FEBRUARY 2021
MEETING

SURGICAL RESEARCH SOCIETY

EASTERN & GREATER SOUTHERN SURGICAL SKILLS TRAINING NETWORK

OUTLINE

1. Welcome to SRS 2021
2. Education Session + Q&A: Applying for Ethics with the SESLHD
    - Marie Le Bechennec
3. SRS Education
4. SRS Research
5. Current Project Update
6. SVH Update
7. Feedback, Ideas, Questions

OBJECTIVES

1. Encourage and facilitate opportunities for exposure and experience in quality improvement and research activity at Prince of Wales Hospital
2. Provide a networking platform for individuals with similar interests in research topics
3. Provide opportunity for feedback on current projects
4. Encourage education and teaching on relevant research topics
5. Collate a database of current and upcoming research project opportunities

WELCOME 2021/2022 SRS COMMITTEE

President - David Abi-Hanna
Vice President of Research - Avinesh Chelliah
Vice President of Education - Nick Skladnev
Vice President of Network Relations - Thomas Warburton
Secretary - Ben Xie
Research Coordinator - Matthew Rackemann
Education Coordinator - Amy Weber
Network Relations Coordinator - SVH based
Immediate Past President - Niamh Ramsay

Education Session - Obtaining Ethics Approval

Marie Le Bechennec

Project Officer - SESLHD Research Directorate

SESLHD Ethics and Governance applications

Surgical Research Society (SRS)
25th February 2021
Cardiology Conference Room
Prince of Wales Hospital

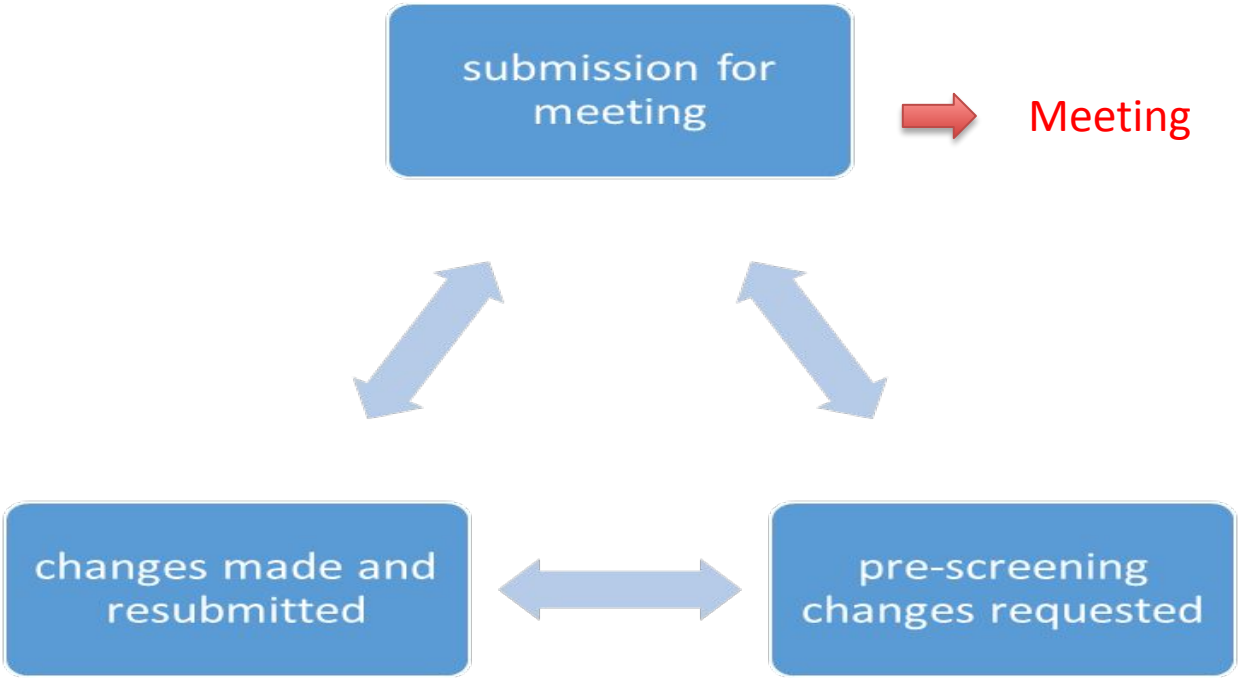
Marie Le Bechennec
Project Officer
SESLHD Research Ethics and Governance Office

Topics

- Research application process
- GCP definition and roles
- REGIS (MoH)
- Application advice towards approval

