



REGU/REGIS Newsletter | 2025 Issue 5 | 19 March 2025

In this issue

- **NSW Health Research Handbook 1.1**
- **Uptake and Use of the Statewide Clinical Trial Management System (CTMS)**
- **Forum Focus**
 - TGA AI & CDSS Regulatory Updates - What They Mean for Research Governance & Ethics
- **Survey Corner**
- **Previous Versions of REGU/REGIS Newsletter**

NSW Health Research Handbook 1.1

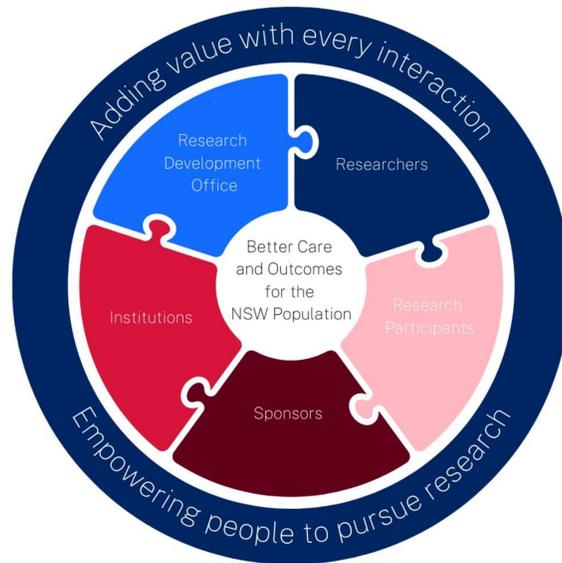
Audience: Everyone

The Research Ethics and Governance Unit (REGU) is excited to announce the release of the updated NSW Health Research Handbook 1.1, an initial set of Standard Operating Procedures (SOPs) and process map.

This release also marks the beginning of our second 6-month consultation period to refine these resources and further strengthen NSW Health's commitment of embedding a research-enabling culture. Your insights are crucial to ensuring the Handbook and SOPs are practical, user-friendly, and aligned with the needs of researchers, Research Development Offices, Research Governance Officers, and Human Research Ethics Committees.

We encourage you to share these resources widely with your teams and networks and use them extensively.

How can you contribute?



1. **Review the documents:** [Access the NSW Health Research Handbook 1.1, an initial set of SOPs and process map here](#) and [complete your feedback using this feedback form for the NSW Health Research Handbook 1.1 and associated documents](#)
2. Submit your feedback by **July 1st, 2025**
3. Have feedback you want to provide but exceeds the 4000 character limit? Please send it via email to MOH-ResearchEthics@health.nsw.gov.au

Uptake and use of the Statewide Clinical Trial Management System (CTMS)

Audience: Research Offices/Researchers

Clinical trial staff across all districts continue to show strong engagement and consistent system use and this is building high quality clinical trial insights and efficiencies across NSW Health.

As we complete the Quarter 1 CTMS audit for 2025, the benefits of excellence in data collection are showing with sites better equipped to meet accreditation requirements, improved financial management and overall enhanced visibility of clinical trial activity across our health system. The CTMS team would like to thank the hospital trial staff who have been using the system for their daily trial management. The data captured through the CTMS is already being used to support hospital accreditation to the national clinical trials framework and is informing statewide initiatives to support the delivery of clinical trials.

The CTMS project team continue to work closely with end users and our CTMS vendor to make sure we have a suitable and sustainable system to help with clinical trial management into the future. This has recently included work to prepare for the integration of the Statewide CTMS into the Single Digital Patient Record (SDPR). Stay tuned for more updates or to find out more or provide feedback please contact us at moh-statewidectms@health.nsw.gov.au

Remember, If you are new to the CTMS we are here to help and you can register for access, find our useful training resources or book in a virtual support session [here](#) or if you are unsure if your investigation is required to be entered into the Statewide CTMS you can find more details [here](#).

Be sure to keep an eye out for the CTMS team this coming International Clinical Trials Day May 20th where we will be sharing in the celebrations and recognising the important role clinical trials play in improving health outcomes across our system.

Contact us at moh-statewidectms@health.nsw.gov.au

Forum Focus - TGA AI & CDSS Regulatory Updates - What They Mean for Research Governance & Ethics

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.

We have shared some key takeaways from the recent TGA consultations on AI in therapeutic goods and Clinical Decision Support System (CDSS) software and more importantly, how these changes might impact research governance and ethics reviews.

The TGA has been reviewing how AI and CDSS tools are regulated, and while the framework is largely seen as effective, there are proposed changes to improve transparency, accountability, and compliance.

[Head on over to the forum 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!

[Project Registration Improvements Survey](#)

We are extending the close off date for this survey until **Tuesday 26th March**.

A number of updates to Project Registration are proposed to better guide the applicant, provide clearer instructions and allow better access to in form guidance. We are seeking your feedback on these proposed changes and how they do or do not address the above issues.

[This link will take you to view images](#) of the current and proposed changes to the Project Registration.

You can [access the feedback form here](#), which will close **Tuesday 26th March** and updates will be visible in the system on Thursday 13th April.

[REGIS User Feedback Surveys](#)

The eHealth REGIS team continuously work on enhancing and improving the system through feedback provided from our users.

We aim to do this via regular 'user feedback' surveys and have created a Microsoft form to allow us to create a distribution list of users who would like to receive these surveys.

All you need to do is indicate that you would like to receive these types of surveys and provide your name and email address! You can [complete the form here](#).

[Upcoming events and dates](#)

Audience: Research Office/Researcher



[2025 Dates and Events](#)

Research Office REGIS Training: Registrations for the July cycle of Research Office training is now open! [Click here](#) to register.

Researcher REGIS Training: Registrations for the June cycle of Researcher training is now open!
[Click here](#) to register.

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