

HEALTH + MEDICAL RESEARCH



REGU/REGIS Newsletter | Issue 23 | 30 November

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Australian Commission on Safety and Quality in Health Care (ACSQHC)

Final Report - The National Pilot of the Governance Framework

Audience: Research Office/Researcher

The ACSQHC have released the final report for the National Clinical Trials Framework Pilot.

Pilot aim and objectives

The aim of the pilot was to evaluate health service organisations with clinical trial services against the actions within the NSQHS Standards Clinical Governance Standard and Partnering with Consumers Standard, as provided in the Governance Framework and to familiarise the clinical trial workforce with the accreditation process. The objectives of the pilot were to evaluate:

- Health service organisations conducting clinical trials to understand the intent of the Governance Framework
- The Governance Framework enables health service organisations to identify and address gaps in safety and quality for clinical trial service provision
- The structure, sequence and format of the Governance Framework is logical and easily understood
- The language on the intent of the Governance Framework is specific and clear

- The Governance Framework can be implemented by health service organisations providing clinical trials and assessed for compliance
- Identification of additional resources that may be required to support national implementation of the Governance Framework.

Summary

Overall, health service organisations considered participation in the pilot as a valuable experience that provided the catalyst for cross-organisational collaboration between the governing body, executives, quality officers, clinical and non-clinical managers and the clinical trial workforce. Health service organisations that were solutions focussed and achieved early executive and safety, quality and risk officer engagement, more easily and effectively met the actions within the Governance Framework. Strong executive support was essential for success. Although resource intensive, building awareness of the Governance Framework through the pilot enabled health service organisations to undertake a gap analysis between what is currently in place and what needs to be in place, to meet the actions of the Governance Framework. The pilot provided the opportunity for health service organisation to collate the appropriate evidence that quality systems are integrated, embedded and evident in clinical trial operations.

Conclusion

The pilot demonstrated that the systems and processes are already in place for health service organisations to meet the actions in the NSQHS Standards as provided in the Governance Framework and, as clinical research is core health service organisation business, the AHSSQA Scheme provides the appropriate mechanism for accreditation assessment. Effectively incorporating clinical trials into health service corporate and clinical governance systems requires health service organisations to consider the degree of cross organisational engagement and health service executive support for human and financial resources; a cross organisational understanding of clinical trial services; the accreditation process and greater awareness of consumer engagement and feedback strategies. As with accreditation of health service organisations for clinical and corporate governance, implementation of the Governance Framework under the NSQHS Standards will effectively strengthen national governance arrangements for clinical trial services.

Congratulations and thanks to the two NSW pilot sites, St Vincent's Health Network and Sydney Local Health District.

A copy of the report is attached to the email.



The National Clinical Trials Governance Framework Pilot

Final Report for distribution

October 2021



Contingent Workers in Research

Comments/Survey due 7 Dec

Audience: Research Office

On Thursday 28th October OHMR facilitated a session on NSW Health insurance coverage as it applies to research.

iCare's underwriter attended and discussed aspects of the Statement of Cover, and provided an opportunity for attendees to ask questions. One of the most popular questions of the session was a HR query regarding insurance status of contingent workers and external researchers.

OHMR would like to gain a better understanding of which LHDs currently utilise contingent worker status for researchers and why. **Please respond to [this short survey](#) before 7 December.**

Advertised HREC meeting dates 2022

Comments/Survey due 14 Dec

Audience: Research Office

It's that time of year again, please use this link to provide your [HREC meeting dates for 2022](#) by **Tuesday 14 December**.

We will be updating the OHMR website before the end of the year.

New Opportunity

REGIS Onboarding and Support Specialist



Audience: Research Office/Researchers

The REGIS team is expanding with the new role of **REGIS Onboarding and Support Specialist** to coordinate the onboarding program and related activities for new and current users of Research Ethics and Governance Information System (REGIS).

Please visit <https://jobs.health.nsw.gov.au/> and login as an employee using your StaffLink ID then search **REQ275230** to review.

Applications close Thursday 9th December 2021

For role related queries or questions contact Kylie Becker on Kylie.Becker@health.nsw.gov.au

You may like to share this amongst your networks.

This position is open to internal NSW Health permanent employees, or temporary employees who have been employed as part of a merit based selection process for more than 3 months.