The Research Process

The Research Process



The Research Process

Low Negligible Risk Meeting dates Jan – June 2021

Submission cut-off by 9am on:	For LNR meeting on:
29 Jan 2021	Tuesday 9 February 2021
12 Feb 2021	Tuesday 23 February 2021
26 Feb 2021	Tuesday 9 March 2021
12 March 2021	Tuesday 23 March 2021
2 April 2021	Tuesday *13 April 2021
16 April 2021	Tuesday 27 April 2021
30 April 2021	Tuesday 11 May 2021
14 May 2021	Tuesday 25 May 2021
28 May 2021	Tuesday 8 June 2021

The Human Research Ethics Committee meets monthly. Dates for 2021 are as follows:

The Research Process

Submission by 12pm on:	For HREC Meeting held:
Tuesday 5 January	Tuesday 2 February
Tuesday 2 February	Tuesday 2 March
Tuesday 2 March	Tuesday 6 April
Tuesday 6 April	Tuesday 4 May
Tuesday 4 May	Tuesday 1 June
Tuesday 1 June	Tuesday 6 July
Tuesday 6 July	Tuesday 3 August
Tuesday 3 August	Tuesday 7 September
Tuesday 7 September	Tuesday 5 October
Tuesday 5 October	Tuesday 2 November
Tuesday 2 November	Tuesday 7 Decembe

The Research Process

The Research Process

Post meeting:

- We need to receive finalised minutes from the Committee Chair to process correspondence back to the researchers.
- The four outcomes:

a)Approved

b) Approved pending more information (reviewed by the RO)

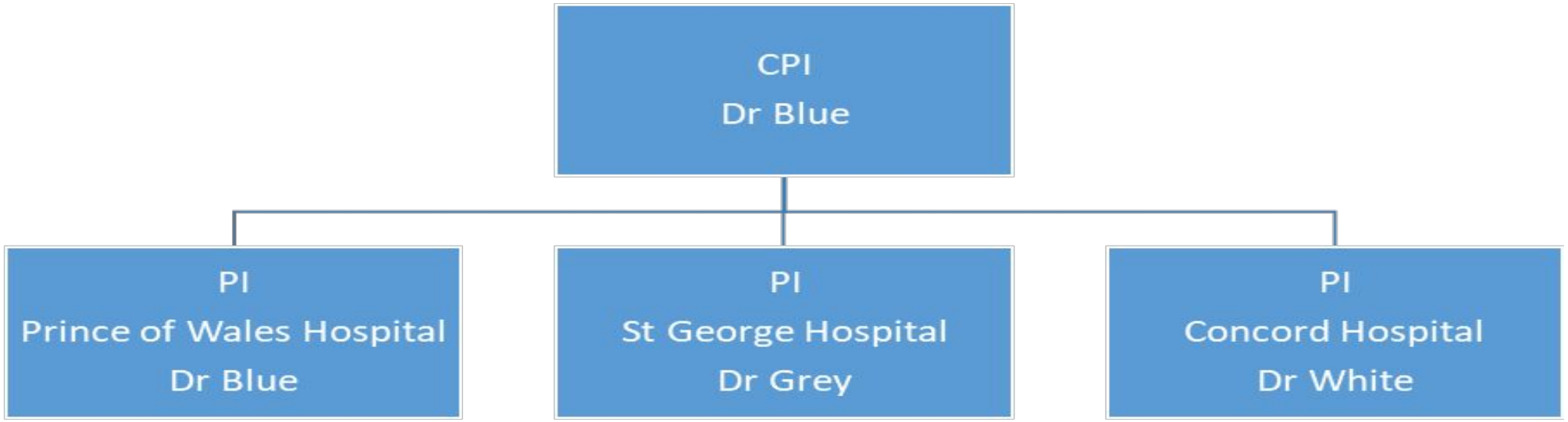
c) Decision pending more information (response requires review at the next meeting and/or requires escalation to HREC Committee)

d) QA/QI this is not an approval or requires SSA but has been acknowledged and an official email will be sent.

IMPORTANT – b) & c) require a resubmission with a cover letter addressing the queries that were sent from the committee.

Good Clinical Practice

Coordinating Principal Investigator vs Principal Investigator



Good Clinical Practice

The role of the **Coordinating Principal Investigator**:

- The Coordinating Principal Investigator has the lead role for communication between the Principal Investigators at each institution and the HREC.
- Compliance with the requirements of and timeframes for reporting on project progress.
- Ensure that the trial is based on a thorough review of scientific literature including whether any relevant systematic review exists.
- Oversee the preparation of the budget and the management of the budget for the conduct of the study.

