REGIS Comms – Tuesday 15 June

Welcome back from your long weekend! We have another jam-packed email, full of useful tidbits.

- Education sessions - Research Office and Researchers
- Feedback from Researcher Training – thought you might like to know
- Researcher Training Videos – Yay!
- From little errors big confusion grows – a real life example – change PI
- HREC approved annual reports – communication flows
- Links in email templates - fyi
- Application Preview from internal portal – very useful!
- Future Releases - enhancement and product update
- Enhancement log - current and how to submit
- Researcher Office contribution…….

Upcoming Education Sessions

The next session starts on Wednesday 16 June, if you would like to register for this round, please email the REGIS inbox urgently!

Registrations are also open for August, October and December.

Who should attend training?

- Any new staff that have not attend these sessions should be attending.
- Anyone who hasn't attended training in the last 2 years.
- Anyone who has attended previously and wants a refresher.

Register now: https://ohmrredcap.health.nsw.gov.au/surveys/?s=ARNFJRFXTE

Training Cycle Agenda
Day 1: (AM/PM sessions are mandatory) AM Session: Understanding the system and settings. PM Session: Ethics and Governance Eligibility.
Day 2: Ethics session – Review and Meeting
Day 3: Ethics session – Create decisions from within a Meeting and from the Application
Day 4: Governance session – Review and Authorisation
Day 5: Governance session – Review and process Amendments, Safety Reporting and Milestone
Day 6: Optional session – Managing and updating the Head of Department List

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

Feedback from Research Training

The most common and consistent feedback from Researchers during training has been around the inconsistent use of REGIS across Research Offices. A few examples of inconsistent requests can be seen below;

.zip file.
REGIS supports the submission of .zip files in the applications and forms. .zip files are useful in Site Applications and post approval activity when Ethics is from another jurisdiction (upload the Ethics approved documents in a single .zipfile)

Researchers should no longer be asked to upload a .zip as a response.

Removing all documents for a response
Please do not request researchers to remove all documents and upload only changed documents for a response. Functionality updates in the Omni product update (application versioning filtering) and REGIS 2.2 (Asterix appears on new/updated documents) enable a Research Office to better determine what has been submitted and what is new/changed.

Researcher Training Videos Online

The full suite of Researcher training videos will be available from Monday 21 June on the REGIS website, [Training Content for Users page].

The link will be distributed to all who registered interested in training and will be advertised on the REGIS [website] and [login portal].

Please feel free to distribute the links out to your researcher community.

From little errors big confusion grows

Case Study - Change of NSW PI – incorrect forms/incorrect flows

An RGO emailed our office to report a possible "glitch" *#triggered*. A researcher had submitted a Notification of amendment - Change PI request to the lead HREC in REGIS and the HREC approved and sent off the approval email (so far so good). But RGO did not have a decision to approve/note (not as good).

We are able to work with the RGO to make the manual changes to the system, so the new PI was recognised. BUT WHY WAS THERE NO DECISION FOR THE RGO?

On further investigation the helpdesk noted that the Researcher had chosen "PI (All Other)" instead of PI (NSW Health). So, the expected NSW Health/Site in REGIS workflows didn't kick off.

A simple case of a small error made by the Researcher also not picked up by the Research Office. Something that could have easily happened to any Office.

So a friendly reminder to anyone processing Ethics amendment, when processing a Change of PI make sure they type of investigator is correct.

Clinical trials: please update the CTRA, indemnity form, and local Patient Information Sheet/Informed Consent Form (PICF), where relevant, with the new investigator & name and contact information.	
Type of Investigator *	PI (All Other)
Name of the Outgoing CPI/PI *	Dr Anne Capp
Reason for change of CPI/PI *	Current PI has left/taken extended leave
Incoming Investigator Details other	

Type of Investigator Changing *

Only select one type of investigator for this form. If multiple changes are required please submit a form for each change.

CPI · PI (NSW Health) · PI (All Other)

Site of outgoing PI* · Outgoing PI name*

But as with everything Ethics and Governance this example is not that simple. On this occasion the site was Calvary Mater Newcastle. Calvary Mater is one of 2 Affiliated Health Organisation that are currently in REGIS (St Vincent's Hospital Network is the other).

In this case it's easy to see why the Researcher may have selected PI (All Other) instead of PI (NSW Health) and similarly why a Research Office may have overlooked this piece of information.

So, we have made a very small adjustment to the amendment form, see below.

Type of Investigator Changing *

Only select one type of investigator for this form. If multiple changes are required please submit a form for each change.

CPI · PI (NSW Health/Sites exist in REGIS) · PI (All Other/Non REGIS)

Site of outgoing PI* · Outgoing PI name*

And on the output form.

Sheet/Informed Consent Form (PICF), where relevant, with the new investigator & name and contact information.

Type of Investigator *	PI (NSW Health/Sites exist in REGIS)
Name of the Outgoing CPI/PI *	Kylie Becker
Reason for change of CPI/PI *	
Details of the incoming investigator (NSW Health/Site exists in REGIS)	
Site name *	NSW Health Pathology - site

contact information.

Type of Investigator *	PI (All Other/Non REGIS)
Name of the Outgoing CPI/PI *	
Reason for change of CPI/PI *	
Incoming Investigator Details other (Site does not exist in REGIS)	
Site name *	

What is an Affiliated Health Organisation (AHO)?

