

Hello to all Research Offices,

If I haven't yet had the pleasure of speaking to you this year, Happy New Year to you. 2020 was a bit of a doozie, wasn't it?! I am sure we are all hopeful that 2021 is a bit kinder.

The REGIS team has certainly hit the ground running and already have a list as long as their (socially distanced) arms they are working on. 2020 was also a really big year for the REGIS platform and for you in the Research Offices and Researcher's alike. We released REGIS 2.2 which provided the governance post approval functionality that RGO's had been so patiently waiting for. It was a BEAST of a system change and was always going to be a big change to take in. The User Group did a fantastic job on really thinking about how items could flow through the system and where efficiencies could be found. You are now all seeing and experiencing these changes in the real world and the User Group can now start to address areas that may need a tweak here and there.

After the 2.2 release we have received a lot of calls and have collated some information we think will be generally helpful.

REGIS 2.2 - Ethics flow on affecting Governance

There are several steps that are completed by Ethics that will now affect Governance. This means if the study is a multi-site study the Ethics Office's actions may affect multiple Governance Offices across the state.



1. Approval Emails – List of approved documents


It is important the Research Offices make sure the document list is clear and complete before it is provided to the Researcher.



GL2010_014 notes an approval letter needs to include "A list of all approved documents including version numbers and dates".

As part of the 2.2 release the HREA and the STE forms ask for Document Type, Document Description, Document Version and Document Date. When entered correctly by the applicant this should significantly reduce the need for manual changes to the approval emails. If the applicant does miss a section or adds incorrect information the research office can now pick this up during their quality checks (qc) and opt to either ask the researcher to correct details when responding to a RFI or correct this data from the internal portal.



Related documents

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Title *	isaverylongdrugname X18937-11-04-Dec-2018
Document type *	Investigator Brochure
Document version	11
Document date	20/12/2004 
Document descriptor	isaverylongdrugname X18937
Replace file	<input type="checkbox"/> No

 Save  Cancel

Related documents

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Title *	isaverylongdrugname X18937 Version 11 Dated 04-Dec-2018
Document type *	Investigator Brochure

RO can update the title of the document to have it ready for the email approval.

When the email is created, and the documents are selected the document type and the document title (which is made up of the description, version, and date) are listed in the email. If the RO has completed qc checks as they have been reviewing, then the email should be close to create and send. However, if this is not part of your qc process then you will have to manually update the email AND the email list will not match the list in the related documents section. This will probably cause confusion in the future and if it is an ethics approval will cause confusion to the RGO who is trying to match up the approved document list to the shared documents.

[I would like a webinar on approval emails, including document selection and how documents are listed in the email section.](#)

2. Approval emails – removing critical statements

Some research offices continue to use their own email templates, with the introduction of 2.2 there are several critical statements that have been included in the REGIS email templates, these items need to be included, removing these statements is affecting researchers who are using REGIS to submit governance post approval.

For example the ethics general amendment approved subject line and body will automatically pull through the Ethics form ID which is required for sites investigators to select to link the two actions and for Research Offices to use to search for the Ethics Documents.

The 2.2 post approval flow and communication document that was circulated also notes these communication points.

[I would like a webinar on approval email, critical statements.](#)

3. Document Sharing

One of the factors the User Group considered when deciding on the rules for the governance post approval flow in REGIS was to reduce duplication. The obvious duplication was the submission/resubmission of Ethics approved documents to sites.

With the release of REGIS 2.2 Researchers are actively told in the form guidance to NOT submit ethics documents in the site application form when ethics already exists in REGIS and that these documents will be shared with the RGO on approval. A number of these processes have been automated, meaning the ethics office doesn't have to manually share documents. These are:

- Ethics approval (where documents are selected when creating the approval letter)
- Amendment – HREC extension
- Amendment – Change CPI
- Amendment – Change PI
- Significant Safety (except the HREC approval/noting email, this needs to be shared manually)
- Milestone/Annual Report – (except the HREC approval/noting email, this needs to be shared manually)

There are some instances where the ethics office will, after approval need to share documents so the RGOs can see them. These instances are:

- General Amendment including approval email
- Safety notification HREC approval/noting email
- Milestone/Annual Report HREC approval/noting email

It is VERY important that these documents are shared as an RGO cannot see these until they are shared.

