

HEALTH+MEDICAL RESEARCH



# REGU/REGIS Newsletter | Issue 16 | 1 September 2023

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## Ethics and Governance KPIs

**Audience:** Research Office



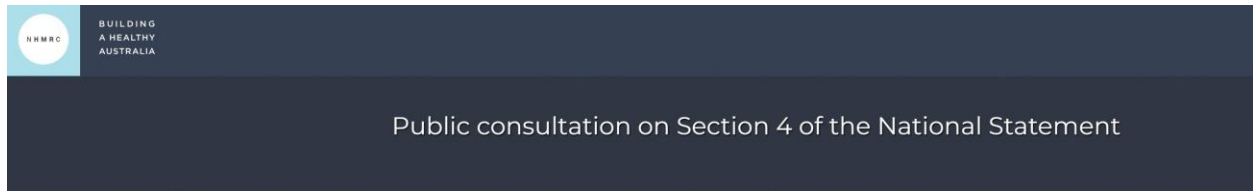
The Ethics Application Approvals and Research Governance Application Authorisations measures set out in the *KPI and Improvement Measure Data Supplement 2023-24* have remained unchanged from 2022-23.

HREC Approval KPI will continue to be measured within 90 calendar days and Research Governance Authorisation KPI within 60 calendar days.

Consultation conducted by System Purchasing Branch during the first half of 2023 canvassed moving the KPIs to 75 and 45 days respectively. Taking into account a number of considerations, including feedback received during the consultation round, the decision was taken within the Ministry to retain the current performance thresholds.

KPI information can be found on the secured Health Information Resources Directory (HIRD) metadata repository maintained by Systems Information and Analytics Branch within the Ministry of Health.

## Public Consultation on Proposed Revisions to Section 4 of the National Statement



**Audience:** Research Office/Researchers

The NHMRC is keen to ensure that the Australian community has the best opportunity to participate in developing guidance on the ethical design, review and conduct of human research and is conducting a public consultation on proposed revisions to Section 4 of the National Statement on Ethical Conduct in Human Research.

NHMRC is also proposing the inclusion of revised language in other sections of the National Statement to support the update to Section 4. Developed by NHMRC's Australian Health Ethics Committee, the revised Section 4 provides advice for both researchers and Human Research Ethics Committees (HRECs) addressing ethical considerations specific to participants in research.

Interested parties are invited to provide feedback on whether the revised section provides sufficient guidance to address the key ethical considerations specific to participants in research and is presented and written in a manner that is appropriate for the target audience (researchers, HRECs).

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*[You can provide your feedback here](#), with this public consultation closing at 5:00pm (AEST) Friday 15 September 2023.*

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## InFORMed Template and User Guide

**Audience:** Research Office/Researchers

The InFORMed Project template was created with the intention of facilitating a participant-centric, streamlined, nationwide Participant Information and Consent Form (PICF).

The team behind the CT:IQ InFORMed Project has devised a condensed and considerate PICF template for conveying research-related details to participants. This template serves to empower participants in making well-informed choices regarding their potential involvement.

The overarching goal is to enhance the effectiveness and influence of health and medical research within Australia. This objective is pursued by simplifying the decision-making process for individuals interested in taking part, thereby contributing to improved efficiency and impact.

You can read more information about the project and review the template and user guide [here](#).

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*If you would like more information around this project, please contact Dr Lisa Eckstein, CT:IQ Programme Director: [lisaeckstein@bellberry.com.au](mailto:lisaeckstein@bellberry.com.au) and if you have any feedback, [the CT:IQ InFORMed Project team would like to hear from you!](#)*

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## Knowledge Share: Certificate of Currency Milestones in REGIS

**Audience:** Research Office/Researchers

A current Certificate of Currency (CoC) is required to be kept on file for all Commercially Sponsored Clinical Trials. The CoC is the same document across all sites. In REGIS, one site, which is always the first authorised site, submits the CoC. The system automatically creates a CoC milestone for the first authorised STE, upon authorisation.

As only one CoC milestone is automatically created, this can lead to confusion for related sites and researchers. This can also lead to scenarios where Researchers ask their Research Governance Office (RGO) to manually create the CoC milestone which results in unnecessary and additional CoC milestones.

Important things to remember:

- The first authorised site has the CoC milestone automatically created
- The first authorised site submits the CoC milestone
- Once the CoC milestone is submitted and processed by the Research Governance Office, it will then be visible to all related sites

**Q:** What happens if I cannot see the CoC milestone?

**A:** If you cannot see the CoC milestone, this would usually mean that another site was authorised first, and will have the milestone created against their STE and is responsible for the submission. The site that is responsible for the milestone, will have the milestone appear on their homepage within their 'Top 5 Milestones Due' and in the Milestones section of the STE project.

