

Release notes for Wednesday 25 August system update

System enhancements

System enhancements are created from direct feedback of the REGIS User Group, the REGIS Researcher Interest Group and enhancement log.

Related Documents uploaded into any application/form

Issue: REGIS forms prescribe mandatory format of Document type, Descriptor, Version and Date. Not all documents have a version and/or date and this is causing confusion and frustration for researchers.

	Document type - please select from the list*	Document descriptor - your name for the file *	Document version •	Document date*	Upload New Maximum file size is 20.00 MB
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Enhancement: All applications and forms that have the functionality to upload documents will now have only 2 sections to be completed. Document Type (dropdown) and Document Descriptor (free text).

	Document type - please select from the list*	Document descriptor - your name for the file *	
	•		Upload New
			Maximum file size is 20.00 MB
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How will this effect the RO:

Before the release the title was a combination of the Descriptor, version and date entered by the applicant on the form.

After the release the title will be what is typed into the Document Descriptor.

Foun	d 7 items				
	Title				
0	№ 2021/ETH00591 v1_00 - v1_01 Changes	Related documents			
0	411 HREA	+ Add document	view		
0	A HREA	Title *	Master version 1 dated 25 July 2021		
0	Master version 1 dated 25 July 2021	Document type * Participant Information Sheet			

There will be a transition period where applications that have been submitted to the Research Office (submitted, information provided) before the release and are sent back to the researcher after the release (ineligible, information requested) will require Researcher action. Research Offices are encouraged to add a statement to outgoing communications, an example has been provided below.

"Since the initial submission of this application there has been system update to streamline how document details are entered into forms. The document version and date fields no longer exists and you will need enter

these details into the Document descriptor

e.g. Document Type = Participant Information Sheet Document Descriptor = Arm 1 Master version 1 dated 22 June 2021"

RO should be vigilant to confirm and update document titles before approving a study to ensure consistency.

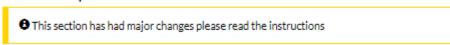
Researcher: When completing the updated forms researchers will put all details into the document descriptor section of the form.



Document Type = Participant Information Sheet Document Descriptor = Arm 1 Master version 1 dated 22 June 2021

Update flags have been added to all forms and on page instructions have been edited to be clearer.

Part F: Upload Attachments



There will be a transition period where applications that have been submitted to the Research Office (submitted, information provided) before the release and are sent back to the researcher after the release (ineligible, information requested) will require Researcher action.

Researchers will be required to manually enter the document version and date (if one exists) into the document descriptor field.

It is the combination of the Document type and Descriptor that will appear of the approval email. Participant Information Sheet, Arm 1 Master version 1 dated 22 June 2021

Related Document Tags in Project

Issue: Currently when a Notification of an amendment to a research study is submitted a document tag is created based off its type. This is very useful for the research offices to quickly identify the type of amendment it is and assign to the appropriate review pathway. We would like this to happen with all forms.

Enhancement: all documents submitted to the RO will have a document tag assigned to it depending on the type selected by the applicant.

How will this effect the RO: RO will notice an increase in document tags in the internal portal.

ETH Milestone: Progress Report

Tag type: Annual Report When study status is: Not yet commenced, In progress or Completed

Tag type: Final Report When Study status is: Closed, Abandoned, Terminated

ETH Significant Safety Issue

Tag type: USM When form type is: Urgent Safety Measure

STE Amendment

Tag type: General when amendment type is: General amendment

Tag type: CPI Change When amendment type is: CPI Change notification
Tag type: Pi Change When amendment type is: PI change notification

Tag type: HREC extension When amendment type is: Extension of HREC approval notification

Tag type: Investigator Change When amendment type is: Change site investigators or site

admin contacts

Tag type: Contract When amendment type is: Change to contracts

Reporting Local Safety Events to the Institution

Tag type: External SSI When type of safety event is: SSI from approving HREC (external to REGIS)

Tag type: Local Safety When type of safety event is: Local Safety Event (SUSAR/USADE/URSAE)

Researcher: Researcher will notice no changes

Related Document tag/token

Issue: Form and type to automatically pull through in email communications

Enhancement: A token that lists the document type e.g. Notification of an amendment – General or addition of site. Email templates have been updated to include token.

How will this effect the RO: RO should have to make fewer manual changes to the email templates.

Researcher: Researcher will notice no changes

A list of HREC approved sites not in REGIS

Issue: Currently there is nowhere in the system that lists HREC approved sites that are external to REGIS

Enhancement: A list of sites is now created from the Project Registration "other sites" tab and Notification of amendment sites "other".

How will this effect the RO: RO will see a new menu option under Management called external sites. Site are automatically created from information entered at Project Registration.