ERM training for Applicants

Audience: Research Office/Researchers

It is the lead sites responsibility to register new studies in each/any of the jurisdiction application systems. If you have trial groups that take on lead site responsibility they may like to attend ERM training.

The Coordinating Office will resume ERM training starting in December and will continue into 2022.

Available sessions will cover Introduction to ERM, SSA application and Post approval/authorisation.

The sessions will be conducted online via Microsoft Teams.

Choose a suitable date from the training schedule and register before the registration date closes by emailing [Parmeet at Victoria Health](#). Registration is required - state the session date, the training session and include your email address.

Please note: these sessions are not managed by NSW Health all queries and registrations should be directed through the link above.

Training date Time: 2 – 4 pm	Registration date	ERM training
Tuesday 07 December	03 December	Introduction to ERM
Thursday 09 December	03 December	SSA application
Tuesday 14 December	10 December	Introduction to ERM
Wednesday 15 December	10 December	SSA application
Tuesday 11 January	07 January	Post approval and post authorisation
Thursday 13 January	07 January	Post approval and post authorisation

Research Office Contribution

NLSHD Clinical Trials Forum

A vertical poster for the NSLHD Clinical Trials Forum. The top half has a dark blue background with the text 'NSLHD CLINICAL TRIALS FORUM' in white, bold, sans-serif font. To the right of the text are two overlapping speech bubbles, one orange and one yellow. Below the title, the date and time 'WEDNESDAY, 24 NOVEMBER 2021 9.30 - 10.30 AM' are written in white. Below that, the location 'WHERE: MS TEAMS BY [CLICKING HERE](#)' is written in white, with 'CLICKING HERE' in blue and underlined. The bottom half of the poster has a dark blue background with white text. It starts with 'Involved in Clinical Trials within NSLHD?' followed by 'Please join us for this inaugural event as we provide an update about Clinical Trials across the District and hear about projects underway.' Below this is a section titled 'Speakers include:' followed by a bulleted list of names and titles.

**NSLHD
CLINICAL
TRIALS
FORUM**

**WEDNESDAY, 24 NOVEMBER 2021
9.30 - 10.30 AM**

WHERE: MS TEAMS BY [CLICKING HERE](#)

Involved in Clinical Trials within NSLHD?

Please join us for this inaugural event as we provide an update about Clinical Trials across the District and hear about projects underway.

Speakers include:

- Deb Wilcox, Chief Executive NSLHD
- A/Prof Rory Clifton-Blyth, Chair, NSLHD Clinical Trials Reference Group
- Selin Armutcu, District Research Business Manager
- Jodi Humphreys, Research Manager, Clinical Research, Governance and Support
- Prof Manuela Ferreira, Institute of Bone and Joint Research
- Shelley Burnett, clinicaltrialsNSW, NSW Ministry of Health

In 2020 a Clinical Trial Reference Group (CTRG) was formed at NSLHD, with the aim of growing the numbers of high quality clinical trials across the District, enabling clinical trial capacity and capability,

and growing visibility and participation in clinical trials. CTRG responsibilities include identifying and addressing barriers, facilitating training, and promoting enablers for clinical trials.

Recently we held our first Clinical Trials forum, which was led by the NSLHD Chief Executive, Deborah Willcox.

We intend on holding clinical trial forums approximately quarterly, with the aim of bringing clinical trial staff together, providing important updates on matters such as ethics and governance, CTMS and accreditation, and to create a Clinical Trials Community of Practice.

At the forum we also shared information on recent appointments to research positions, contact information, updates from finance, and information on grants.

Last but not least, a researcher provided a fascinating presentation on placebo clinical trials in surgery.

Feedback and questions were received via the 'chat' and the audience response was extremely positive.

The team of presenters and the CTRG feel encouraged and are looking forward to the next forum

Who's next?

How is your office reaching out to your local research community? Are you holding online or face to face sessions? Do you have a newsletter? Have you created any support resources?

Share these things with your colleagues, I can guarantee there other research offices that would love to know what others are doing.

If your office is doing anything that you would like to share, please send it through to regis@health.nsw.gov.au.

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/>

Got new team members? Send through their name, role and something about them (and a photo if you want) and we'll welcome them here.