

REGIS Comms – Tuesday 6 April

Welcome to issue 8 of the REGU/REGIS fortnightly email.

It was so lovely to see and talk to you all on Friday at the roundtable. Having the face to face meeting was a reminder that things are slowly (fingers crossed) returning to a new normal. For those who joined us online I hope we will see you at the next roundtable.

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- Issue Log - Site amendment form – add PI – upload document
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## Upcoming Education Sessions

### Research Office Training

Regular Research Office training will continue every two months through 2021, please see agenda and dates below.

Register interest to attend: <https://ohmrrcdap.health.nsw.gov.au/surveys/?s=ARNFJRFXT>

Sessions have been designed to run in a row but can also be attended individually if you are wanting a refresher in a specific area.

After running the earlier cycles, we can confidently say those who follow along with a created study in sandpit **WILL** retain more details than those who just watch.

<b>REGIS Training</b>	<b>Jun</b>	<b>Aug</b>	<b>Oct</b>	<b>Dec</b>
<b>Pre-Training Setup (Wed):</b> All Users	16	11	6	1
<b>Day 1 (Mon):</b> All Users (AM/PM sessions are mandatory) <b>AM Session:</b> Understanding the system and settings. <b>PM Session:</b> Ethics and Governance Eligibility.	21	16	11	6
<b>Day 2 (Tue):</b> Ethics Review and Meeting	22	17	12	7
<b>Day 3 (Wed):</b> Ethics Create decisions from within a Meeting and from the Application	23	18	13	8
<b>Day 4 (Thurs):</b> Governance Review and Authorisation	24	19	14	9
<b>Day 5 (Fri):</b> Governance Review and process Amendments, Safety Reporting and Milestone	25	20	15	10
<b>Day 6 (Mon):</b> Optional Managing and updating the Head of Department List	28	23	18	13

## Researcher Education sessions

We have been thrilled with the number of Researchers that have registered their interest to attend upcoming REGIS training, so far over 400 researchers!

We worked directly with our Researcher Interest Group to build a training package and have just completed the pilot run through of the sessions. Sessions run with an obvious flow from beginning to end but can be attended in any order.

All sessions are 30 min (except the general overview) with up to 4 sessions running per day. The general overview session is 1 ½ hours and is also available to anyone who wishes to touch on the system in general.

Please encourage your Researchers to [register their interest](#) to receive more information.

## Future Releases (Wednesday 5<sup>th</sup> May)

### System Configuration - “New Ethics/Meeting Decision”

**Enhancement Log Request (must have):** Some RO have a dual meeting process for some study types (clinical trials). The application is assigned to a meeting where the decision is to progress the application to the next stage/meeting.

In REGIS there is not a meeting decision that allows this step, which means these RO cannot complete the meetings. Need an internal decision that can be made that indicates the application can progress/can be assigned to the next meeting but is not a request for information or a final decision.

**Configuration:** A new Decision Type “Progress to HREC meeting” is available to the ETH application. The decision can be made in a meeting and in the application decision section.

The screenshot displays the 'Search by approval type' interface. On the left, a search bar is visible above a list of three approval types:

- Application Decision:** The outcome for an application can either be a decision or more information required. Applies to: Application.
- More Information Required:** This approval is used where the committee requires further information from the applicant. This is used for metrics. Applies to: Application.
- Progress to next meeting:** Application to progress to next meeting. Applies to: Application.

On the right, the configuration details for the 'Application' are shown:

- Application: 2021/ETH00546 - Test Classification flow - between Ethics and Site
- System version: 1.00 - Initial Application
- Decision: (None)
- Decision: (None)
- Reason: Application Decision, More Information Required, Progress to next meeting

For those RO who don't use meetings or for RO who use meetings but do not have a dual review process, you will see a new decision type in the ETH application “progress to HREC meeting”.

For RO who have a dual review process they will be able to use the new decision type to make sure every application has a decision made against it in the meeting. This will allow the office to complete the meeting.

This decision can be used when a study has been reviewed by an exec committee and has been identified to be reviewed by the full HREC.