An AHO is a non-profit, religious, charitable or other non-government organisations, listed in Schedule 3 of the Health Services Act, to be treated as part of the public health system. An AHO is treated like a NSW Public Health Organisation and is a Participating Organisation under National Mutual Acceptance and can be listed on any NMA HREC's Approval Letter as a Site. There are 14 Organisations that are described as AHOs in Schedule 3 of the Act.

Two currently exist in REGIS as their own LHD/Institutions

- Calvary Mater Newcastle
- St Vincent's Hospital Network

At least one exists under a PHO/LHD as a site:

- STARTTS

A number of AHOs have approached OHMR to become part of REGIS and it is anticipated that they will be in by the end of the year.

http://classic.austlii.edu.au/au/legis/nsw/consol_act/hsa1997161/sch3.html

HREC approved annual reports

For RO that have previously approved a HREC annual report outside of REGIS, if you are manually uploading and sharing HREC approved annual reports the system is not creating the automatic flows so you need to let the CPI/Admin know they will need to alert the PI's/Admins or RGOs to the documents that are now ready to be viewed.

Links to Quick Reference Guide (QRG) in email templates

Previously the link to QRGs that appeared in the email templates would direct the user to the "How To" page and they would then need to locate the document.

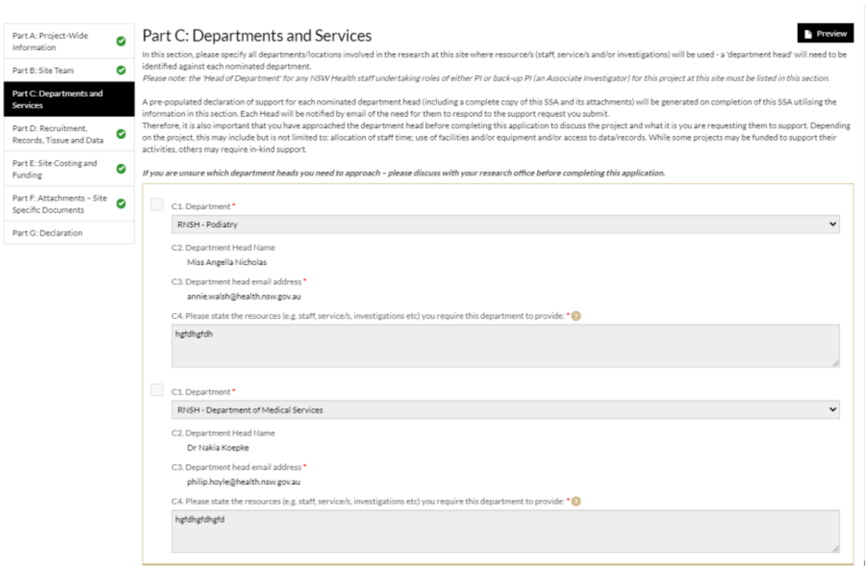
Links were updated last year to link directly to the current document.

Application Preview (see the researcher's application)

Are you ever on the phone to a researcher and they are explaining to you a section of the form and you just wish you could see it? Well YOU CAN!

From the Summary page navigate down to the "Application Identifier" section and click the

This will pop out the current view of the application form



Future Releases

Release date to be provided

Internal Enhancements

Project Registration – Part C Sites, Other Sites - Additional Fields Internal Portal
The sites listed as "Other" at Project Registration and Amendment Addition of Site will appear in the internal portal.

A live clock- summary page
A live metric clock will be available in dashboards, reports and the summary page

Notification of an amendment to a research study – General Amendment
Update general amendments to push to STEs like other amendments.

Milestone Annual Report (ETH) When an annual report/milestone is acknowledged by the HREC it needs to become part of the package that is provided to the sites.
Ethics Decisions – approval emails - When Ethics is in REGIS and there is a flow of documents shared from the ETH to the STE to approval email needs to also become part of the STE document pack.
Forms and related documents flow from the ETH to STE's the approval email should also be included to auto share and become part of the download package in the STE decisions

Related Documents uploaded into any application/form - Currently all 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.
Applications will no longer have a version and date section, researchers will be instructed to put all details into the document descriptor. (feedback sought from the Researcher Interest Group)

Internal Portal – Related Documents Tags
Document type tags will be system generated for all forms submitted.

HREA Team details If the CPI is changed from PR to HREA
HREA rules updated so CPI no longer needs to be in position 1 for the ETH project to be created.

Related Document Tag/token
A token will now pull through the document type and subcategory in outgoing communications.

Related PI/Admin token
Updates to the behaviour of the token

External Portal – HREC upload
The HREC approval upload form is being removed and integrated into the STE form, when Ethics is outside of REGIS.

Meetings – Venue details
A new section in meetings to allow RO to add venue details. This will also pull through to the email template.

Omni Product Update
F1 has sent out their latest What's New document detailing updates and upgrades to the OmniStar platform which REGIS is created. A confirmed date for the product update is pending.

Updates will first be released into our testing environment to allow our team to familiarise ourselves and update any current supporting materials such as quick reference guides and videos. We will schedule information webinars to demonstrate how the product update will affect users.

"*F1 Solutions has continued to develop the OmniStar system for clients around Australia over the last 6 months. In version 5.1 we have added a number of new features to make OmniStar more intuitive and configurable and enable functions requested by users. We have also enhanced a number of existing features to simplify and streamline common tasks, add new and useful information to displays, improve the database, and increase overall performance and reliability.*"

Current Enhancement Log

Attached is the current enhancement log, these are the items that each representative was invited to vote and prioritise at the beginning of this year.

