

Hi All,

Welcome to issue 17 of the REGU/REGIS newsletter!

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## LNR NMA

Low and negligible risk research projects will now be accepted under the National Mutual Acceptance (NMA) scheme if the project has been ethically reviewed using a non-HREC level of review described in the *National Statement*, with the exception of South Australia.

At its August meeting, the National Mutual Acceptance Working Group agreed to simplify the application process for multijurisdictional LNR research. Previously, LNR research has been accepted under the NMA Scheme if it has been reviewed by a full HREC.

The attached NMA LNR Policy position (describing the South Australian exception in more detail) and Guidelines (soon to be incorporated as an official NSW policy Guideline) will be posted on the OHMR website under the NMA tab soon. The NMA SOPs and Fact Sheet will be updated.

Please contact MOH-ResearchEthics [MOH-ResearchEthics@health.nsw.gov.au](mailto:MOH-ResearchEthics@health.nsw.gov.au) with any queries.

## Case Study – Homepage – Applications not appearing

**Problem:** A Research Office reported that one of their team members was not seeing applications in their homepage tile. This team member was wanting to see Site applications that were in the status of Eligible and had been tagged with their name.

Edit dashboard tile	
Title	New SSA tile
Display	Title
Program	Site
Submission type	Site Application
Submitted only	No
Status	Eligible
With tags	My name
Without tags	
Classification	
Decision status	
Sort order	Ascending
Sort by	Date modified
Unassigned only	No

**Troubleshooting the problem:** Look into the filtering for the problem tile

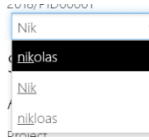
**There are two areas that raise flags with the REGIS team.**

1. Tags
2. Submission type (spoiler alert it was the submission type)

**Solution:** A minor tweak to the tile to remove the Submission type filter fixed the issue.

For those that are interested in the long version

## Tags



Tags are a useful tool to create a visual flag for an application, project, document or form. Offices have created multiple similar tags system and if the incorrect tag is used the tile will not filter. It is recommended that Research Offices adopt using role tags rather than name tags.

e.g. If Nik moves on and someone else comes into the role all tiles, applications, projects, documents and forms using Nik will have to be updated and the Nik tag may become obsolete. Using a role tag e.g. EO1, would allow the new person to seamlessly integrate into the established Research Office processes without having to make updates.

*Have you created a tag with a spelling mistake?* Please let the REGIS team know so we can delete it from the system. Tags are system wide and another office can unknowingly start using this tag.

## Submission type

As part of the Omni 4.9 upgrade in 2020 an additional application tile filter was introduced “Initial Application” and “Application Resubmission”.

In the homepage tile example above the tile was set up to filter only “Initial Application” however the applications that were not appearing were resubmissions.

2021/STE02722 - Cross correlation study: Implementation of a “Fast pharmacology” approach in Therapeutic Drug Monitoring by L... Eligible Site

2021/PID01991 ETH Approved WfDone Nik

Summary

Application

Title Cross correlation study: Implementation of a “Fast pharmacology” approach in Therapeutic Drug Monitoring by LC-MIS/MIS

Short title

System version Submitted 1.01 - Application Resubmission

Stage Site

Owner Kocic, Danjela (danjela.kocic@svha.org.au)

Editors (None)

Viewers (None)

Principal organisation St Vincent's Health Sydney

Coordinating Principal Investigator Danjela Kocic

Approval date

Expiry date 21/07/2026

Application identifier 2021/STE02722 CP

Submitted date 30/07/2021

Responsible users

All activities

No date (1)

## Updated guidance in forms related to the document upload section

**Audience:** Research Office/Researcher

The most accessed forms that have a document upload section will have a warning notification. This will remain on the forms for 8 weeks.

**i** This section has had a major change please read the on page instructions. You may also like to watch this [short video](#).