[I would like a webinar on approval email, critical statements.](#)

Project Not creating after approval – see attached

One of the most common reasons for a Research Office to contact the helpdesk is for a project not creating for an approved HREC. 99% of the times this is due to the CPI not being recognised in the system. The attached document describes how the CPI details need to appear in the HERA for the Project to be created on approval. If you have any questions, please let us know.

We are currently in talks with the Vendor to streamline this but in the meantime it is important the Ethics team understand how this part of the form/system behave.

[*I would like a webinar on understanding why the Project did not create.*](#)

Principal Investigators update outside of REGIS (pre 2.2)

If a HREC was not using the REGIS amendment form there may be instances where a Principal Investigators details have not updated in the STE correctly after an approved amendment. Prior to the release of 2.2 this was not an issue as there was no governance post approval activity in REGIS. RO may notice an increase in calls regarding this. This is not a technical fault to be forwarded to the helpdesk.

How to update the PI details in the STE Project: Locate the STE → Management → Contacts → Click edit → Locate the Principal Investigator (without a relationship indicated) → click edit item → at top of screen set an expiry date (any date in the past, if you know the actual date the change was made use the actual date) → Click Ok → Click +Add Contact → click on the role drop down select Principal Investigator → select the contact/new PI → add approval date (any date after the old PI was expired) → Click OK → Click save.

You will need to update the owner details in the Details section of the **application** and **project**

Details → Summary → Edit → Click three dots next to owner → search for new PI → click tick at bottom of screen → Save

[*I would like a webinar on understanding how to update the Principal Investigator.*](#)

Governance Post Approval Transitions

If you have not yet set up your homepage tiles for site post approval please do this **ASAP**, it is highly likely that you will have post approval activity waiting to be processed. The following QRGs are available to assist you. [Setting up a homepage](#), [homepage tiles described](#)

If not already, Research Offices should be in the final stages of transitioning across to the governance post approval in REGIS. Please note for those still transitioning, regardless of your current transition plans REGIS is creating governance post approval activity against your studies.

We are also receiving feedback directly from Researchers who want to submit through REGIS that they are being directed to submit through Research Offices external forms. We ask that Researchers who are willing and able to submit through REGIS are not redirected to local forms.

Education Sessions

A comprehensive training schedule has been put together for the first half of 2021. A separate email has been sent out with further details.

There have been a number of changes in the system in the last 48 months and we suggest all Research Offices attend the training. Feedback from the training provided in November noted that even experienced users found the training valuable.

Walkthrough Videos

We have created a range of walkthrough videos for the Research Office and Researchers. Where possible we have kept each video as 10min or less. The videos are available on the [How To](#) page of the REGIS website with the quick reference guides.

Walkthrough videos for Research Office

- Ethics - Processing an Ethics Milestone Report
- Site - Processing a Governance Site Amendment, Requesting Further Information and Processing Information Received
- Site - Processing Governance Milestones
- Site - Processing a Governance/Local Safety Event

Walkthrough videos for Researchers and other users

- Completing and submitting Project Registration
- Completing and submitting Ethics Application
- Completing and submitting Site Application
- Responding to a request for information - initial application

More videos will become available in the first quarter of this year.

Site Visits

At the end of 2020 the REGIS team began face to face site visits, this is expected to continue through 2021. These visits are designed to see how the Research Office is currently using REGIS and if there are any areas that our team can suggest potential changes or run through functionality that may have changed (there been a few changes!). We also want to see the great ways people are using the system so we can share this with other offices.

As much as we would love to be able to travel across the state there may be some sites, we won't be able to physically visit (or you may not want a face-to-face visit) we can also schedule a Skype/Teams meeting where we can provide the same type of support.

Please let our team know if you would like a site visit so we can schedule you in.

There is one tiny caveat to our site visits, you must have had at least one team member attended the recent training provided November 2020 or the current advertised rounds.

REGIS communications

Whilst we are a flurry of activity here, we understand that you are also very busy. We want to avoid as much as possible adding to your stress so have decided to send out a weekly communication from the REGIS team. This will list items such as: any areas for information, upcoming releases, upcoming education sessions, upcoming webinars etc.

Do you think a weekly communication would be useful or would fortnightly be more manageable?

[Click here to indicate REGIS communication frequency.](#)

If there are specific items that you think would be helpful to include on the update, [please let us know.](#)

This email is intended for research office staff/internal portal users of REGIS, this is not intended for wide distribution.