**The use of this decision has no impact on metrics.**

## System Configuration - New Classification: Waiver of Consent

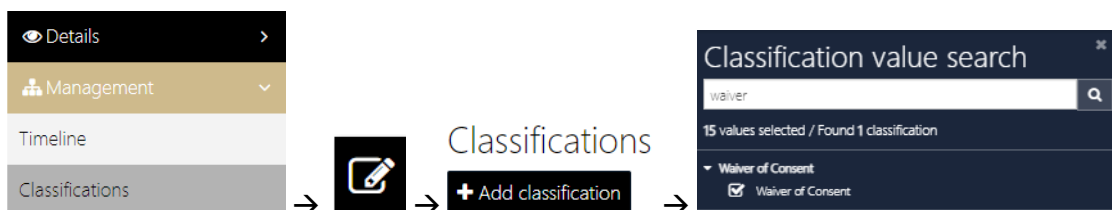
**Enhancement Log Request (must have):** Research Offices would like a way to categorise/indicate in the system when a study has a waiver of consent.

Phase 1 of enhancement: The classification is available for RO to **manually** enter at Ethics (ETH) and Site (STE).

Phase 2 of enhancement: Automation of initial completing of classification based off combination of responses in HREA. To be completed 2021/2022

**Use of classification:** RO should add the classification to indicate when there is a waiver of consent aspect to the study.

e.g. a waiver of consent has been requested (regardless of if it was approved or not approved), some parts of the study will utilise waiver of consent, all parts of the study will utilise a waiver of consent.



## 2021/STE01014 - Tighten up test

2021/PID00701

ETH Approved Low or negligible risk review pathway x Add tag...

### Classifications

+ Add classification

Found 15 items

Name	Value
Waiver of Consent	Waiver of Consent Waiver of Consent / Waiver of Consent

Classifications should be created **BEFORE** approval/authorisation. **Why?** The Ethics approval email template has been updated to capture the data from the Waiver of Consent classification so you can easily identify a study that has a waiver of consent classification when creating the approval email.

Where waiver of consent classification exists the text waiver of consent will show.

If waiver of consent, **Waiver of Consent** The Committee granted a waiver of the usual requirement of consent for the use of re-identifiable information held by NSW agencies, in line with the State Privacy Commissioner's Guidelines for Research and the Health Records and Information Privacy Act 2002 (NSW) and the Guidelines approved under Section 95/95A of the Privacy Act 1988. **If Waiver of Consent**

Where waiver of consent classification does not exist the text is not visible. Statement can be deleted.

If waiver of consent, **ApplicationClassification Waiver of Consent** The Committee granted a waiver of the usual requirement of consent for the use of re-identifiable information held by NSW agencies, in line with the State Privacy Commissioner's Guidelines for Research and the Health Records and Information Privacy Act 2002 (NSW) and the Guidelines approved under Section 95/95A of the Privacy Act 1988. **If Waiver of Consent**

**PLEASE NOTE:** The coloured text exists to guide the RO when creating approval emails and should be deleted before sending. For example, if a waiver of consent DOES exist please delete all green text at beginning and end of paragraph. Where waiver of consent DOES NOT exist please delete the entire paragraph including the green text.

### System Configuration: New Classification: Teletrial

**Ethics Classification: Teletrial** to be collected manually by the RO (ETH) when a study is a Teletrial.

When to collect: At application/before approval, when a study is identified as a teletrial.

This classification can be added to a study retrospectively for studies that already exist in REGIS that are Teletrials or studies that become a teletrial post approval.

Why is it collected: collection of this classification is mandatory for National Aggregate Statistics (NAS).

#### 2021/ETH00550 - Waiver of Consent

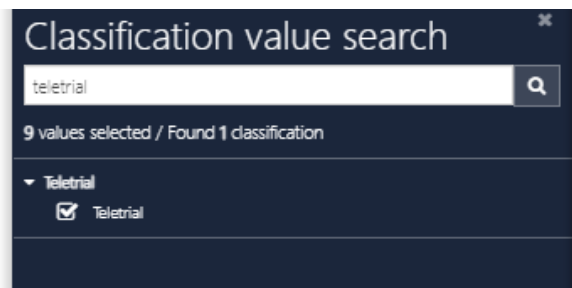
2021/PID01032

Greater than low risk review pathway **✖** Add tag...