Each item that has a "must have" priority is being workshopped by the User Group and then provided to the Vendor who will provide a quote for each individual request. If the quote is greater that the allocated funds for enhancement the User Group will have to prioritise again.

How to add something to the enhancement log

Got an idea or want to see a change in the system? Great! Your User Group representative is who you need to speak too, they can submit an enhancement request on your behalf.

https://ohmrredcap.health.nsw.gov.au/surveys/?s=T4PA3DEA8X

Research Office

Nothing, zip, zilch, zero…..

Current Enhancement Log

ID	Description	Priority
2020-9	(455) External - Form – Notification of an amendment – Change CPI/PI Description: If the CPI is being changed and is also the PI at a site, the system should pick this up and request if they will be changing in both scenarios Reason: A CPI will often by a PI at a site	Must have
2020-33	Metrics Visibility Research Office Need visibility of clock for each application - VERY HIGH PRIORITY for our HREC. Research Office Need visibility of clock for each application - VERY HIGH PRIORITY for our HREC. a real time count is required to show in the timeline Also (new) Governance 15 day KPI - Would it be possible to add some sort of live tracker to this applications? Some way to check the live time with the Research Office (that isn't the timeline)	Must have
2020-40a	Ability to extract data - we hope we can get that out of REGIS rather than maintain a separate spreadsheet.	Must have
2020-40b	40b Reporting training for interested RO to create own reports or edit available reports.	Must have
2020-52	File size - 1. HREA - When reaching max limit on the form there should be an error message	
2020-80	File size - 1. HREA - When reaching max limit on the form there should be an error message Email templates - REGIS generated email is not easy to read and to check off the documents approved are correct (? Table format would be better) Related items Q134, Q135, Q142 & Q27	Must have
2020-10	Serious Breach - Description: The current New Serious Breach Notification form (third party) separates into two options. 1. Serious Breach Notification Form (Sponsor) 2. Suspected Breach Notification Form (Third Party) Heading to be changed to reflect the two forms.	Must have

2020-18	Meeting Attendees able to provide comments Situation: Ø Created a Meeting Ø Assigned Applications Ø Manage Attendees – Selected 2 Lead Reviewers (names show on screen now "beautiful") the rest of the attendees are nominated as HREC Members. Question: Can one or all HREC Members give feedback on any/all protocols? HREC members only seem to be able to download documents, there does not seem to be any way they can provide feedback within REGIS unless they have been assigned as the Lead Reviewer as they do not get the Reviewer Box that takes them to the Review/Comments fields. it is important that all members of a Committee get to provide feedback and it should be possible to do this in REGIS. Just a thought, Could they put their comments in the "Note Section" or is this section more for the Research Offices?	Must have
2020-41	Visibility of anything - documents, emails etc If we're going to the fix for "downloading" on iPad, I'm guessing it will mean opening the attachments in a browser window. Can this be extended to all documents we would download, including sent emails.	Must have
2020-42	Research Office comment Ability for Research Office Staff to provide their comment/review for committee to see in REGIS.	Must have
2020-46	In meetings the research office can't download/view the forms or documents that have been attached to the meeting. This would be helpful when making notes and sending out email communications to be able to access the documents of the meeting from the meeting Viewing meeting documents from the internal portal - Research Offices need to access the documents attached to a meeting from the internal portal to be able to make notes or finalise communications. RO would like to be able to access the same documents available to the committee from the internal portal. E.g. Applications, Milestones, Projects, Forms – selected documents.	Must have
2020-49	External Portal - Viewing Issues - Ø Submission name view – there is no differentiation between different items that have been submitted so it is very difficult to navigate to a given submission (most appear as" An amendment to….")	Must have
2020-53	File size - 2. HREA - File load limit needs to be bigger (paed have bigger files/pictures)	Must have
2020-97	Updating selection of Site: Currently the application site is selected at the time of Project Registration submission. If the researcher enters the incorrect site at this point there is no easy way to adjust the selection down the track. It is proposed that the researcher should be able to change the site to a different site within the same Centre at the time of completing their SSA. This would allow for the rest of the information on the SSA to remain the same and only the site to change. Points to consider • Up to what point can this be changed? At this stage it is thought that the change could be permitted up to the point of the SSA being made Eligible.	Must have

2020-119a	Agenda and Minutes - Have the ability to build the agenda minutes, the ability to start and save within REGIS a document 119a – have a meaningful agenda and minutes template available in the system. (acknowledging there has been a working group that has completed a suggested template.)	Must have
2020-119b	Agenda and Minutes - Have the ability to build the agenda minutes, the ability to start and save within REGIS a document 119b – currently if you want to make changes to the document it has to be saved outside of REGIS and then reuploaded.	Must have
2020-126	Withdrawn by applicant - when completed in external portal by researcher status should show as “withdrawn by applicant” as opposed to “withdrawn”	Must have
2020-2	More Sophisticated HREC Review processes I am assuming this is having the Review functionality and Meeting functionality talk to each other.	
2020-3	Other Sites listed at PR to be viewable in the internal portal The “other sites” listed in Project Registration and approved by the HREC need to be easily visible in the Internal Portal for the RO/EO to refer back to. XXHREC A lead HREC often extend ethics approval to multiple sites. Many of these sites can be private sites. It is critical to have easy access to a list of the approved sites. This list would sit under “Organisations” in REGIS.	Must have
2020-19	Document Types for Attachments is possible to have one of the document types for attachment in REGIS as a Waiver of Consent	Must have
2020-20	Search on meeting attendance We would find it supper helpful if we could search on which committee members attended which meetings. At the moment we can search to see which ones that were invited to. Is it possible to include the attended field on a yes, no, maybe selection? No biggie, but it would help enormously with our accounting. e.g. pull a report?	Must have
2020-21	Amendment Application Reference I noticed in the “notification of an amendment to a research study” document the application reference is the same as HREC Reference number. I was thinking it would be helpful, if possible, for the Application reference to be the Form Identifier.	Must have