**Project Registration:** based of a response in part a of the project registration the system will identify if Ethics is in REGIS (NSW/ACT HREC) or external to REGIS (SA/QLD/VIC/WA) and will provide the specific guidance for document uploading.

Shown for all applications

**FOR ALL REGISTRATIONS**

- **Maximum** document size is 20MB (larger documents can be converted to a .zip)
- **Total upload** can not exceed 95MB. If your application exceeds this limit consider converting files to .zip or contact the research office managing the application for alternate document submission process.
- **Uploading** the same document multiple times e.g. Protocol at F1 and F2 may cause the system to crash.

Shown when Ethics is in REGIS (NSW/ACT HREC)

For those registrations which will submit to a NSW/ACT HREC

- **REGISTER ANY** document you intend to submit to the HREC. You can upload a draft document, documents can be updated, added and removed when completing the HREA.
- The details entered at **Type** and **Document Descriptor** is what will appear on the approval email.
  - **Type** = select option from the dropdown menu
  - **Document Descriptor** = list here exactly as you would like 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.

*For example, if type were selected as "Participant Information Sheet" and document descriptor is entered as "Arm 1 Master version 1 dated 22 June 2021" the system generated approval email (decision notification email) will display **Participant Information Sheet – Arm 1 Master version 1 dated 22 June 2021***

- 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 site application form.

Shown when Ethics is external to REGIS (SA/QLD/VIC/WA HREC)

For those registrations that have submitted the Ethics in another jurisdiction

- **Ethics approval letter** (If available)
  - **Type** = Ethics application decision notification
  - **Document Descriptor** = Ethics approval dated XX
- **Approved documents** upload the approved document, as listed on the approval letter, as a single .zip file
  - **Type** = Ethics application (HREA or other)
  - **Document Descriptor** = approved documents
- The form will allow you to upload documents individually, however this is NOT recommended.

\*NSW/ACT support parallel submission of ethics and governance applications. If you are submitting the site application/s in parallel to an ethics application that is currently under review the Ethics approval letter will be requested to be uploaded in the SSA/STE form, when it becomes available.

**Site application form (STE/SSA):** Selectable buttons have been created to provide the applicant with instructions specific to their scenario.

Select the option below for the specific guidance to appear.

Ethics in REGIS (NSW/ACT HREC)

Ethics external to REGIS (SA/VIC/WA/QLD HREC)

When Ethics in REGIS

For site applications where Ethics was submitted to a NSW/ACT HREC

Uploading new documents to the form:

- The details entered at Type and Document Descriptor is what will appear on the approval email.
  - **Type** = select option from the dropdown menu
  - **Document Descriptor** = list here exactly as you would like 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.
- REGIS supports parallel submission and review of site applications. The site application will have a copy of the initial Ethics application and supporting documents automatically uploaded with this application in the section above the editable table. The document title is the ETH reference id. DO NOT clear content selection.
- If Ethics has been approved: Documents that have been submitted to the HREC and are listed on the Ethics approval email e.g. Protocol, Master Documents, **do not** need to be uploaded with the site application. The system will automatically share the Ethics approval email (Decision Notification email) and all Ethics approved documents with all related Research Offices (RGOs).

Updating a document that has previously been submitted (after ineligible or request for information)

- Locate the document in the list/table
- Select Clear content selection at the end of the row and follow the wizard to upload the new document
- Update the Document Descriptor if the document version and date have changed.
- If you have been requested to upload a tracked version of a document add a new document row at the bottom of the table by clicking the "+" icon.
  - **Type** = select option from the dropdown menu
  - **Document Descriptor** = include tracked in the descriptor e.g. Site Participant Diary version 2 dated 5 July 2021 **tracked**

Select the option below for the specific guidance to appear.

Ethics in REGIS (NSW/ACT HREC)

Ethics external to REGIS (SA/VIC/WA/QLD HREC)

When Ethics is external to REGIS

- The details entered at Type and Document Descriptor is what will appear on the approval email.
  - **Type** = select option from the dropdown menu
  - **Document Descriptor** = list here exactly as you would like 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.

