HEALTH+MEDICAL RESEARCH

NSW GOVERNMENT

REGU/REGIS Newsletter | Issue 11 | 7 June 2022

In this issue

The National One Stop Shop - OHMR Statement

Audience: Research Office/Researcher

A big thank you to those that were able to meet with OHMR last week. Below is a summary of the discussion points. Please pass it on to colleagues in your network who need to be across this.

The Australian Commission on Safety and Quality in Health Care (the Commission) have been engaged by the Australian Government Department of Health to conduct national consultations and draft recommendations for a national health and medical research approvals platform, 'The National One Stop Shop'. At the recent ARCS conference the Commission provided an update on the recent consultation process and planned next steps.

During the conference update there was some communication about an imminent timeframe for the program, and that decisions had seemingly been made about what will be included in an end product. OHMR has had discussions with the consultation leads and can confirm that the National One Stop Shop is still under consultation and will require further review prior to approval. The exact scope of the software solution has not yet been determined and will be informed by further rounds of consultation. It is likely that once a scope is finalised a request for funding will be submitted by the Commission to the Commonwealth to custom build a software solution via formal tendering process. If custom built, then this solution will take a significant period to be developed, tested, and then implemented.

At one stage of the ARCS update, there was mention that the One Stop Shop will contain Clinical Trial Management System (CTMS) functionality. As a result, OHMR has fielded queries from stakeholders about whether this would impact on NSW's implementation of the Statewide CTMS. Further discussions with the consultation leads have confirmed that there are **no plans** for this to be included in the solution, as a CTMS is a workflow management tool rather than reporting software.

We encourage your involvement in the consultation process, and would be happy to discuss further as needed.

Here is the link to register for the consultation events being held on 17th, 24th and 29th June 2022: https://events.humanitix.com/tours/national-one-stop-shop-consultations

NSW Health Statewide CTMS

NSW Health has secured a clinical trial management system (CTMS) licence for all NSW public hospitals and health services conducting clinical trials.

A CTMS is a software system which supports administrative workflows which relate to clinical trials. The system maintains and manages planning, performing, and reporting functions, along with participant contact information, and tracks deadlines and milestones. The electronic infrastructure of the CTMS is designed to assist the state's clinical trials sector through reduced administrative burden, increased visibility of clinical trial activity, and improved financial management.

A project unit has been established within the Office for Health and Medical Research to coordinate implementation with change managers recruited to deliver local training and provide support at districts.

Pilot LHDs Northern Sydney LHD and Illawarra Shoalhaven LHD are planned to commence training from July 2022. Training at other districts will follow in a phased approach throughout the year, with a training calendar detailing the different offerings released soon.

For more information please visit www.medicalresearch.nsw.gov.au/clinical-trial-management-system/ or contact MOH-StatewideCTMS@health.nsw.gov.au if you have any questions

Collecting Proposed Updates to the Medicines Australia (MA) Clinical Trials Research Agreement (CTRA) Templates

Audience: Research Office/Researcher/Local Sponsor of Clinical Trials

Research Governance Office (RGO), site start-up officers, contract specialists and managers:

We are seeking your suggestions/feedback to update the Clinical Trials Research Agreement (CTRA) templates.

The current version of the suite of Clinical Trials Research Agreement (CTRA) templates was finalised in 2017.

The SEBS panel resolved to update the suite of CTRA consulting with the clinical trials community in May 2022.

If you see repeated amendments to the terms of CTRA accepted by the contracting parties that may:

- further clarify the current wording,
- bring the terms more aligned with the current regulatory framework, or
- better reflect the current industry standards.

Please email your suggested wording with justification to MOH-SEBS@health.nsw.gov.au. The SEBS Application Form can be used as sample format to organise your suggestions and justifications.

The SEBS panel will be collecting your suggestions/feedback, with the hope to start the negotiation of contract templates from the end of 2022 or beginning of 2023.

We appreciate your valuable insight.

Research Office Contribution

Illawarra Shoal Haven Local Health District - IMJ Paper

Congratulations to Marianna Milosavljevic, Lyndel Hewitt, Janaye Fish, Jose Cuenca and Bruce Ashford on the published paper "Ethics in Medicine - How to streamline the low and negligible research ethics and governance review process from 80 to 10 days: submission to decision"

INTERNAL MEDICINE JOURNAL

ETHICS IN MEDICINE

How to streamline the low and negligible research ethics and governance review process from 80 to 10 days: submission to decision

Marianna Milosavljevic, Lyndel Hewitt, Janaye Fish, Jose Cuenca and Bruce Ashford

Abstract

Most clinicians find research ethics and governance difficult and time consuming. This study aimed to develop a better local review process for low-risk research. We used real-time processing, leveraged local expertise and streamlined paperwork. As a result, turnaround times decreased from more than 80 days to 10 days, creating an efficient review process for low-risk projects.

Introduction

One of the foundations of evidence-based medicine is clinical research, as it plays an essential role in providing the best quality care to patients.[1] As such, clinical research needs to be supported and facilitated to develop.[2] When conducting research within an Australian public health institution it must comply with the National Health and Medical Research Council (NHMRC) National Statement on Ethical Conduct.[3] In addition, all public health institutions require an approval process called a research governance review in accordance with the appropriate level of ethical review.[4] These processes ensure that only high quality, ethical and endorsed research is conducted. However, there is growing evidence that current processes are too risk-averse[5] and, at times, stymie clinical research.[6–8] This is a major concern given within Australia there is an underresourcing of research within the clinical setting.[9] Within our local health district (LHD), most of the research is undertaken by clinicians within their own time.

Compounding these issues is the definition of what constitutes low-risk research. This can be a source of contention and inconsistency. A recent survey assessed the level of agreement between ethics committees and found there was a significant level of variation.[6] Not only are there variations in how ethics committees define risk, but also variations in how research governance requirements are interpreted and applied.[10–12]

Therefore, it is no surprise that researchers experience significant levels of discontent and frustration when dealing with the ethics and governance processes. This has led to a recent 'call to arms' by a group of Australian researchers who are demanding change.[13]

Locally, we were experiencing significant delays, on average more than 80 days between submission to approval for low and negligible risk (LNR) research. To address these concerns, a review of local LNR review processes was undertaken to identify issues and develop long-term solutions.

The aim of this article is to outline how a LHD in New South Wales (NSW), Australia, created a LNR committee that was efficient and agile.

"Ethics in Medicine - How to streamline the low and negligible research ethics and governance review process from 80 to 10 days: submission to decision"

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 are 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.

Upcoming events and dates

Audience: Research Office/Researcher

6 July - MRFF - Clinical Trials Activity Grant **Opportunity**

6 July - REGIS Research Office Training: Registrations open for 6 July and 28 September Research Office training cycles. Click here for training schedule.

12 September - REGIS Research Training: Registrations open 12 September and 10 October Researcher training cycles

ARCS Training Schedule

PRAXIS training opportunities

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/