Good Clinical practice

The role of **Principal Investigator**:

Delegates duties of the project on that particular site hence responsible that:

- They are responsible for the entire conduct of the study on that particular site
- Staff are adequately qualified/competent and insured (if not staff members- must consult HR to apply as a contingent worker)
- Submit safety reports and annual reports
- Responsible (and/or their delegate) for all documents (archiving, contract signatures, version control and submissions)
- Submit post approval amendments (protocol changes, variation agreements)
- Ensure that the entire team is conducting the study according to the latest version of the protocol.
- Please note-if you delegate a contact person = please provide a contact phone number and make sure they have been given editing rights

REGIS – Research Ethics Governance Information System

- Study project
  - Registration
  - Year/PIDXXXXX

  - Ethics /HREA
  - Year/ETHXXXXX

  - Governance/SSA
  - Year/STEXXXXX
  - For each site

REGIS

All applications must be submitted through REGIS:

All applications will only be reviewed and approved through meetings

Quality Assurance / Quality Improvement and Case Reports (LNR)

Negligible Risk (LNR) – foreseeable risk is more than inconvenience (e.g. medical records reviews or short non-personal surveys).

Low Risk (LNR) – Foreseeable risk is one of discomfort (e.g. anxiety as result of simple interview/ survey or non-invasive medical assessments)

Greater than Low Risk (HREC)– Risk is more serious than discomfort, (the types of projects outlined in the National Statement Clause 5.1.6).

REGIS

Regis links:

- REGIS IT Help desk on 1300 073 447 for **technical queries** such as system issues or faults, and account access issues. The Help desk is available 7am-7pm
- How-to guides – **For content queries** https://regis.health.nsw.gov.au/how-to/

- IMPORTANT- be sure to upload your documents in the correct categories within REGIS so that it is easier for the review to see them. Have within the title the correct version and date so that this will automatically populate when your decision email is created with the correct details.

Advice and tips

Advice and tips

HREA = Human Research Ethics Application

- This can be edited (though your registration can not)
- Do not confuse the roles of CPI and PI. Ensure they are matching on the 1) HREA 2) Registration 3) protocol 4) Site Governance Application
- The CPI must answer yes to question 1.9.11 or it will not be eligible for review at a meeting
- Please provide a phone number for contact person. Ensure that the project team use @health email accounts where possible.
- Q.2.2.8 waiver of consent – a few people misunderstand that you are not asking for a waiver of consent if you do not require a consent.

Governance/SSA = (if applicable) ensure that CTRAs are on Medicine's Australia templates and that it is partially executed so that the GM is the last person to sign on behalf of the organisation.

Advice and tips

The clearer the application = the easier and quicker to review!

Please ensure that all your relevant documents have the correct version and date within the title AND the footer. Please be sure that all documents have page numbers.

Relevant Documents

Protocol and patient information and patient consent form templates are on our website:

https://www.seslhd.health.nsw.gov.au/services-clinics/directory/research-home/resources/ethics/forms-templates

Please include the REGIS number on your PISCF so that any complaints from participants back to the research office have a reference number.

Where applicable:

Data collection sheets

Budget (including non-financial/services in-kind)

Survey questions

Thank You

If you have any queries – please send them to the Research Office Inbox:

SESLHD-RSO@health.nsw.gov.au

Please see tip sheets before submitting and all the best for 2021!

SRS Education Plan 2021

Nick Skladnev & Amy Weber

EDUCATION PLAN

- Finding a Research Topic & Team
- Research Development
  - Protocol
  - Ethics
  - Data Management
- Conducting a Project
  - Data collection and analysis
  - SPSS/Excel/R/Python sessions
  - How to successfully conduct an audit
  - How to successfully conduct a literature review
  - Working within health registries
- Writing it up/Presentations
  - Referencing, posters, presentations
  - 6 minute thesis/3MT practice sessions
  - Poster design and format session
  - Getting published!

SRS Research Plan 2021

Matt Rackemann & Avi Chelliah

The Team

Dr Matt Rackemann

Research Coordinator

Dr Avinesh Chelliah

VP

Engagement with Seniors (Registrar, Consultant)

Assessing interest:

- Broadcast email: regarding SRS purpose and objectives

Follow-up

- Invitation to collaborate and present ideas directly

Liaise

- With potential interested parties

Presentation:

- present research work at monthly meetings +/- at mid-year and end-of-year research showcases

Engagement with Juniors (RMOs, JMOs, Medical Students)

Wide reach as a network (POWH & SVH):

- Increase in hospital data, greater consultant contact

Group projects

- Shared authorship, double the amount of research

Research contracts

- Clear responsibilities, editing

Support

- Research templates and practice presentations
- present research work at monthly meetings +/- at mid-year and end-of-year research showcases

Current Project Updates

SVH Updates

GOOD LUCK IN 2021!

SURGICAL RESEARCH SOCIETY

EASTERN AND GREATER SOUTHERN SYDNEY