If your application form is showing the section for the Ethics approval and approved documents:

- Ethics approval letter (If available)
  - **Type** = Ethics application decision notification,
  - **Document Descriptor** = Ethics approval dated XX
- Approved documents upload the approved documents, as listed on the approval letter, as a single .zip file
  - **Type** = Ethics application (HREA or other)
  - **Document Descriptor** = approved documents
  - The form will allow you to upload documents individually, however this is NOT recommended.
- REGIS utilised smart form technology and this application will only request the upload of the initial Ethics approval letter/email and approved documents if not already recognised in the system (submitted by another site). If the form is not specifically directing to upload the Ethics approval documents, they are already available to the RGO in the system.
- If this site application is due to a HREC approved amendment to add a new site you will need to upload the HREC amendment letter
  - **Type** = Ethics application decision notification
  - **Document Descriptor** = Ethics amendment approval dated XX.

Updating a document that has previously been submitted (after ineligible or request for information)





- Locate the document in the list/table
- Select Clear content selection at the end of the row and follow the wizard to upload the new document
- Update the Document Descriptor if the document version and date have changed.
- If you have been requested to upload a tracked version of a document add a new document row at the bottom of the table by clicking the "+" icon.
  - **Type** = select option from the dropdown menu
  - **Document Descriptor** = include tracked in the descriptor e.g. Site Participant Diary version 2 dated 5 July 2021 **tracked**


Document Title

Document Type

## Notification of an amendment (ETH): Improved general guidance for the document upload section

## Document upload

 Preview  Save  Previous  Next

 This section has had a major change please read the on page instructions. You may also like to watch this [short video](#)

- This section allows the applicant to submit amended versions of documents already approved by the HREC or to submit new documents.
- Only upload documents to be reviewed by the HREC. Site Specific documents that relate to this amendment, should be submitted directly to the RGO using the site amendment form.
- If there are no documents to be uploaded select the checkbox and the ' ' icon and progress to the next section.
- A tracked copy of a changed/updated document is required to be uploaded to allow the HREC to easily identify the changes made. Please upload one tracked copy of each new version of a document.

Am I uploading as a new version Yes/No?

Yes when the document you are submitting to the HREC already exists in the system.  
e.g a Study Protocol will always have a previous version.

No when you want to upload a new document that does not have a previous version already existing in the system. note: studies that have been migrated from a legacy system will have HREC approved documents but they may not yet be available to update in REGIS, in this case No should be selected.

selectable buttons have been created provide the applicant with instructions specific to their scenario.

### Instructions to upload a new version

Instructions to upload a new version

- Upload new version: Yes
- Document Title/Descriptor: Select document to update from dropdown
- New Document Title: Type exactly what you want to appear in the approval email e.g Master Participant Diary version 2 dated 5 July 2021.
- Document Type: not selectable

Uploading a tracked version of an updated document

*tracked documents allow the HREC and/or Ethics Officer to easily identify the changes made to the document*

- Upload new version: No
- Document Title/Descriptor: if uploading a tracked version include tracked in the descriptor e.g. Master Participant Diary version 2 dated 5 July 2021 tracked
- Document Type: Select option from dropdown menu





### Instructions to upload a new document

Instructions to upload a new document

- Upload new version: No
- Document Title/Descriptor: Type exactly what you want to appear in the approval email e.g Master Participant Diary version 2 dated 5 July 2021
- Document Type: Select option from dropdown menu

## Significant Safety Issue (ETH):

### Document uploads

 Preview  Save  Previous  Next

This section allows the applicant to submit documents directly related to the Safety Report for review by the HREC.

If there are no documents to be uploaded select the checkbox and the ' ' icon and progress to the next section.