2020-24	Internal Portal - Meeting Decision - Progress to next meeting We have some applications which go to the Scientific Sub-Committee (ScSC) and then through to full HREC for review. Is there a way we can mark these applications as “ScSC recommended the application to full HREC” without making a final decision on the application/meeting until it has been to full HREC? Is this possible for future enhancements? We have some applications which go to the Scientific Sub-Committee (ScSC) and then through to full HREC for review. Is there a way we can mark these applications as “ScSC recommended the application to full HREC” without making a final decision on the application/meeting until it has been to full HREC? Is this possible for future enhancements? We have the ability it config to set status in internal portal that are not seen in the external portal. Should also be able to config another decision/workflow to show this	Must have
2020-29	Ability to provide notes to help the EO or research office to process the application according to the committees wishes Sometimes the committee will specify a condition that if satisfied will deescalate the level of review eg ‘If they agree to use de-identified data it can be reviewed by EO otherwise it must come back to HREC.’ It would be good to have a place to keep such notes.	Must have

2020-133	Governance Post Approval - 2.2 tighten up - Ethics General Amendment - On approval the Ethics General Amendment Form, supporting documents and approval email should auto share with all sites. Ethics approval annual report (ethics in REGIS) - the milestone approval email should auto share with sites. When more information is submitted is should auto appear in the document download section of the decision. this is happening for some but not for all. Annual Report from an external jurisdiction - currently RO have to manually create the milestone for the researcher to submit. either there needs to be an option in the external portal for the applicant to create the milestone or we need to work out a rule for when the milestone should be auto created. COC - currently a COC milestone is only created for the first STE. On noting the documents are shared with the other RGOs but no decision is created or other notification. Should a decision be created that the RGO can tick off or could this be a task created to remind other RO to confirm a COC has been submitted? Site General Amendment - Currently a researcher MUST submit the ETH general amendment and then a STE general amendment. If the study is a single site this is a duplication of effort for the researcher. It is also a duplication of effort for some research offices who would approve the site documents at the same time. There needs to be a simplified way to submit for single site studies.	Must have
2020-144	Single Site Post Approval General Amendment now seems more complex because the ethics and site amendment form need to be submitted separately. There needs to be a streamlining of this process.	Must have
2020-138	Ethics - Noting Documents - A form type for documents to be noted by an HREC. Currently we manage noting documents via the general amendment pathway and request applicants be clear in identifying that the submission is for HREC noting only. This works at the moment but would be nice to have a specific HREC noting form for applicants to manage the submission of DSURs, annual DSMB outcomes etc.	Must have
2020-136	Administration Contacts for ETH - Think we could tidy up the Administration Contact in HREA, currently they have to tick they are the contact for the study and then select “Other” and then enter type of contact, Why can’t we have “Administration Contact” in the list to select. Potentially add to the PR asking to confirm who the admin contact is and then mapping to the HREC like with CPI and PI	Must have

2020-43	Amendment reviews While amendment forms can be assigned to meetings for decision, it isn’t possible to set up reviews for comments and questions - this would be a useful feature. Is the database structure such that the review function is only possible with applications and if so, can amendments be submitted as an application? Or would it be possible to have forms linked to the review process somehow? OR have the ability for committee members to make comments/decisions into a meeting.	Must have
2020-45	Access Requests Ability to process access requests in REGIS	Must have
2020-76	Decision errors in Meeting - If the wrong decision is made (or a decision made at the wrong time) for an amendment form in a meeting, there is no easy way to change the form’s status back to ‘Assigned to meeting’ . (forms don’t have a status but I think this refers to not being able to undo a decision outcome?)	
2020-96	Make Changes in Internal Portal - Move to all Applications - There are a number of changes that can be made in the internal portal that should automatically flow through to all applications/projects. Some include • CPI and PI • Sponsor • Some status * classifications	Must have
2020-100a	HOD to indicate that they are not making a decision Enhancement - If a HOD is incorrectly selected, they should have an option that indicates they are not the correct person and are not making a decision. Potential ability to indicate who should be included.	Must have
2020-100b	100B – HOD can delegate (create a rule) for xx timeframe that XX person can make the decision.	Must have
2020-107	Process to change the PI for an in progress SSA. - currently if a HREA is approved and a STE is “in progress” the change PI process can not be used.	

