

Hello All,

A day late but short and sweet. Hope you're all well.

In this issue:

- Seeking Feedback -Participant Information Sheets – Increasing length and complexity
- Expression of Interest – SEBS panel
- Register your interest – National One-Stop-Shop – consultation
- New metrics definitions

## Participant Information Sheets - increasing length and complexity – seeking your feedback

**Audience:** Research Office

In the last newsletter HNELHD contributed an area of growing concern for their HREC which was their concern in the increasing length and complexity of Participant Information Statements, particularly (although not exclusively) for sponsored clinical trials.

OHMR would be interested to hear the experience of other HRECs so we can try to scope the issue. We would be keen to get the views of and possible solutions from other HRECs regarding PICF length and readability.

Please provide a response by COB Friday 6<sup>th</sup> August: [redcap survey](#)

## SEBS Panel – Expression of Interest

**Audience:** Research Office

REGU is seeking expressions of interest from Research Governance Officers (and/or those currently reviewing/processing CTRAs) to contribute to the SEBS Panel's monthly meetings. A legal background is not essential. The involvement could be tailored to an individual's background, skills and experience. Once acquainted with the panel and with support from REGU we would like the RGO to perform a review of an application allocated during the month and to present this to the monthly meeting.

If interested, please email the SEBS Inbox to express interest: [SEBS@moh.health.nsw.gov.au](mailto:SEBS@moh.health.nsw.gov.au)

Previous LHDs that have taken up this offer include SWSLHD and NSLHD.

The Southern and Eastern Border States (SEBS) is a multijurisdictional panel that reviews and approves applications by external sponsors for amendments to the MA CTRA & MTAA CIRA suites of templates. It forms a single negotiation point for commercial and non-commercial sponsors to have clauses approved for use across public health organisation sites in participating jurisdictions.

## National One-Stop-Shop – Consultation - Register your Interest

**Audience:** Research Office/Researchers

National One-Stop-Shop for health and medical research - The Australian Commission of Safety and Quality in Health Care is conducting national consultations to scope the requirements for a national health and medical research platform – a National One-Stop-Shop.

Consultations start in July to gather the requirements for the National One-Stop-Shop and the National Clinical Trials Front Door.

Register your interest now to get updates on the consultations and how you can be involved.

<https://www.safetyandquality.gov.au/our-work/national-platform-health-and-medical-research>

## New Metrics Definitions

**Audience:** Research Office

Many Research Offices have had questions regarding the definitions of the new metrics. The below preliminary guidance has been prepared.

Queries should be direct to the REGU team [MOH-ResearchEthics@health.nsw.gov.au](mailto:MOH-ResearchEthics@health.nsw.gov.au)

### NSW HREC Submission Closing Date to NSW HREC Approval (Metric 3)

**All greater than low risk ethics applications that are approved within the reporting period, processed within 90 calendar days**

#### Greater than Low Risk – included in CE Service Agreement

Metric 3 (Total Time) measures from the advertised submission closing date of the first meeting the application is assigned to until the Decision Notification Email is sent.

#### Low and Negligible Risk – not included in CE Service Agreement

Total Time measures from the date an application is first submitted until the Decision Notification Email is sent.

#### When is an application's first meeting?

The first meeting is any meeting where the application is first discussed. Where a Research Office processes new applications through dual meetings e.g scientific subcommittee, this meeting must be managed in REGIS. This meeting will be publicly advertised to researchers with submission closing dates available.

REGU may conduct audits on advertised vs actual submission closing dates, and an auditing guide will be made available.

Example 1:

*An application is initially assigned to an executive meeting before it is determined that it should go to a full HREC. The executive meeting submission closing date counts as the start date.*

Example 2:

*An application is required to be reviewed by a Drug Committee prior to going to a full HREC. The Drug Committee meeting submission closing date counts as the start date.*

## Date SSA Application Received by RGO to Site Authorisation (Metric 4)

**All greater than low risk site applications that are authorised within the reporting period, processed within 60 days**

### Greater than Low Risk and Low and Negligible Risk

Total Time measures from one of the following dates start dates through to the date the decision notification email is sent.

Start Dates:

- Date application was first submitted (if ethics is already in place) \*
- Date of ethics approval – where Ethics exists in REIGS (if submitted prior to ethics approval)
- Date application is uploaded into REGIS from an approved interjurisdictional HREC

**An application must have Ethics Approval before Total Time is measured**

\*this start date is changing from the first time it is submitted to the RO to the first time it is submitted.

Example 1:

*An SSA is submitted at the same time as the ethics application (parallel submission). The date of ethics approval will be the start date (even though a research office may work on it beforehand)*

Example 2:

*An SSA is submitted from a Victorian HREC. The date the first documents are created in REGIS will be the start date (unless ethics has not been approved, in which case the start date is the date that ethics approval is recognised in REGIS).*

## REGIS User Group

**Audience:** Research Office

Members of the REGIS User Group would like to thank our outgoing Chair Annamarie D'Souza for her contributions to the group over the last year and a bit. We would like to welcome our new Chair Merela Ghazal.

## Log an enhancement request

**Audience:** Research Office

Got an idea or want to see a change in the system? Great! Your User Group representative is who you need to speak too, they can submit an enhancement request on your behalf.

<https://ohmrrredcap.health.nsw.gov.au/surveys/?s=T4PA3DEA8X>

See previous issues

**Audience:** Research Office

<https://regis.health.nsw.gov.au/news-and-events/regis-office-webinars/>

