

HEALTH+MEDICAL RESEARCH



REGU/REGIS Newsletter | Issue 4 | 14 March 2023

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CTIQ PICF Template: EOI to Review

Audience: HREC Members

The [InFORMed Project](#) was initiated by CT:IQ in March 2021. This project group has reviewed the template information sheets and consent forms (PICFs) for clinical research currently housed on the NHMRC website and used by many sites. These templates often result in long and complex PICFs, containing information unnecessary for most potential participants to make an informed decision. InFORMed is developing nationally consistent, simplified, and more respectful PICF templates.

A draft template and user guide have been created. Consumer testing has been completed, and the group is now seeking feedback from HRECs to review the current PICF template. If you are interested in contributing to the NSW HREC group feedback [please register your interest here](#) by **28 March 2023**.

Please circulate this to your HREC members.

National Clinical Trials Governance Framework: Implementation Begins

Audience: Research Office/Researchers

From **March 2023**, all health service organisations conducting clinical trials will need to implement the [National Clinical Trials Governance Framework](#) in alignment with assessment to the National Safety and Quality Health Service Standards.

Accreditation timeframe

To give health service organisations time to implement the Framework, for the first three years, or one accreditation cycle, health services will be assessed against a maturity scale.

Health service organisations will be assessed as either having Established systems, Growing systems, or Initial systems in place to meet the NSQHS Standards for clinical trial service provision.

Support

To assist implementation, the Commission has developed [new resources](#), including a tool to conduct a self-assessment, manage examples of evidence and report on trial operations.

Organisations can also access direct support through the [Safety and Quality Advice Centre](#), and join preparatory information sessions to learn more. If you'd like to join a session please email the clinical trials team at HMR@safetyandquality.gov.au.

Background

The Framework is recognised as a significant reform for the clinical trials sector. It embeds clinical trials into routine health service provision under the NSQHS Standards. Importantly, it will do so in a way that will reduce duplication and increase efficiency, cohesion and productivity across the clinical trials sector.

Stay updated

To stay updated on the progress of the National Clinical Trials Governance Framework, visit safetyandquality.gov.au/ctgf and join the NCTGF mailing list by emailing your contact details to HMR@safetyandquality.gov.au.

AUSTRALIAN COMMISSION
ON SAFETY AND QUALITY IN HEALTH CARE



**The National Clinical Trials
Governance Framework**

Updated Policy Directive: Intellectual Property arising from Health Research

Audience: Research Office/Researchers

NSW Health are constantly reviewing and updating policy directives, one of the more recent updates has been to the NSW Health Policy Directive [Intellectual Property arising from Health Research \[PD2023_007\]](#) which has now been published. The previous Policy Directive [PD2005_370] has been rescinded.

Clinical Innovation and Research division within the NSW Ministry of Health



Audience: Research Office/Researchers

Susan Pearce AM, Secretary of NSW Health, has announced the establishment of a new Clinical Innovation and Research division within the NSW Ministry of Health.

The new division will include the Office for Health and Medical Research and the Agency for Clinical Innovation. The creation of the new division will provide a central point for co-ordination and strategy setting, and drive focus on state-wide research and innovation priorities.

The structure for both the Office for Health and Medical Research and Agency for Clinical Innovation will continue as two separate entities overseen by a Deputy Secretary.

Dr Jean-Frédéric Levesque has been assigned the role of Deputy Secretary for Clinical Innovation and Research, and Chief Executive of the Agency for Clinical Innovation and he will guide the transition of this new division. Dr Antonio Penna's as Executive Director of the Office for Health and Medical Research is unchanged.

Further information and updates will be shared over the coming weeks and months.

REGIS Training 2023

Audience: Research Office/Researchers



OTHER
SYSTEM
TRAINING



REGIS
TRAINING

REGIS training for 2023 is back!

Researcher training will commence March 20th, with three more cycles to be held every two months (May, July and September).

Research Office training will commence April 12th with three more cycles also to be held every two months (June, August and October).

You can register your interest via this newsletter using the registrations links under 'Upcoming events and dates' or via the REGIS website under '[Training Content for Users](#)'.

Training Content for Users: *The Researcher training webinars will be updated in this section over the coming months.*

The RGO portion of Research Office training is already available! The Ethics portion of training webinars will be uploaded over the coming months.

Research Office Contribution

WNSWLHD - Change is coming!



Size isn't everything, of course, but the footprint of the Greater Western HREC stretches over 615,044 square kilometres which is slightly bigger than France but without the same number of cheese varieties. We cover Western, Far West, Murrumbidgee and Southern LHDs and we're growing.

Recently, Illawarra Shoalhaven LHD asked the GWHREC to take over the review of ethics applications within their district. As you all, may or may not, know, the current arrangement is for a joint committee with Wollongong University but it was felt that the time has come for a change that will benefit both the LHD and the university. The change has the support of the respective Chief Executives and the ethics committee itself. It will mean quite a few administrative changes e.g. the full committee to only review Greater Than Low Risk applications and an extra sub-committee. The new arrangements are expected to be effective from 1 July 2023.

Due to the geographical spread of its members, the committee meets via Zoom except for one annual face-to-face meeting which this year was at the Western Plains Cultural Centre in Dubbo. This meeting allows us to invite guest speakers and helps fulfill the requirement for ongoing training and education.

*Up next is **NSW Pathology!** We look forward to your contribution for **Issue 5 - 28 March 2023***

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 first cycle of Researcher training will be held in **March** with three more cycles scheduled in **May, July and September**. [Register your interest here.](#)

Research Office Training: The first cycle of Researcher training will be held in **April** with three more cycles scheduled in **June, August and October**. [Register your interest here.](#)

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/>