2020-108	Homepage tiles - a review and update (all obvious homepage requests have been merged into one) Homepage search/filter options - RO to have ability to control Boolean logic/complete own formula - when filtering homepage tiles Forms requires functionality review - The Amendments tile does not show enough information in regard to the type of amendments, what project they are for and when they were submitted. Also does not show the status of the amendment (i.e. submitted, in progress, approved) Review tile requires functionality review The Reviews tile is also not helpful in that it does not show the date the review was submitted or whether the review is overdue. We have had to keep separate spreadsheets to maintain this information so that we don't fall behind or miss any application Ability to have multiple homepages. Ability to add notes/descriptor to each homepage I have too many tiles on the home page to manage effectively, I'd like more than one home page - say one for ethics, one for governance - possibly more. The way items move from tile to tile becomes complicated and confusing it is difficult to remember and keep track of how and why we set the various logic formulas the way we did. Each tile should have a space a not can be added giving a comprehensive description of how it should be used and why. It's often unclear how the various fields work when programming the tiles - e.g. if adding multiple tags to a field 'with tag' is this 'AND' i.e. only returning items that have all the listed tags, or 'OR' i.e. returning items that have any of the listed tags. Previously we noticed some of the fields (in forms tiles I think) were detecting tags on the application or project as well as on the form. Much clearer information is needed about how the fields work. It's currently not possible to sort form by low risk or greater than low risk - because now the field has been 'corrected' to not include tags on the project - so this is another area that we have to manually sort forms by adding our own tags - which is redundant with the system tag on the project. Update Review tile to show Identifier and then description Reason: Consistency amongst the tiles, the Review tiles is the odd one out Proposed Solution: Update review tile to have consistent ordering of columns Update all tiles to show Identifier then Application Title Reason: The Round / Program does not add value here; it would be more useful to show a truncated title Proposed Solution: Update the columns displayed to be Identifier and Title. ability to hide/minimise/move page edit currently on the home page the first widget on the second row is obscured by the page edit. Have the ability to display the CPI's surname (e.g. Identifier-Surname-Title) for an application. I know the CPI surname is visible if you hover over Application Title, but is it possible to add CPI Surname to the columns being displayed? Or to search Applications by CPI surname? (801) Tiles While the date modified order (ascending/descending) is helpful, it would be useful to have the Date and Time modified visible on the tile as an at a glance feature to assist workflows in the office* Tiles - Assigned to Meeting' - we need to see the meeting date. Tiles - Should have a number in the top corner showing how many items in the tile. similar to an app that shows how many notifications	Must have

2020-143	Forms submission (other than ethics amendment) - When a form is submitted for ethics or site a tag should be automatically created on the form and related documents similar to the ethics amendments. e.g. site amendment, safety notification, local safety. it should relate to the type of sub document if there are types. e.g. ssi, usm, local safety, site general,	Must have
2020-146	REGIS status - Status definitions, especially once the SSA/HREA is approved. It used to be open/closed in this research office but now there are a lot more options. Are they all necessary or can we have an exercise where we reduce some of the options? Just as a sample, some status options include suspended, halted, declined, suspended (COVID), declined, Pause (COVID), potential, successful. Complete/closed post	Must have
2020-147	Progress Final Report Status - In particular, the progress/final report status seems to be confusing for users and I'm not sure there is benefit in changing the status of the HREA/SSA post approval – I mean open/closed seemed to work okay here. The "completed" and "closed" statuses causes a lot of confusion, people often report a closed study as completed… personally, I think the definitions as written in the QRG may be confusing to some readers, particularly novice clinician researchers, and I am pretty sure that come the end of the study, no one is looking up the definition in the QRG to ensure they have it correct for the HREC or REGIS. I also think, closed (post analysis) but not yet archived is confusing – is closed not when the final report is presented to the HREC?	Must have
2020-39	Application timeline to include emails sent Please include the subject line of Communications sent to the Researcher in the Application Timeline. At present the Timeline just shows project status changes, but as changes can be made without communications sent, there isn't a simple way for a Research Office to see if a communication has been sent, when and by whom in the Research Office. The "History" display is probably more useful for an IT person, but not for a HREC administrator.	Must have
2020-56	Internal portal - Decisions - internal portal - when a decision that is always based off a form is selected the entity should auto change to the most selected entity e.g. all amendments should be selected against the entity project related form. Reduce clicks and errors.	Must have
2020-68	Decisions - Why do we have to enter 'user' this should be the name of the person logged in unless otherwise indicated. Seems preference is user that is logged in auto shows.	Must have

2020-118	Internal portal - decisions made in meeting should show email sent icon in decisions. Currently if a decision notification (e.g. amendment) has a decision made in a meeting the decision shows in the application/project decisions but it appears as the email has not been sent as the email sent icon does not show. This can lead to confusion around if a decision notification has been sent. The icon should also show in Decisions if sent at a meeting.	Must have
2020-151	Milestone processing bulk emails document token. Year of progress report attach milestone report to outgoing email Ethics committee token	Must have
2020-152	Milestone – with the introduction of the milestone reminders – have XX reminders with warning that ethics approval will be revoked – this would need to flow on to any sites in REGIS. related PIs.	Must have
2020-153	Output forms Where the form shows an ethics expiry show visually when expired e.g. show date in red when expired. Show warnings on researcher form view that HREC is going to expire in XX months.	Must have
2020-15	External Portal - auto popup help text unless select not to receive To increase the users reading the help text to guide them through PR/HREA/SSA and any related forms the help text should appear automatically. There would be an option to opt out/not receive the auto help text. This is based loosely on the digital adoption platforms that use AI to guide users through a system to increase engagement. To increase the users reading the help text to guide them through PR/HREA/SSA and any related forms the help text should appear automatically. There would be an option to opt out/not receive the auto help text. This is based loosely on the digital adoption platforms that use AI to guide users through a system to increase engagement.*	Should have
2020-17	Use quick search to find related forms Research Office staff would like to be able to use the quick search at the top of the internal portal to locate a related form ID (eg an amendment form). Research Office staff would like to be able to use the quick search at the top of the internal portal to locate a related form ID (eg an amendment form).	Should have
2020-61	Status - Should also include the date the status changed .* Question Preview	Should have