#### Classifications

+ Add classification

Found 8 items



**Site Classification: Teletrial Site Type, Primary Site/Satellite Site** to be collected manually by the RO (STE) when a study is a Teletrial and a site will be a Primary or Satellite Site

When to collect: At application/before authorisation, when a site is participating in a teletrial as a Primary or Satellite Site.

This classification can be added to a site retrospectively for studies that already exist in REGIS that are Teletrials or sites that become a Primary or Satellite site post approval.

#### 2021/STE01031 - Waiver of Consent

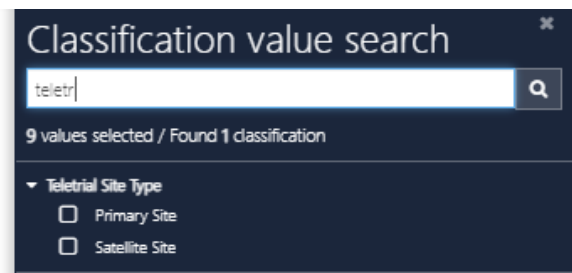
2021/PID01032

Add tag...

#### Classifications

+ Add classification

Found 9 items



### System Configuration: Email Template Update

- Application HREA - Approved
- Application HREA – Approved with conditions

Templates updated to capture Waiver of Consent classification

If waiver of consent, **Waiver of Consent** The Committee granted a waiver of the usual requirement of consent for the use of re-identifiable information held by NSW agencies, in line with the State Privacy Commissioner's Guidelines for Research and the Health Records and Information Privacy Act 2002 (NSW) and the Guidelines approved under Section 95/95A of the Privacy Act 1988. **If Waiver of Consent**

Where waiver of consent classification does not exist the text is not visible. Statement can be deleted.

If waiver of consent/ **ApplicationClassification Waiver of Consent** The Committee granted a waiver of the usual requirement of consent for the use of re-identifiable information held by NSW agencies, in line with the State Privacy Commissioner's Guidelines for Research and the Health Records and Information Privacy Act 2002 (NSW) and the Guidelines approved under Section 95/95A of the Privacy Act 1988. **If Waiver of Consent**

**PLEASE NOTE:** The coloured text exists to guide the RO when creating approval emails and should be deleted before sending. For example, if a waiver of consent DOES exist please delete all green text at beginning and end of paragraph. Where waiver of consent DOES NOT exist please delete the entire paragraph including the green text.

### System Configuration: Minor Form Updates

**Site amendment form (change of personnel)** – ability to upload document (CV)

**Annual report form** – updates to forms to ensure form title comes through

### Document Management Hints and Tips

Document management remains one of the more challenging aspect of the system. There have been a number of enhancements that have been introduced into REGIS to address these issues.

- Researchers
  - no longer have to keep the same electronic filename for document versioning to work
  - there is no character limit to the Document title/Descriptor
- Research Offices have greater flexibility in updating/correcting document details in the internal portal.

We have put together

When a document is submitted with a form (this example is a general amendment form) the applicant is asked to complete the document details in the following format:

List all documents that are being submitted for review

Upload as a new version *	Document title/ Descriptor *	Document Type *	Version *	Date *	Upload file *
<input checked="" type="checkbox"/>	Master Intervention	Participant Information Sher	1	8/04/2021	<a href="#">Clear content selection</a> (Master_PISCF_Interventional_v1_8Apr21.doc) <a href="#">[Open]</a> Maximum file size is 20.00 MB

### Internal Portal Related Documents

Title	Filename	Size	Document type	System Version	Tags
Master Intervention	052313 Master_PISCF_Interventional_v1_8Apr21...	104.0 KB	Participant Information S	1 *	General Amendm...

The **Title** is the combination of the information entered into the form by the applicant.

