HEALTH+MEDICAL RESEARCH

NSW GOVERNMENT

REGU/REGIS Newsletter | Issue 20

In this issue

Last Chance to give feedback - **Due Friday 22 October**

NMA Committee Seeking Feedback - Suggested update to standard PICF wording (ionising radiation)

Audience: Research Office

The National Mutual Acceptance (NMA) Committee met on Wednesday 29th September.

Victoria presented a suite of documents they have created to standardise and operationalise the ARPANSA Statement on Ethics Review for Multi-centre Trials released in February 2020.

The committee is seeking feedback from all jurisdictions regarding agreement on suggested wording in the Master and Site Participant Information Sheets regarding the radiation risk statement. (document attached)

- PICF wording re ionising radiation

Provide feedback here: **NMA ARPANSA Feedback Form** - *the feedback provided here will determine the NSW response to potential wording changes to PICS for multi center clinical trials.*

Feedback required: Friday 22nd October (next NMA committee meeting Wednesday 27th October)

For more information on the ARPANSA Statement on Ethics Review for Multi-centre Trials

The documents shared by Victoria for the operationalisation of the ARPANSSA statement which can be used/implemented by any NSW RO are available on the REGIS website, Issue 19.

The EQR Steering Committee Research Governance Project seeking feedback from Research Offices and Researchers

Audience: Research Office/Researcher

NSW Health's Embedding Quality Research (EQR) Steering Committee has commenced a pilot project to explore, analyse and recommend ways to more rapidly and effectively authorise high-quality research projects across NSW Public Health Organisations.

As part of the initial phases of the project, the Committee is seeking to clearly capture and understand the existing causes of delays to research governance authorisations and develop recommended solutions to address the identified barriers.

EQR is conducting anonymous surveys with Research Governance Office (RGO) staff and researchers across NSW to explore their experience with the current research governance system and their views on areas where they believe improvements and/or reform are possible.

Survey Link for Researchers

Survey Link for RGO Staff

The survey is now open and your feedback is requested by Thursday 4th November 2021.

Annual HREC Chairs meeting

Tentative date Friday 3 December

Audience: Research Office

The annual HREC Chairs meeting has been tentatively scheduled for Friday 3 December.

The meeting will be at Rydges World Square, registration details will be sent out shortly.

Please make sure we have current HREC Chair and Deputy Chair contact details, if they need to be updated please use the research office contact details.

Contracts and Forms of Indemnity

Audience: Research Office/Researcher

MTAA Post Market CIRA and Form of Indemnity

The Sponsor indemnifies the Institution against any claim or proceeding that is made, threatened or commenced, and any cost, liability, loss, damage or expense (including reasonable legal and other professional costs on a full indemnity basis) (Liability) that the Institution incurs or suffers, as a result of:

(1) a negligent or wrongful act or omission of the Sponsor; or

(2) a breach of Relevant Privacy Laws by the Sponsor;

However, the Sponsor is not required to indemnify the Institution to the extent that the Liability results directly from a negligent or wrongful act or omission of the Institution, or its Personnel, a breach of this Agreement or a failure to follow the Protocol.

The Sponsor must provide indemnity to the Institution and members of the Reviewing HREC against claims arising from the Study on the terms and conditions set out in the relevant Medical Technology Association of Australia Form of Indemnity for Clinical Investigations as set out in **Schedule 3**.

Query: A query has come from the MTAA Clinical Investigations Forum with respect to the recently approved and released Standard Clinical Investigation Research Agreement Post Market agreement template. "*We have had a number of sites happy to use the post-market template but still requiring the Standard Form of Indemnity. Would you be able to provide some clarity around this?*"

Response: The post-market investigation agreement template **does not require** the standard form of indemnity to be submitted, as the appropriate indemnity wording is contained in the body of the template agreement itself.

The same wording also appears in the Medicines Australia Clinical Trial Research Agreement - Phase 4 Clinical Trial (Medicines) agreement template and also **does not require** the standard form of indemnity to be submitted.

MTAA CIRA templates are available here

Medicines Australia templates are available here

Contact for Notices on the front page of a CTRA

Query: A query has come from a Research Office regarding the contact for notices on the CTRA "Can this be a generic role/email e.g. Cardiology Clinical Trial Coordinator and *XXLHD-CardiologyTrials@health.nsw.gov.au,* or does this have to specify a specific person?"

Response: ***No it doesn't have to be a specific person.*** The purpose of the 'Contact for Notices' is to specify the contact point when one party has to notify the other party of something arising out of the contract. There are a number of clauses throughout the CTRA which require this. In doing so, they contact the other party's 'Contact for Notices' and they have fulfilled their contractual obligation to notify.