2020-95	External Portal - Access Issues: Having two forms of access (application and Project) is confusing the CPI's (Application and Project access should be one in the same) if you have access to application you should then be able to access the project once approved by HREC	Should have
2020-32	Logic to only allow specific HRECs be selected for early phase clinical trials If this mod happens, please consider including any data linkage projects to be directed to PHSREC. I havent had enough time to think through all possible consequences so let's talk if this looks likely.	Should have
2020-34	More functionality for Research Office to note & manage COIs At the moment there is "COI" information on the Review page, but I have no idea how to do anything with it/change anything on the page. Also, it would be good to have this information imported on to the Minutes. At the moment there is "COI" information on the Review page, but I have no idea how to do anything with it/change anything on the page. Also, it would be good to have this information imported on to the Minutes	Could have
2020-35	Cross-talk between Reviewer Comments and Meeting Commnents & Decisions / Suggestion for "Guidance for Research Offices" manual We need better cross-talk between the Reviewer comments, the Meeting Comments & Decisions steps and the Decision email sent to researcher. For example, the Reviewer feedback gives a field of "anything you want to send back to the researcher"? But where is this captured for the Research Office to follow up? If I tried to run a meeting in REGIS, entering Comments, Decisions etc. as it was unfolding, it would be next to impossible. It would be good if this sort of workflow could be entered into the "Guidance for Research Offices" Manual.	Could have
2020-36	Is there a way to filter out Meetings without making them inactive? If XXHREC places its 11 Full HREC meetings and ~40 Executive Committee meetings into REGIS, it is quite difficult to filter/sort through upcoming meetings when they are all active. So most future meetings have to be made Inactive. Is there a way to sort Meetings for a particular date range without making them inactive? Ethics - Completing Meetings - A way to filter out completed meetings from view both on the administration and reviewer side	Could have

2020-37	Population of Decision Emails with Reviewer Comments Need ability to bring Reviewer Comments from Meeting-Application Notes over to Decision email - OR if this function is available, please provide more description at the top of the Comments/Additional Notes box. When conducting reviews, and filling out Comment boxes, it is not clear at which point said comments will be copied into Email template/Meeting documents. So you don't know whether to copy the same comment over each time, or whether there are specific requirements at each point.	Could have
2020-38	Customisability of Decision Pending email template The Decision Pending Further Information Email template needs to be more customisable with links to Meeting date etc. It would be good not to have to copy this multiple times for each email	Could have
2020-47	External portal ○ Have buttons/actions such as decisions and forms available when you click on the three dots next to the application/project. ○ All columns should be auto visible or move order of columns e.g. decisions you have to zoom out (intuitiveness issue)	Could have
2020-48	External Portal - Viewing Issues - Ø Project name display- is truncated (we currently have 13 studies in Start up, 20 recruiting and 29 in follow up) makes it very difficult to navigate to the trial you want	Could have
2020-50	External Portal - Viewing Issues - Viewing- once a form is submitted you cannot view this, if you have questions you have to download the attached documents to see what you are looking at A form can not be viewed in the same way an application can be after submission	Could have
2020-51	Internal Portal - locked applications - Locking applications/project - why in some sections do you need to click on the red X to unlock the application.	Could have
2020-54	File size 3. HREA/STE/Amendment - Unable to upload video files into the application form (pediatric specific) - f1 config change	Could have
2020-55	External Portal - email select - AUTO select email to be viewable in external portal	Could have
2020-57	Search screens - There is no advantage to having a separate search screen for 'projects' and 'applications' - if needed it could easily be an options button or dropdown list selection.	Could have
2020-58	Search screens/ Search Bar - the options button/list should be closer to the 'find' button	Could have
2020-59	Indemnities/HREC Only Indemnities - REGIS should automatically detect and prompt when HREC Only Indemnities are required	Could have
2020-60	Dates - Should sort in chronological order (as opposed to apha-numeric)	Could have

2020-62	Related documents/ Meeting Invitations - Emails to committee members should not be added to 'related documents' for the applications reviewed at the meeting.	Could have
2020-63	Metrics – Date trial activated – NEW Description: · Commercially Sponsored Clinical trials are required to have been activated at site within 30 calendar days of site authorisation. · Required for commercially sponsored clinical trials. Optional for all other clinical trials. · The PI needs to be able to add this data point in to the external system. · Perhaps a new milestone is created with an automatic reminder at 30 calendar days after site authorisation. · Data point needs to be collected to be reported on but does not need to be represented in a status change. However, it might be nice to be seen in the history? Reason: Site Activation = The date that the Sponsor has notified the site that study activities, including recruitment, can commence at the site. For clinical trials, this is sometimes referred to as "green light"	Could have
2020-64	Correspondence Correspondence and related documents should be in separate areas	Could have
2020-65	Eligibility assessment report - Eligibility assessment report' should also show the email/corro sent to the investigator	Could have
2020-66	timeline, meetings, documents and everything - A comprehensive visual representation would be good - eg a flow diagram showing each round of review, the meeting it went to, the feedback generated (and where delegated to), and for each round, the response submitted including any updated documents with version number etc, and so with each subsequent round. This is the at-a-glance visual that EVERYONE want's. Ideally - each visual component is clickable - and linked to the eg document, meeting, feedback etc. The visual could (probably should) have collapsible /expandable components.	Could have
2020-67	Left side menus - Why do we need a separate section for 'management' and 'details' when there are only three items in Details - put together to make less clicks	Could have
2020-69	amending and editing docs - When uploading an 'updated document' either as amendment or response to initial review, REGIS should ask for a tracked changes version - if none available can be uploaded later, or justification can be provided by the researcher.	Could have
2020-70	Approving application -managing documents - Having the rubbish bin symbol on the opposite side of the screen from the document title frustrating - difficult to be sure of what you're deleting - adds time and effort to what should be a simple task. (there were some document management enhancements that would have helped with this in 2.2. but was removed as taken out due to budget.)	Could have

