REGU/REGIS Newsletter | Issue 21 | 12 November 2024
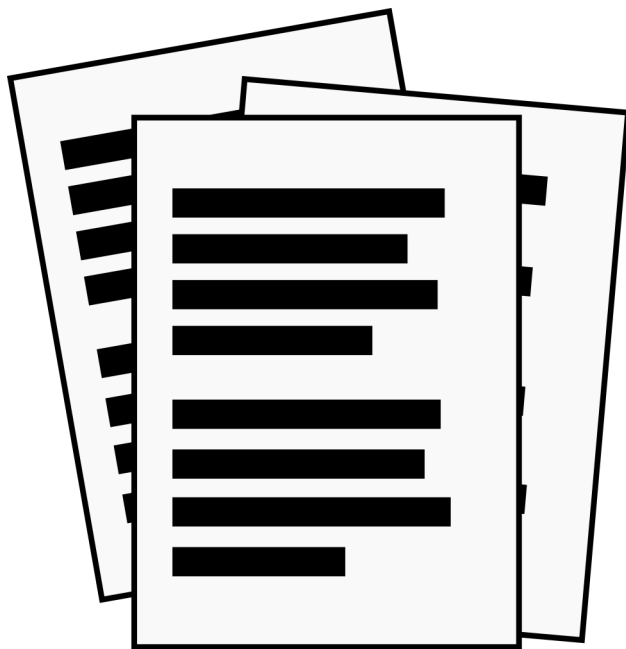
In this issue

Research Office Supplementary Post Approval Forms Request

Audience: Research Office

The National Mutual Acceptance (NMA) Group is putting together a working group to draft a suite of NMA post approval forms. We understand that some research offices have introduced supplementary forms to fulfill local requirements. We ask that you **please send a copy of any of these forms to** MOH-ResearchEthics@health.nsw.gov.au with a short description of what they are used for and why they are needed so we are able to ensure a full understanding of the actual needs of our research offices when these sessions begin.

NSW Health Policy Spotlight: NSW Health Accessible Communications Policy

Audience: Everyone

The NSW Health Accessible Communications Policy is useful for anyone wanting to create accessible communications that are clear, easy to understand information, available in different formats and languages and ensure everyone can access the information they need. This may apply to any consumer facing materials used to engage clinical trial participants, their families and communities.

The Accessibility Matters webpage has links to the policy, tools and resources to help with developing accessible communications, including NSW Health's Plain English principles.

More Tools and Tips!

SHeLL Editor can be used to adjust the readability of communications and has been specifically designed for health contexts, with health literacy in mind, and suggests suitable alternatives for health and medical jargon, where changing these is feasible.

- **In terms of privacy rules around the SHeLL editor:** You can view the Terms and Conditions here. Note that the Terms and Conditions specifies asks users to "agree to use reasonable efforts to not submit information to the Editor that may identify an individual."

- **In terms of how the SHeLL editor compares to the Hemingway tool:** The Hemingway App, Grammarly, StyleWriter, and VisibleThread are web-based tools that variously provide feedback on aspects of the text such as readability (including long words and long sentences), unnecessary adverbs, passive voice, formality, tone, and engagement. However, only some of these provide specific suggested alternative phrasing to reduce the complexity of health information, with none specifically addressing health and medical jargon, such as terms identified by the Centre for Disease Control and Prevention's Everyday Words for Public Health Communication. Further, none have been specifically designed for health contexts or with health literacy guidelines in mind.

Forum Focus - Data Breach Process

Audience: Research Offices

The forum is a great place to start conversations but it is also a great space to see what other research offices are doing and how they handle similar queries and situations.

Question: We have received notification of a data breach. Accidental in nature, someone sent their patient log to the sponsor with 50+ identifiable patient data. To make matters worse, this was a HREC approved waiver of consent.

It was a ICU study so some of the participants may have passed away.

I would really love other people's process to deal with data breach in general (both from HREC and RGO), just to make sure we are doing the right thing.

Also, as the patients did not consent to the study, there was some confusion if the participants should be notified of the breach. Some say Yes, we must be transparent, and others say No, as it only went to the sponsor, and they deleted all the information from their systems and servers. And no real harm was caused. But isn't the ethical thing to do is let the patient know via a HREC and RGO approved letter. But having said, that one doesn't want to contact deceased patient's families and let them know their data has been breached either. Any help and guidance would be much appreciated.

Jump in now and join the conversation!

Survey Corner

The Research Ethics and Governance Unit (REGU) is committed to continuous improvement and delivering the best possible experience and resources for our stakeholders. To help us achieve this, we regularly seek feedback to:

- **Improve our current processes** and ensure we are meeting your needs.

- **Gather input on stakeholder-facing documents** as we work to make them more clear, relevant, and user-friendly.

- **Identify areas for innovation** based on your insights.

Your feedback is essential to shaping the work we do and ensuring that it aligns with your expectations, we are also conscious of the potential for 'survey fatigue' so that is why we have created a dedicated survey section in this newsletter called 'Survey Corner'.

Here we will group together surveys we are seeking your feedback on, and share surveys from our colleagues in the Office for Health and Medical Research.

We would like to invite you to take a few minutes to complete the short surveys below, based on your role which is identified in the 'Audience' section. Your thoughts and suggestions truly matter to us!

Research Office - Internal Portal Feedback Request
Audience: Research Office

F1 Solutions have some exciting updates on the horizon for OmniStar! In the next few months, you can look forward to an improved internal portal (research office) user interface, user experience and accessibility.

Your feedback will directly influence the development priorities and help ensure the new features align with your needs. OmniStar's evolution is guided by users' experiences and requirements and by sharing your thoughts, you are helping create a more efficient, accessible, and user-friendly platform.

*Research offices are asked to kindly provide any feedback via this **short survey**.*

R3-CTEP Pathology Research Coordinators Survey

Audience: Research Coordinators

NSW Health Pathology and the Rural, Regional, and Remote Clinical Trial Enabling Program (R3CTEP), managed by the Office for Health and Medical Research**,** invite you to complete a **survey** about your experience with NSW Health Pathology (NSWHP) support for clinical trials in Rural, Regional and Remote NSW.

This survey is open to all staff who have use or may use NSWHP services for clinical trials, particularly in R3 areas**.** The results will inform improvements to current NSW Health Pathology services in R3 locations and will provide a baseline for the R3CTEP Pathology Research Coordinator project. The project is to pilot the employment of two Pathology Research Coordinators to support clinical trials activity in R3 NSW.

Please share the survey link with your clinical trials colleagues across NSW Health; the more participants in the survey, the more accurate and reliable our results will be.

*The survey takes approximately 10 minutes to complete and will be open until **18 November 2024.** The survey can be complete anonymously with an option to provide your contact details.*

Thank you for taking the time to share your input!

Upcoming events and dates

Audience: Research Office/Researcher

2024 Events and Dates

REGIS Research Office Lunch & Learn 2024: The Lunch & Learn webinars for 2024 is now complete! Dates for 2025 will be scheduled shortly. [Click here to view the themes, topics and previous Lunch & Learns.](#)

Research Office REGIS Training: Research Office training for 2024 is complete! Training dates for 2025 will be released in the new year.

Researcher REGIS Training: Researcher training for 2024 is complete! Training dates for 2025 will be released in the new year.

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.nsw.gov.au/news-and-events/regis-office-webinars/

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