The **Filename** is a combination of the **form id** that this document relates too (in this case the general amendment form) and the **electronic filename** of the document uploaded by the applicant.

A \* indicates this is a new or edited document that has changed since the last submission.

## Related forms

Identifier	Title	Submitted date	Status	Tags
052313	Notification of an amendment to a research st...	23/04/2021 10:57:33 AM	Submitted	General Amendm... Add tag...

You can use the form id to locate all documents related to this form

Filters

Search: 052313

Document types: Please select...

Found 2 items

General Amendment	1	✕
Participant Information Sheet	1	✕

It is the **Document Type** and **Title** that pull through to approval emails.

- type for the documents here

The following documentation is included in this approval:

- General Amendment, Notification of an amendment to a research study - General Amendment
- Participant Information Sheet, Master Intervention-1-08-APR-2021

A RO can now update/edit the Related Document section in the internal portal to make it easier to manage documents.

In this screenshot the title is showing as formatted by the system.

## Related documents

+ Add document | Bulk download

Title: Master Intervention-1-08-APR-2021

Document type: Participant Information Sheet

Document version: 1

Document date: 20/04/2008

Document descriptor: Master Intervention

Replace file:  No

Save | Cancel

Found 2 items

General Amendment	1	✕
Participant Information Sheet	1	✕

Title	Filename	Size	Document type	System Version	Tags	Date modified	Modified by	Relationship
Master Intervention-1...	052313_Master_PISCF...	104.0 KB	Participant Inform...	1 *	General Amendm... Add tag...	23/04/2021	Becker, Kylie	

In this screenshot the RO have made a change to the Title in the related document section.

## Related documents

Title \*

Document type \*

Document version

Document date

Document descriptor

Replace file  No

---

Found 2 items

General Amendment 1

Participant Information Sheet 1

<input type="checkbox"/>	Title ^	Filename	Size	Document type	System Version	Tags	Date modified	Modified by	Relationship
<input type="checkbox"/>	Master Intervention v...	052313_Master_PISCF_...	104.0 KB	Participant Inform...	1 *	General Amendm... Add tag...	23/04/2021	Becker, Kylie	

The changes made in Related Documents are shown in the approval email.

The following documentation is included in this approval:

- General Amendment, Notification of an amendment to a research study - General Amendment
- Participant Information Sheet, Master Intervention version 1 dated 08 April 2021

## What if documents are appearing not as expected?

The example below shows a list of documents that have been uploaded into the progress report form. The title has not created (an issue with the form has been identified and is being fixed - **pending upload.....**).

Found 74 items

<input type="checkbox"/>	Title ^	Filename	Size	Document type	System Version
<input type="checkbox"/>		ACTICCA-1 Master...	87.0 KB	Milestone Report	1
<input type="checkbox"/>		ACTICCA-1 Master...	88.0 KB	Milestone Report	1
<input type="checkbox"/>		ACTICCA-1 PICF A...	47.5 KB	Milestone Report	1
<input type="checkbox"/>		ACTICCA-1 PICF A...	50.5 KB	Milestone Report	1
<input type="checkbox"/>		Capecitabine Prod...	2.9 MB	Milestone Report	1
<input type="checkbox"/>		Gemcitabine Prod...	262.7 KB	Milestone Report	1
<input type="checkbox"/>		Cisplatin Product I...	260.8 KB	Milestone Report	1
<input type="checkbox"/>		DSMB Report 9 A...	1.6 MB	Milestone Report	1
<input type="checkbox"/>		DSMB Report 10 A...	1.5 MB	Milestone Report	1
<input type="checkbox"/>		SAE LISTING NOV...	12.0 KB	Milestone Report	1

In this scenario the RO should (log this with helpdesk – because somethings not right) enter the details in manually, before approving, at the Related Document section.

Related documents

[+ Add document](#) [Bulk download](#)

Title \*  This field is required.