2020-71	Timeline - If F1 (or anyone else) does things that change the time line (e.g. submitted-in progress-submitted, eg see 2019/ETH11753) info needs to be added so we know documents have not changed - esp if we had already assigned it to a meeting.	Could have
2020-72	EO Review - Unlike with a meeting, there is no process to make this easy, no packaged response documents and easy referal back to queries.	Could have
2020-74	Commercially sponsored clinical trials - Standard indemnities and HREC Only indemnities shoud be managed in REGIS, the medicines Austraila versions should auto populate and prompt the coordinator to get them completed.	Could have
2020-75	EO Review/Approval - there is no way to manage and responses to EO when needed	Could have
2020-77	External portal - Log in message - tone down the licence system warning on the login. Apparently I can be “prosecuted to the full extent of the law” on login and are being monitored at all times. I have a number of junior doctors who are reluctant to submit ethics due to the many unknowns of the process. Presenting them with that message immediately on login isn’t the friendliest way for them to commence an application. Most applications require multiple edits, and new applicants are not entirely sure how to answer some of them on their first attempt, but could they still go to Golburn prison if they save an inappropriate answer? Most of us do not want, following many years of study at medical school and postgraduate work, to end up in front of court because we clicked a button wrong. Can consideration please be made to have a slightly more approachable login message. Or alternativly, could be a list of chargeable crimes and possible penalties including length of jail terms could be added as “full extent of the law” isn’t really that clear	Could have
2020-78	External Portal Searchability - Search ability is a problem when you have multiple studies. Search functionality needs to be expanded from PID number alone. Most studies have a study acronym which should be viewable and would be more useful than full title /reference numbers in terms of search ability (the RO can add a short title to the application - wonder if having an option to add a short title/acronym at PR would help)	Could have
2020-79	External Portal Searchability - PID number listed as the identifier on main page. This is generated at project registration but the number is not displayed/recorded on any other document produced by REGIS. The Ethics application has an ETH number and the SSA applications have an STE number. This makes it very difficult to locate a particular project. You can only search on PID numbers.	Could have

2020-81	sharing - Sharing projects – in some instances the project is shared with edit access but the account it has been shared with cannot access the project. This involves a call the HREC office for them to investigate the issue, takes up everyone's time.	Could have
2020-82	External portal document download - Downloading documents - REGIS is inconsistent in what it will download depending on the method chosen. The advice is to click on the 3 dots and choose 'download application'. The 'download application' does not always appear. When it does, the file does not contain the actual HREA – which is quite important for the sponsor. When using the "Preview" method on the ETH application the download contains	Could have
2020-83	External portal - Approvals are difficult to find and even more difficult to download, here is the method our HREC office devised because nothing else works: 1. Tick and download the document 2. Open the zip file 3. Right click and copy the folder 4. Paste to your desktop 5. You will get an error message, click 'skip' 6. Open the folder 7. Open the file	Could have
2020-84	External Portal - Submission acknowledgment email – Can the system be configured to always provide an acknowledgement with A zip file of submitted documents? Sometimes it does include the zip file, others it doesn't. it is essential that sponsors see the whole Submission and the system zip file is the best way to provide evidence of what was submitted.	Could have
2020-85	External Portal - editors can share application - 1. Allow the CPI to delegate administrative tasks on the system a. eg allow edit users to invite people to register b. eg allow the research office to share project (they can only share application)*	Could have
2020-86	External portal - An area on the dashboard where notifications are listed (and not just as emails to the CPI)	Could have
2020-87	External portal - how to use the notification centre (bell icon at top right of page) - list notifiacations	Could have
2020-91	External portal - Remove the warning messages that appear (twice) when you want to leave a page	Could have
2020-92	Visibility of anything - documents, emails etc If we're going to the fix for "downloading" on iPad, I'm guesiing it will mean opening the attachments in a browser window. Can this be extended to all documents we would download, including sent emails.	Could have
2020-93	External Portal - Lack of pertinent detail for identification purposes: Ability to click on a user to see who they are, where they're from. Identification on STE/Forms/PID in the system is by CI or PI email address (not even the person's real name) At large centres we don't deal directly with the site PI, more usually the site coordina	Could have
2020-94	External Portal - Access Issues: Access to all forms listed if you have edit permissions	Could have