RO will have to manually edit the details in the Project e.g. an addition of an external site or change in PI from an external site.



Researcher: Researcher will notice no changes.

External Portal – HREC approval upload in SSA form

Issue: When project registration is completed and ethics is outside of REGIS and the application indicates that the HREC review is still underway a Upload HREC approval form is created as part of the STE forms.

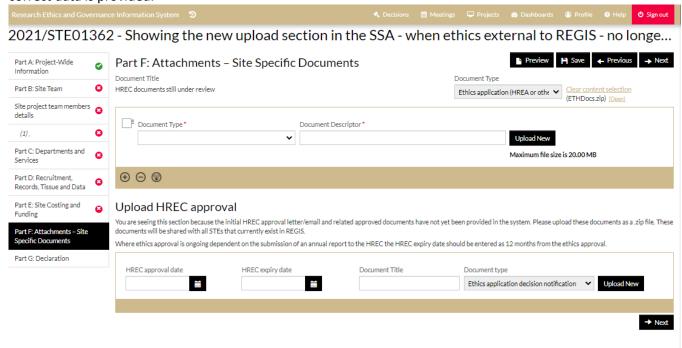
There has been low uptake on the use of this form. Applicants appear to prefer to upload the details into the STE.

Rather than having a separate form integrate this into the NSW SSA form. Either to be uploaded in the document upload section or a new section of the form when Ethics approval is not completed at PR.

Enhancement: SSA form has been updated to recognise if ethics is pending and will request HREC approval in the document upload section.

How will this effect the RO: RO should notice no difference.

How will this effect Researcher: Researchers will see a new section on the form at Part F. Where ethics approval is not recognised in REGIS they will be guided to upload into the form. The document type is locked to ensure correct data is provided.



If another site has entered the HREC approval and approved documents the following message will show. This is to reduce duplication in the system for users.

The initial ethics approval and related documents have already been uploaded by another site and are visible to to the Research Offices, you do not need to upload any of this information in this form.

If this site application is coming from an amendment for an addition of site then the amendment approval email/letter should be uploaded as a Ethics application decision notification document type, if there are multiple ethics documents please upload as a single zip

CPI in HREA

Issue: HREA required the Coordinating Principal Investigator to be in position 1. This information is mapped from Project Registration. But if the details are changed in the HREA the system often doesn't create a Coordinating Principal Investigator Contact role and this stops the project from being created.

Enhancement: Form changes to map CPI from any position. Hide question 1.9.11 do you have authority to sign.....only the CPI has the authority.

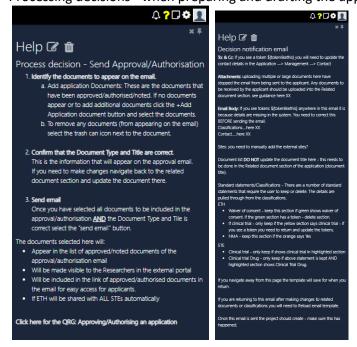
How will this effect the RO: RO will no longer have to confirm CPI is correctly listed at position 1 in the Team Details section of the HREA.

How will this effect the Researcher: Researchers should notice no difference.

Help text for internal portal (Research Offices)

Configuration Change: Help text has been added to some internal pages.

How will this effect the RO: RO can click on the help icon to access page specific help. Processing decisions - when preparing and drafting the approval/authorisation emails.



Researcher: Researchers should notice no difference

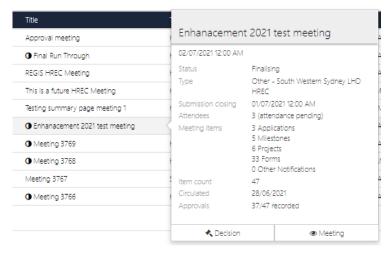
PRODUCT CHANGES

Product changes are created to the base product by the vendor.

Meeting details pop up

System Upgrade: In the Meeting search page when you hover of the meeting title a meeting details will pop up you can navigate to the meeting from here.

How will this effect the RO: Improved "at a glance" viewing options and navigation.



How will this effect the Researcher: Nil

Status Map for Meetings

System Upgrade

2.2 Status Map for Meetings

Version 5.0 introduced the Status Map for Applications and Projects. Version 5.1 adds this feature to Meetings.

The Status Map helps the user by providing a visual representation of the Meeting process, what actions have been completed and what needs to be done next.



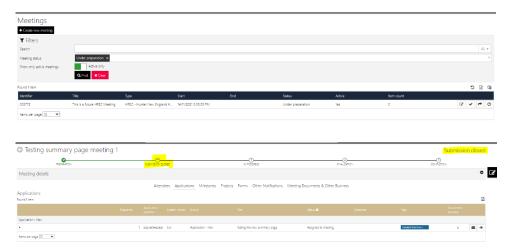
How will this effect the RO: Improved visual representation of meeting progress.