If this notification has resulted in safety-related changes to trial documentation these need to be submitted as an amendment not in this form. See REGIS quick reference guide: [Ethics Amendment - Completing and Submitting](#)

Document Type: Select option from dropdown menu

Document Title/Descriptor: Type exactly what you want to appear in the approval/noting email

## Site Amendment (STE): Improved general guidance for the document upload section

## Site Specific Document Upload

 This section has had a major change please read the on page instructions. You may also like to watch this [short video](#)

- This section allows the applicant to submit amended versions of documents already authorised by the Site or to submit new documents.
- If there are no documents to be uploaded select the checkbox and the '+' icon and progress to the next section.
- A tracked copy of a changed/updated document is required to be uploaded to allow the RGO to easily identify the changes made. Please upload one tracked copy of each new version of a document.

Only upload site documents to be reviewed by the Site/RGO.

If Ethics exists in REGIS all Ethics approved documents (listed on the Ethics approval letter) have been made visible to the Site/RGO

If Ethics exists outside of REGIS you will be guided to upload the Ethics approval email/letter AND the approved documents in a separate section "Ethics Approved Document Upload". It is recommended they are uploaded as a single .zip

Am I uploading as a new version Yes/No?


Yes when the document you are submitting to the Site/RGO already exists in the system.  
e.g a Site Specific Participant Information Form that has previously been authorised.

No when you want to upload a new document that does not have a previous version already existing in the system. note: studies that have been migrated from a legacy system will have Site/RGO authorised documents but they may not yet be available to update in REGIS, in this case No should be selected.

Upload a new version

Upload a new document

selectable buttons have been created to provide the applicant with instructions specific to their scenario.

 Upload a new version


Instructions to upload a new version

- **Upload new version:** Yes
- **Document Title/Descriptor:** Select document to update from dropdown
- **New Document Title:** Type exactly what you want to appear in the approval email e.g Site Name Participant Information Sheet version 2 dated 5 July 2021.
- **Document Type:** not selectable

Uploading a tracked version of an updated document

tracked documents allow the Site/RGO to easily identify the changes made to the document

- **Upload new version:** No
- **Document Title/Descriptor:** if uploading a tracked version include tracked in the descriptor e.g. Site Name Participant Information sheet version 2 dated 5 July 2021 tracked
- **Document Type:** Select option from dropdown menu

 Upload a new document

Instructions to upload a new document

- **Upload new version:** No
- **Document Title/Descriptor:** Type exactly what you want to appear in the approval email e.g Master Participant Diary version 2 dated 5 July 2021
- **Document Type:** Select option from dropdown menu

## REGIS Release Update

**Audience:** Research Office

Issues reported and actions:

- Research offices reported being able to see other principal organisations non-accessible data when using the top quick search bar. This data was non-accessible and if selected a red error message appeared at the bottom of the screen. This was reported to the Vendor and a fix was identified and implemented.
- Research offices advised they could see other principal organisations reporting data when creating a report. This issue was reported to the REGIS team who reported it to the Vendor and a fix was implemented within 5 minutes of being reported.

- Research offices advised that when downloading an output form (such as applications, amendments etc.) it had some information cutoff. This was reported to the REGIS team who reported it to the Vendor and is currently under investigation.

[See release note](#) for all system enhancements and updates from the 1 September 2021 release.

## System access for REGIS Production and Sandpit environments

**Audience:** Research Office

Research Offices are currently requesting user role changes via the HOD template, some of which are Research Office staff that require sandpit access; however some staff are temporary and sandpit access is not required.

The person responsible for requesting role changes needs to clearly indicate if sandpit access is required so that appropriate action can be taken to ensure this access is provided.

## Research Office Contribution

**Audience:** Research Office

NNSWLHD Fee Policy: NNSWLHD have recently implemented a Research Governance fee policy effective from 1 August 2021. This fee policy is available to view via the [NNSWLHD Human Research Ethics and Governance website](#).