Context: From the Institution's end, it should always be someone who is well across the study; the trial coordinator would be the ideal position to nominate here. While it could be any position with the Institution, in most cases, the RGO or the legal/risk officer would likely be inappropriate, as the purpose is primarily about managing the contract rather than serving a legal process (which the nominated 'Contact' could forward on anyway). If the generic email you have nominated is always manned, then it's perfectly fine to put that down. It's probably better than nominating a specific person because if the person leaves then you have to find out which contracts they are nominated on and contact the sponsor to update the contact details. By using a generic role/email, you're sure you're not missing a notification.

Help is here - Approval and Authorisation Letters

Audience: Research Office

What is Help? It's the little question mark at the top right of the screen.

What does it do? Click on it to find page specific guidance and links to relevant QRGs or Videos.

How does it work? Click on it and a pop out screen appears. If you navigate to another screen the help window will remain open and show the new pages help. To close the window click the X at the top right.

What has help already? The most comprehensive help text is currently on the process decision and decision notification pages (sending the HREC or RGO approval/authorisation letters)

When will more help arrive? Between now and the end of the year comprehensive help text will be uploaded to all major pages.

If you would like to see us focus on a specific area please let us know regis@health.nsw.gov.au

We have created this short (4min) video which is also be available in the help text.

Preparing the Approval Decision Notification Email Understanding what prefilled information to update, keep or remove when completing the Ethics approval decision notification email in REGIS.

You can expand the video screen size by clicking the expand icon on the bottom right hand side of the video.

How Australian Doctors Drastically Reduced Deaths from Vaccine-Linked Blood Clots

1 - Photograph: Carly Earl/The Guardian

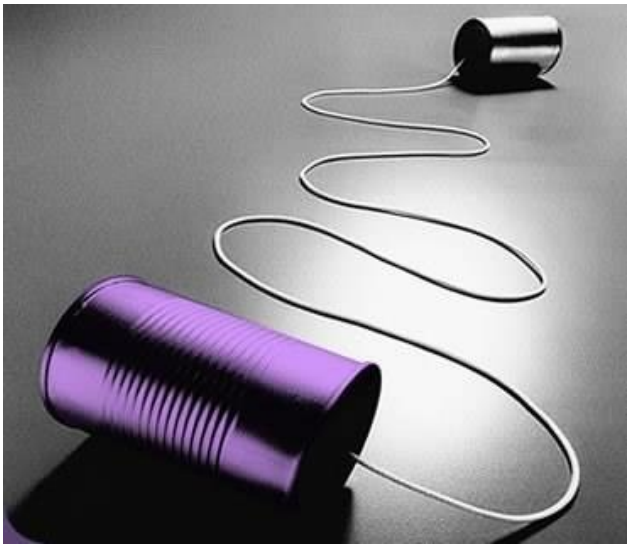
Audience: Research Office/Researchers

with thanks to the Sydney Research e-Update 11 October 2021

Australia's low death rate from the rare syndrome linked to the AstraZeneca Vaccine is due to a huge collaborative effort. The meetings to work on treatment guidelines and early diagnosis were organised

and led by **Professor Vivien Chen, Senior Hematologist, Concord Hospital and Leader of Platelet and Thrombosis Research, the University of Sydney**. Prof Chen took the initiative to bring clinicians, laboratory scientists and researchers together, and is the reason there was a treatment protocol in time for the first patient. Prof Chen and her team developed the treatment guidelines, putting in hours on the weekend and in the evening to maintain commitment to their regular jobs. Simultaneously, Prof Chen was also setting up diagnostic testing for Australia, talking to experts in Germany to access blood samples from positive and negative cases abroad. These diagnostic and treatment guidelines have been shared through the **Thrombosis and Haemostasis Society of Australia and New Zealand (THSANZ)** to assist health care workers widely. Read More and to support Prof Chen and her teams research efforts donate directly here

Current NSW Ethics and Governance Research Office Contact Details - **Due Friday 22nd October**



Audience: Research Office (NSW)

Thank you to those offices that have already sent through their updated contact details.

The Research Ethics and Governance Unit (REGU) are in the process of updating their website "Ethics and Governance Contacts" and have created a short survey with the required details needed from the NSW Research Offices.

Only one person from each Research Office is required to provide the Ethics and/or Governance contact details using this link https://ohmrredcap.health.nsw.gov.au/surveys/?s=LKP4CXCLANNRDTHJ

Research Office Contribution

SLHD - eConsent guidelines

Audience: Research Office

As part of the their COVID-19 Response SLHD have been encouraging the uptake of eConsent for studies, especially in COVID wards. The Research Office has created eConsent guidelines including instructions on how to set-up eConsent on REDCap.

https://www.slhd.nsw.gov.au/rpa/research/eConsent.html

Also see the REDCap eConsent instructional video created by University of Colorado.

https://youtu.be/0yRdK6GBvfo

Any queries can be directed to Merela Ghazal SLHD Executive Researcher Manager 02 9515 7176

Thank you to SLHD for sharing this information, we look forward to seeing more Research Offices sharing the great work they are doing in future issues.

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

Introduce new team members

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.

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/