Applications Details Forms Milestones

Project milestones are on this page.

Export CSV

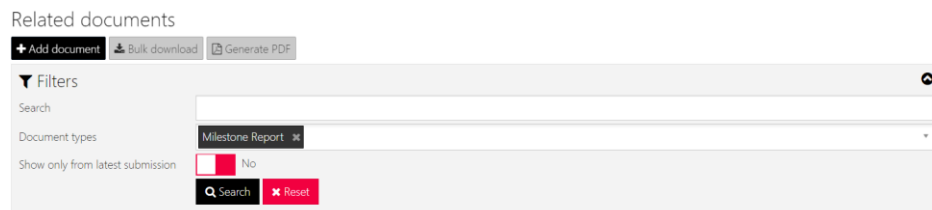
IDENTIFIER	MILESTONE TITLE	DETAIL	ORGANISATION	STATUS	DAYS REMAINING	DUE DATE
2022/STE00031	Certificate of Currency		Gosford Hospital	Pending	-3 days	29/08/2023

For migrated studies, a CoC milestone may need to be manually created by the Research Governance Office for the first numerical site, under the Milestones section within the STE Project.

**Q:** Why can't the Research Governance Office see the CoC document?

**A:** If the CoC was submitted via the milestone and processed correctly by the Research Governance Office, it should be automatically visible to all related sites Research Offices; it does not need to be made 'visible' and a new milestone should not be manually created by any related site. Currently, the related sites Research Offices do not have an RGO decision created as only a single Research Governance Office is required to approve it, the related sites will be able to view the CoC document and approval email via the Related Documents.

**Quick Tip for RGOs:** To find the CoC, navigate to the STE Project, select Management and then Related Documents. Within the Filters section, search for Milestone Report in the Document Types drop down menu and then select search.



You will be able to see if one has been submitted and approved within the last 12 months. The Researcher should have confidence that the Research Governance Office can see their CoC and from a legal perspective, there is no issue if the Research Governance Office cannot see the CoC, the sponsor will still be covered by their insurance policy.

## Research Support Coordinator (Research Governance Officer) Role - HNELHD Research Office



**Audience:** Research Office/Researchers

The HNE Research Office is seeking applications for a permanent Research Support Coordinator to provide a range of activities that assists in the facilitation and effective operation of the HNE Research Office, particularly Research Governance.

- You will be working in a role to improve health services through supporting research and innovation and will provide high level support to assist the functioning of the HNE Research Office.
- You will predominantly be responsible for the duties of the Research Governance Officer which include but not limited to review/recommendation of site applications/access requests and standard research contracts ensuring compliance to local, state and national policies and guidelines.

Please access further details and application via: [Research Support Coordinator Job in Newcastle, Newcastle, Maitland & Hunter NSW - SEEK](#)

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*For role related queries or questions contact Kristy Morris on [Kristy.Morris@health.nsw.gov.au](mailto:Kristy.Morris@health.nsw.gov.au)*

***Applications close: Tuesday 5 September 2023***

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## Research Office Contribution

WSLHD - The team are working on an amazing contribution for next time - looking forward to it!

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*Up next is JHFMHN! We look forward to your contribution for Issue 17 - 12 September 2023*

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## Researcher/Coordinator Contributions

Are you part of a research team that has created some great resources or worked through an issue or teamed up with your Research Office to streamline a process? We know this newsletter is going out far and wide AND we also know YOUR colleagues would love to hear what you've been doing. Feel free to send in a short blurb about what you're up to and we'll sing your success from the rooftops!

## Upcoming events and dates

**Audience:** Research Office/Researcher



## 2023 Events and Dates

**Researcher Training:** The final training cycle for 2023 is scheduled for **September**. [Register your interest here.](#)

**September:** The forthcoming HREC Chairs Meeting is scheduled for Friday 8 September.

**September:** The forthcoming Ethics and Governance Bi-Annual Roundtable is scheduled for Friday 22 September. Invitations and agenda to be sent two weeks prior.

## Previous Versions of REGU/REGIS Newsletter

**Audience:** Research Office/Researcher

All previous version of the fortnightly email are available from the REGIS website: <https://regis.health.nswT.gov.au/news-and-events/regis-office-webinars/>

*REGU/REGIS Newsletter: Inspiring other units within OHMR and LHDs since February 2021*