How will this effect the Researcher: Nil

Meeting Status

System Upgrade: Based on the status mapping a meeting is given a status.





How will this effect the RO: Status can be used when searching and filtering meetings.

How will this effect the Researcher: Nil

Customisable tables

System Upgrade: Internal portal users will have increased flexibility to manage views on some pages.

2.4 Customisable tables

Several screens in OmniStar have been updated to improve useability and personalisation. Specifically customisable tables have been added to search screens, document screens and structured data collection screens.

The customisable tables provide the ability for users to reorder columns, resize columns and hide and show columns. Columns can be reordered by clicking and dragging and can be hidden by unticking the relevant box in the **Columns** drop-down menu.

The changes that a user makes to the display of tables is persisted so they are not lost on existing the screen or system.

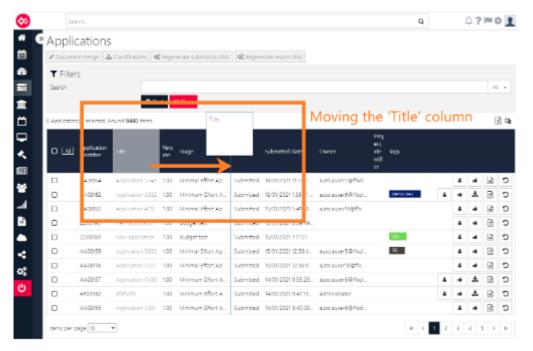


Figure 5. Reordering columns in the upgraded Applications search screen results table with click-and-drag

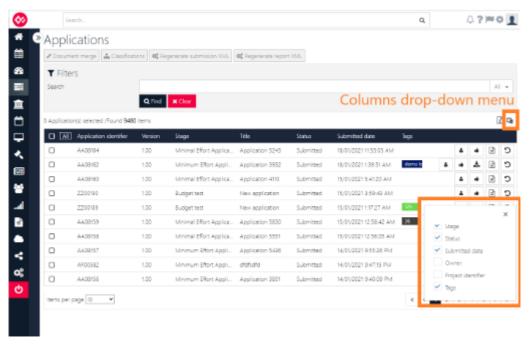


Figure 6. Hiding the 'Owner' and 'Project identifier' columns using the new table's drop-down menu

How will this effect the RO: RO can edit the views when they are in table view.

How will this effect the Researcher: Nil

Multiple eligibility assessments

System Upgrade (use f1 doc details if sufficient): Multiple eligibility assessments can be created per application version.

2.9 Multiple eligibility assessments

OmniStar now supports multiple eligibility assessments to be performed per application version. Previously, there could only be one eligibility per application version.

This supports the scenario where an eligibility assessment needs to be redone or overridden. The new eligibility assessment is always performed on the most recent version of an application.

The eligibility wizard can be launched from the application search screen or from the application viewer.

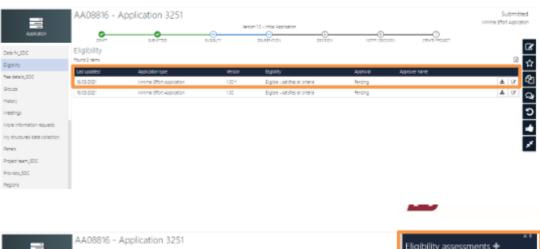




Figure 16. Eligibility assessments panel

How will this effect the RO: RO can create another eligibility against a version to correct an error.

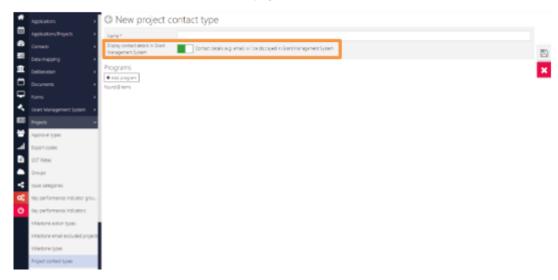
How will this effect the Researcher: Nil

Project Contact Details

2.14 Project contact details

Version 5.1 now shows email and phone number contact details on the Project Contact page in the External Portal.

The display of this information to external users can be controlled via a setting on the contact type which indicates whether contact information is to be displayed in the External Portal.



How will this effect the RO: Nil

How will this effect the Researcher: When switched on additional details will be visible from the external portal.

Bulk Project Update

2.15 Bulk update project contacts

A new feature has been added to the Project Search screen to allow for project contacts to be changed in bulk. Using this feature allows for project contacts to be added or updated on selected projects in one action rather than editing each record individually.

