138 - Ethics
2018/ETH00178 - Ethics
2018/ETH00187 - Ethics
2018/ETH00219 - Ethics
2018/ETH00255 - Ethics
2018/ETH00264 - Ethics

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Application (EO Review)

Identifier	Title
2018/ETH00484	Retrospective Review of Outcomes I...
2018/ETH00492	A retrospective analysis of the SHALT...

SESLHD Gov

Home

SSA- Submitted

Identifier	Title
2018/STE00525	Evaluation of project: Increasing cerv...
2018/STE00526	Evaluation of project: Increasing cerv...
2019/STE00001	'GenFact': The psychosocial impact o...

For RGO review - Valid and Eligible

Identifier	Title
2018/STE00504	A social practice approach to improv...

Information requested

No data found.

Researcher's response

No data found.

Forms - Amendments

Identifier	Title
3661	Notification of an amendment to a r...
3941	Notification of an amendment to a r...

With Researcher

Identifier	Title
2018/STE00187	Von Willebrand Factor/Factor VIII co...
2018/STE00245	Outcomes of rehabilitation of patient...
2018/STE00288	Length of stay patterns in elderly pat...
2018/STE00361	Assessing residual cone function in R...
2018/STE00399	Retrospective Review of Outcomes I...
2018/STE00439	Oral Intake at the End of Life: Deter...

Submission Pending - with HOD

2018/STE00183 - Site
2018/STE00267 - Site
2018/STE00308 - Site
2018/STE00326 - Site
2018/STE00378 - Site
2018/STE00409 - Site
2018/STE00426 - Site
2018/STE00433 - Site
2018/STE00434 - Site

Approved

2018/STE00037 - Site
2018/STE00044 - Site
2018/STE00063 - Site
2018/STE00108 - Site
2018/STE00124 - Site
2018/STE00135 - Site
2018/STE00174 - Site
2018/STE00177 - Site
2018/STE00222 - Site

Withdrawn

Identifier	Title
2018/STE00107	Tumour infiltrating lymphocytes in tri...

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HNELHD

Home

New Amendments

3429 - Notification of an amendment to a research
3689 - Notification of an amendment to a research
3711 - Notification of an amendment to a research
3779 - Notification of an amendment to a research
3880 - Notification of an amendment to a research

Full HREC Applications - Assigned to ...

2018/ETH00548 - Ethics

SSA's (with HOD)

2018/STE00052 - Site
2018/STE00053 - Site
2018/STE00085 - Site
2018/STE00110 - Site
2018/STE00157 - Site
2018/STE00160 - Site
2018/STE00294 - Site
2018/STE00327 - Site
2018/STE00328 - Site

SSA (signed off by HOD, but not Subm...

2018/STE00203 - Site
2018/STE00496 - Site
2018/STE00536 - Site
2018/STE00571 - Site

SSA Submitted to RGO

2018/STE00030 - Site
2018/STE00169 - Site
2018/STE00257 - Site
2018/STE00331 - Site
2018/STE00334 - Site
2018/STE00342 - Site
2018/STE00345 - Site
2018/STE00396 - Site
2018/STE00398 - Site

SSA with CE

2018/STE00030 - Site
2018/STE00169 - Site
2018/STE00257 - Site
2018/STE00331 - Site
2018/STE00334 - Site
2018/STE00342 - Site
2018/STE00345 - Site
2018/STE00396 - Site
2018/STE00398 - Site

Authorisation Pending

No data found.

SSA's - Authorised

2018/STE00005 - Site
2018/STE00007 - Site
2018/STE00008 - Site
2018/STE00010 - Site
2018/STE00011 - Site
2018/STE00012 - Site
2018/STE00013 - Site
2018/STE00014 - Site
2018/STE00015 - Site

Eligible - LNR Applications

2018/ETH00662 - Ethics
2018/ETH00686 - Ethics
2019/ETH00027 - Ethics

LNR Applications - Under Review

2018/ETH00317 - Ethics
2018/ETH00410 - Ethics
2018/ETH00411 - Ethics
2018/ETH00544 - Ethics
2018/ETH00547 - Ethics
2018/ETH00580 - Ethics
2018/ETH00644 - Ethics
2018/ETH00646 - Ethics
2018/ETH00662 - Ethics

LNR Applications - Response to More I...

2018/ETH00662 - Ethics
2018/ETH00686 - Ethics
2019/ETH00027 - Ethics

LNR Applications - More Information R...

2018/ETH00027 - Ethics
2018/ETH00050 - Ethics
2018/ETH00113 - Ethics
2018/ETH00180 - Ethics
2018/ETH00232 - Ethics
2018/ETH00238 - Ethics
2018/ETH00265 - Ethics
2018/ETH00270 - Ethics
2018/ETH00316 - Ethics

LNR Applications - Approved

2018/ETH00002 - Ethics
2018/ETH00003 - Ethics
2018/ETH00004 - Ethics
2018/ETH00006 - Ethics
2018/ETH00008 - Ethics
2018/ETH00010 - Ethics
2018/ETH00013 - Ethics
2018/ETH00015 - Ethics
2018/ETH00016 - Ethics

Eligible - Full HREC Applications

2018/ETH00342 - Ethics

Full HREC - More Information Request...

2018/ETH00113 - Ethics
2018/ETH00232 - Ethics
2018/ETH00238 - Ethics
2018/ETH00265 - Ethics
2018/ETH00316 - Ethics
2018/ETH00471 - Ethics
2018/ETH00519 - Ethics
2018/ETH00521 - Ethics
2018/ETH00573 - Ethics

Full HREC - Response to More Informa...

2018/ETH00365 - Ethics
2018/ETH00490 - Ethics
2018/ETH00543 - Ethics
2018/ETH00602 - Ethics
2018/ETH00641 - Ethics

Full HREC Applications - Approved

2018/ETH00013 - Ethics
2018/ETH00075 - Ethics
2018/ETH00114 - Ethics
2018/ETH00196 - Ethics
2018/ETH00228 - Ethics
2018/ETH00286 - Ethics
2018/ETH00287 - Ethics

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Approvals Pending

No data found.

Amendment (Response to Request for...

No data found.

New Ethics Applications

2018/ETH00317 - Ethics
2018/ETH00365 - Ethics
2018/ETH00410 - Ethics
2018/ETH00490 - Ethics
2018/ETH00543 - Ethics
2018/ETH00544 - Ethics
2018/ETH00547 - Ethics
2018/ETH00580 - Ethics
2018/ETH00602 - Ethics