2020-99	Updating Site Details when new site button used - If the new site button is used (pre ethics approval) there is no document created to indicate a new site was created. Can the new site form have an output that also lives at the PID level? And sites listed in eth approval letter should be adjusted. Recommendation: Business rule to be scoped.	Could have
2020-102	External Portal In the Project view in the external portal there are three column that will never show data “Overdue Milestone”, “Revision Milestone” and “Total Milestone”. These should be removed/hidden from this view.*	Could have
2020-103	External Portal - Change “Invite user to register or share application” simply to “Share Application” similarly change the menu option wording from “Invite user to register or share project”to “Share Project” This has been an issue for 99% of our CPIs when requesting they share the project.	Could have
2020-104	External Portal User Experience - Is it possible for users to be able to change their default display setting for number of projects? Currently, every time you log in, REGIS defaults to only showing you 10 projects, and you have to manually select that you want to view more (25, 50 or 100). For those of us managing many projects, we have to change the view every single time we log in. Can this be updated?	Could have
2020-105	External Portal User Experience - Under “Milestones”, is it possible to please provide the respective project title? When you are working with >50 projects migrated over to the REGIS system, it is very difficult to identify what project each of the upcoming milestones are referring to (at present, you have to go back and manually search through ETH reference numbers to find the corresponding project)*	Could have
2020-110	In Progress - It is not possible to add comments or tags (and possibly and other functions) as may be necessary to administer the application (e.g. to flag a necessatry action in the next round) while the status is ‘In Progress.’ Please unlock for internal portal those aspects that do not directly impact on the review and timeline.*	Could have
2020-112	Amendments - When reviewed at a meeting, it would be great if the the currently approved protocol and main PIS&CF (or other core documents) were aoutomatically included as reference documents.	Could have
2020-113	File Names -Whether created by REGIS or the investigatro a strict limit on the lenth of file names is needed.	Could have
2020-116	Information Provided - Responses to Queries/requests from committee could e submitted using a form in a manner simmilar to an amendmet - this could provide a means of organising and tracking the documents and updates from meeting to meeting.	Could have

2020-121	Locking Documents it is probably a good option if we have the ability to “lock” documents that we think are final, so that the researchers can’t update them anymore and if they do, they’ll have to request us to unlock or add a new document instead.	Could have
2020-122	Selecting Documents for HOD Request it would be great if I could “Select documents” from “Related documents” – for existing (but unprocessed) HOD decisions.	Could have
2020-123	External Portal - Project Registration Expiry Date - Submitted PID and the expiry date was showing the following date, this makes it seem like I need to submit my whole application by then - can this be more clear?	Could have
2020-124	When the milestone/Annual report is processed as approved it should auto attached to approval email	Could have
2020-127	when adding a milestone to a meeting have status or form id	Could have
2020-128	ability for RO to open and edit a document in REGIS rather than having to save to external drive and resave into REGIS	Could have
2020-129	Review form for CE integrated into REGIS internal portal - We have adapted the “Review Form SSA for NEAF” (https://www.medicalresearch.nsw.gov.au/site-authorisation/) which we complete when reviewing each SSA and upload for our CE/Delegate when requesting authorisation. It would be great if this could be adapated to some sort of checklist within REGIS	Could have
2020-131	Chair able to make comments - REGIS does not allow the sharing of amendments with the Chair outside the establishment of a formal meeting. Our process has always been to email amendments to the Chair as they come in, and not have a formal executive meeting. Our Amendment Process is as follows: The Executive Officer downloads the Amendment documents from REGIS and attaches to an email to the chair; The Chair reviews and sends an email response back to the Executive Officer which is then uploaded into REGIS; The Executive Officer either applies the Decision in REGIS, by either ‘Approving’ the Amendment or sending a ‘Request for More Information’ to the researches through REGIS. It would be good if the Chair was able to access an amendment and make a decision against an amendment. We believe the functionality is there in REGIS for this type of process, it would be not dissimilar to the CE Decision making process.	Could have
2020-132	External portal Sharing - The current rules around who gets auto shared with aplications/project is confusing. We need to simplify, this is a major pain point for researchers.	Could have
2020-137	Ethics - Withdrawing Amendments - Whilst we recgonise that amendments can be unsubmitted, it would be nice to have the functionality to withdraw them as you can with new applications.	Could have
2020-139	Ethics - Forms - Allow forms to be deleted by researchers	Could have
2020-140	Document Management - It would be good if contacts could be electronically signed in REGIS	Could have

2020-141	External Portal Document upload - It would be great if there was a way for applicants to drag and drop multiple documents into the forms	Could have
2020-98	Move HOD Decision to Project Registration - Currently the application HODs are selected during the completion of the SSA, it is believed that moving the HOD decision to the Project Registration form so that it is completed at the same time as the sites are selected would minimise the chances of an incorrect site being selected. This is a consideration as an alternative to the above change of making the site within the SSA form able to be changed. Areas of consideration: Move the HOD management to the research office as an option, LHD site structure – simplify site and sign-off structure, HOD upload option – to allow the changes of HOD to be imported.	Won't have
2020-101	RO want a better visibility over if where the ethics application is up to in REGIS - if in progress - why? Ineligible or request for information.	Won't have
2020-111	Managing Amendments - Amendment forms should have their own timeline graphic - occasionally it may be necessary to combine amendmet timelines - e.g. where amendments are submitted simultaneously and interact.	Won't have
2020-114	Managing meetings - Where the office process for adding items to a meeting is some what complex (eg an office review, then pre-meeting review) it would be useful to have a way to manage the items proposed to go into the meeting - such as a holding tank, status 'tentatively assinged to meeting'.	Won't have
2020-115	Contacting researchers - Since researchers seem to refuse to add their phone numbers to REGIS, it would be useful to have our own contact card file thet we can maintain. (or make adding certain details mandatory)	Won't have
2020-117	Internal portal - Related Documents - Sharing - The ability to select the entities that a document is shared with. the share with related entity button and then select which entity to share with. e.g share with 2 of the 3 sites only.*	Won't have
2020-120	Reporting/Metrics build a process in REGIS to capture metric 9 and metric 11	Won't have
2020-125	RGO decision - have a RGO Recommended and Authorised single decision. This is to allow RGO who have delegated authority to do in single step	Won't have