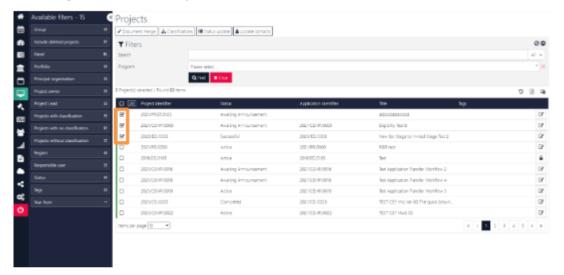


Figure 28. Multiple selection on project list to update contacts

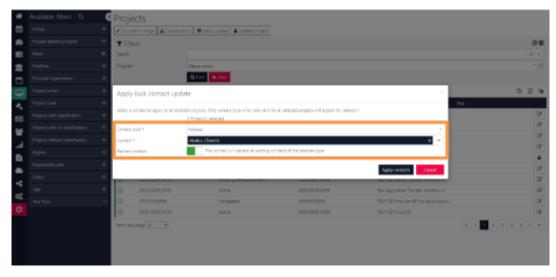


Figure 29. Apply bulk contact update information

How will this effect the RO: No automations or form changes have been made to automatically facilitate this feature. RO should contact the REGIS team to use.

How will this effect the Researcher: Researcher should contact the local Research Office if they have a single person who needs to be added to or removed from multiple projects.

Records Management

2.16 Records management

The documents available on applications, projects, project milestones, and project variations have additional attributes relating to document disposal. In version 5.1, these attributes are made available when user uploads a document. Furthermore, a scheduled task can be created for document disposal delete documents.

Document disposal can be managed through System settings > System processes > Scheduled tasks.

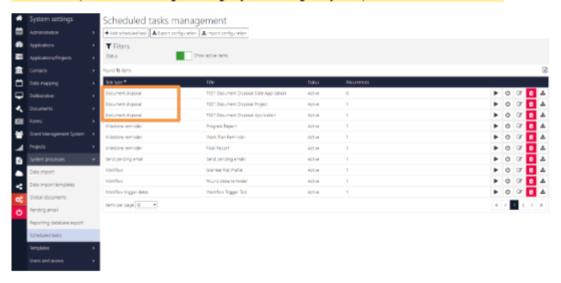


Figure 30. Document disposal in scheduled tasks management

How will this effect the RO: User Group to discuss this feature and the agree on statewide processes.

How will this effect the RO: Nil

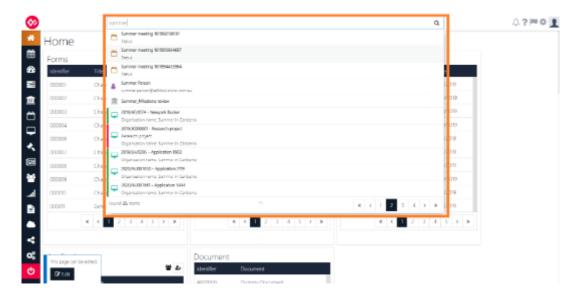
Enhanced quick search

3.2 Enhanced quick search

The Quick Search functionality now also searches for:

- Meetings
- Panels
- Contacts
- Users

This allows users to quickly find records of various types without navigating through the menus.



How will this effect the RO: additional options may become visible when using the quick search

How will this effect the Researcher: Nil

Support for imported and manually entered ORCID details

3.6 Support for both ORCID (imported) and manually entered researcher details

A user's profile (and their entry in Contacts) can include Employments, Funding, Publications and Qualifications. These details can be imported from the ORCID researcher identification system or entered manually. Before version 5.1 it was not possible to add these details manually after adding an ORCID ID as the screens would be locked.

In version 5.1, it is now possible to add and edit these details after adding an ORCID ID, and only the imported entries cannot be altered. The entries added manually will not be affected by adding, removing or changing the ORCID ID.

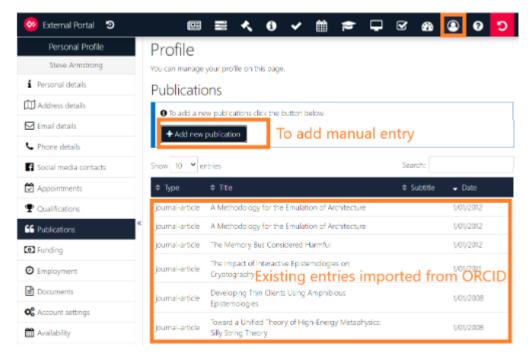


Figure 39. ORCID and manually added profile information

How will this effect the RO: Nil

How will this effect the RO: Researchers can add additional details to their profile without overwriting existing details.