From: no_reply@regis.health.nsw.gov.au
To: Miles Kenny (Sydney LHD)
Subject: X23-325 & 2023/STE03151: SSA - Authorised - Amended
Date: Thursday, 28 September 2023 10:10:49 AM

Date of Decision Notification: 27 Sep 2023 (Amended 28 Sep 2023)

Greater than low risk review pathway

Dear Mr Kenny,

Thank you for submitting the following Site Specific Assessment (SSA) for governance review;
X23-0325 & 2023/STE03151: Educational intervention related to nursing care of Haemophilia patients

The Application has been reviewed by the Chief Executive Delegate who has determined the application has been AUTHORISED to begin at this site:
Royal Prince Alfred Hospital

The following documentation is included in this authorisation:

- Protocol (Version 1, 23 August 2023)
- Participant Information Sheet (Version 1.0, 21 September 2023)
- Participant Information and Consent Form – REDCap (Version 1, 21 September 2023)
- Poster and Intranet Advertisement (Version 1.0, 24 August 2023)
- Recruitment Email (Version 1.0, 24 August 2023)
- Randomisation Email (Version 1.0, 24 August 2023)
- Reminder Email (Version 1.0, 11 August 2023)
- Post Study Email (Version 1.0, 24 August 2023

Site authorisation with cease on the date of HREA expiry 21/09/2028.

The conditions listed in this authorisation letter should be comprehensively reviewed and understood by all members of the research team.

Data and Tissue:

- No data or tissue can be transferred either within Australia or overseas without the appropriate Agreement in place and signed by the Chief Executive of the SLHD.
- NSW Health Pathology (NSWHP) services only - researchers must ensure NSWHP agreements are submitted to the RGO for legal review and Chief Executive sign-off. The study must not commence without the agreements reviewed by the SLHD legal office and signed by SLHD Chief Executive. Principal Investigators are not authorised to sign agreements on behalf of the SLHD.

Medical Records: if you wish to access patient records from the Medical Records Department their head of department's signature must be provided via REGIS.

Aboriginal and Torres Strait Islander (ATSI) Data: In accordance with the National

Statement, chapter 4.7; you must seek ethical approval from the HREC of the Aboriginal Health and Medical Research Council (AHMRC) if you intend to use ATSI status in any presentation or publication.

Ethics Post-Approval Documentation:

- A copy of the annual report, accompanied by a copy of the HREC's acknowledgement letter, are submitted to this office as a REGIS Milestone for review. Please note, if the ethics application has been approved in REGIS the site annual report will automatically be submitted to the Research Governance Office (following HREC approval).
- Proposed amendments to the research protocol or conduct of the research which may affect the ongoing ethical acceptability or site acceptability of the project, and which are submitted to the lead HREC for review, are copied to this office accompanied by a copy of the HREC's acknowledgement letter.

Reporting breaches, complaints:

- Serious breaches, privacy or security breaches, patient or other complaints, should be reported to the Research Governance Office within 24 hours of being notified.

Research Personnel:

- Please note that you are responsible for making the necessary arrangements (e.g. identity pass, staff health checks, working with children checks) for any research team member who is not employed by the Sydney Local Health District and is conducting the research on-site at RPAH
- The appropriate documentation must be submitted to the RGO for authorisation before any external researcher is authorised to conduct research procedures at RPAH
- Student involvement: Site approval is granted on the assumption that all students and early career researchers are adequately supervised by the principal and senior investigators on a project. This supervision would ensure that all privacy concerns are met (including the completion of privacy undertaking agreements by participating students) and that both students and participants are supported in the conduct of the study in line with the approved research protocol.
- Personal Professional Indemnity: where appropriate, you should consult with your Medical Defence Union to ensure that you are adequately covered for the purposes of conducting this study.

For studies involving equipment provided by the sponsor: It is your responsibility to ensure that any study related equipment provided by the sponsor complies with any local clearance requirements. For example Biomedical Engineering equipment clearance requirements.

Checking website
You are encouraged to regularly review the Research Office website for up-to-date information on governance requirements, training and drop-in clinics.
https://www.slhd.nsw.gov.au/concord/ethics/default.html
https://www.slhd.nsw.gov.au/rpa/research/default.html

I wish you all the best with the Research

Yours Sincerely,
Estelle Ali
Acting Research Governance Officer
Research Ethics & Governance Office
Royal Prince Alfred Hospital
Missenden Road CAMPERDOWN NSW 2050
estelle.ali@health.nsw.gov.au
**COVID-19
Response**https://www.slhd.nsw.gov.au/rpa/Research/covid19response.html
For information about submitting an application through
REGIS https://www.slhd.nsw.gov.au/rpa/research/regis.html