Document type \*

Document version

Document date

Document descriptor

Replace file  No

[Save](#) [Cancel](#)

Found 74 items

Title	Filename	Size	Document type	System Version	Tags	Date modified	Modified by	Relationship
	ACTICCA-1 Master ...	87.0 KB	Milestone Report	1	<a href="#">Add tag...</a>	20/01/2021	Shannon, Jenny	

### The advantages of adding/editing details at the Related Document section?

1. If the Title was missing, your RO won't have a list of documents without a title.
2. If/when any documents are shared with sites they have a title, which makes them easier to identify.
3. The details will pull through to the approval email.

If your RO is manually adding/editing document details to approval emails, a small change to practice to do this in the Related Document section (before you send the approval letter) will give the Research Office, the Researcher and Related Sites consistency and the title of the document will match the letter.

### ETH View

Related documents

[+ Add document](#) [Bulk download](#)

Filters

Search

Document types

[Search](#) [Reset](#)

Found 3 items

Title	Filename	Size	Document type	System Version	Tags
2021/ETH00546: General Amendment (52313) - A...	052313_2021_ETH00546_ General Amendm...	18.5 KB	User Generated Email	1	<a href="#">Add tag...</a>
<b>Master Intervention version 1 dated 08 April 2021</b>	052313_Master_PISCF_Interventional_v1_8A...	104.0 KB	Participant Information ...	1 *	<a href="#">General Amendm...</a> <a href="#">Add tag...</a>
Notification of an amendment to a research study ...	052313_Notification of an amendment to a ...	109.3 KB	General Amendment	1 *	<a href="#">General Amendm...</a> <a href="#">Add tag...</a>

### STE View



## 2021/STE01016 - Test Classification flow - between Ethics and Site

2021/PID00702  
ETH Approved Greater than low risk review pathway

Related documents

Bulk download

Filters

Search 052313

Document types Please select...

Search Reset

Found 3 items

	Title	Filename	Size	Document type	System Version
<input type="checkbox"/>	2021/ETH00546: General Amendment (52313) - Approved	052313_2021_ETH00546_General Amendment (5231...	18.5 KB	User Generated Email	1
<input type="checkbox"/>	Master Intervention version 1 dated 08 April 2021	052313_Master_PISCF_Interventional_v1_8Apr21.doc	104.0 KB	Participant Information Sheet	1
<input type="checkbox"/>	Notification of an amendment to a research study - General ...	052313_Notification of an amendment to a research ...	109.3 KB	General Amendment	1

## External portal view

Documents

Download Export CSV Show 10 entries Search: 052313

	Title	File name	Version	Type
<input type="checkbox"/>	2021/ETH00546: General Amendment (52313) - Approved	052313_2021_ETH00546_General Amendment (52313) - Approved.msg	1	User Generated Email
<input type="checkbox"/>	Master Intervention version 1 dated 08 April 2021	052313_Master_PISCF_Interventional_v1_8Apr21.doc	1	Participant Information Sheet
<input type="checkbox"/>	Notification of an amendment to a research study - General Amendment	052313_Notification of an amendment to a research study - General Amendment.pdf	1	General Amendment

Showing 1 to 3 of 3 entries (filtered from 9 total entries)

Previous 1 Next

## What do I do about Research Office staff REGIS access when they leave?

When a Research Office team member permanently leaves your office, you need to notify the REGIS team via email for that team members access to be removed. If they are moving to a different Research Office, they will need to have their new manager advise the type of access they will require in the internal portal.

## Issue Log

**Issue:** Change in Personnel Amendment form - unable to attach CV. Is this a bug?

**Fix:** As noted above the site amendment form has been updated to allow documents to be uploaded.

## Research Office Contributions

As discussed at the roundtable, introducing this new standing item to the fortnightly email. We actively invite and encourage all Research Offices to share. Created a new resource? Share it. Worked through an interesting query or issue? Share it.

Send through the following to the REGIS inbox [regis@health.nsw.gov.au](mailto:regis@health.nsw.gov.au)

- Short blurb ready to be published
  - describe the issue
  - present the resource/outcome
  - include who should be contacted if anyone has questions

- provide the attachment (if there is one)

Your item will be added to the next email/newsletter.