Participant Information and Consent Form

Please read the attached Participant Information Sheet before completing the eConsent form below.

Thank you!

Participant Information Sheet

[Attachment: "MASTER PIS v1.0 21Sep2023.docx"]

CONSENT & AUTHORIZATION

Version: 1Consent formStudy Title: Educational intervention related to nursing care of Haemophilia patients

Principal Investigator: Miles Kenny

This is a consent form for research participation.
It contains important information about this study and what to expect if you decide to participate. Please consider the information carefully. Feel free to discuss the study with your friends and family and to ask questions before making your decision whether or not to participate. Your participation is voluntary. You may refuse to participate in this study. If you decide to take part in the study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your usual benefits. You may or may not benefit as a result of participating in this study. You will be provided with any new information that develops during the study that may affect your decision whether or not to continue to participate. If you decide to participate, you will be asked to sign this form and will receive a copy of the form.

Key Information About This Study
The following is a short summary to help you decide whether or not to be a part of this study. More detailed information is listed later in this form.
You are invited to take part in a research study looking at the impact of an educational intervention on nursing confidence and competence when caring for patients with Haemophilia. The aim of the study is to compare the effectiveness of education as opposed to no educational intervention.

The study is being conducted within Sydney Local Health District by Miles Kenny, Clinical Research Coordinator, Cell & Molecular Therapies, Royal Prince Alfred Hospital. The study will be completed under the supervision of Associate Professor Mark Elkins as part of a requirement for the Graduate Certificate in Health Research course.

---

1. Why is this study being done?
The aim of the study is to compare the effectiveness of education as opposed to no educational intervention on nursing confidence and competence when caring for patients with Haemophilia.

---

2. How many people will take part in this study?
34 participants.

3. What will happen if I take part in this study?
If you agree to participate in this study, you will be asked to sign the Participant Consent Form in REDCap. You will be randomised into an intervention or control group using a computer-generated random number system. There is a 50% chance of being randomised to either group and you will be notified of your group via email.

The educational intervention will be delivered as a 30-60 minute PowerPoint presentation. A link to the presentation recording will be emailed to participants. The presentation will contain information, graphics, and visual aids relevant to Haemophilia and best-practice nursing care for patients/clients with this condition. You will be required to review the educational presentation within 2 weeks. Access to the educational presentation will be monitored and participants will be followed up to review the presentation if necessary. Additionally, an automated reminder email will be sent at the end of the 1st and 2nd weeks of access, to remind participants to review the educational presentation.

The control group will not receive the educational intervention. The control group will be emailed the educational presentation upon study completion.

All study participants will be required to complete a brief Eligibility Criteria Survey to confirm eligibility via REDCap after signing the eConsent form. If eligible, participants will be required to complete a brief Baseline Characteristics Survey via REDCap. These questionnaires should take 5 mins to complete in total. All study participants will also be required to complete a confidence scale survey and a multiple-choice competency questionnaire twice during the study. Once before being randomised to your study group, and again approximately two months later, after the educational intervention has been delivered to the intervention group. You will be given 3 weeks to complete these initial outcome assessments. After 3 weeks, you will receive an email to inform you which group you have been randomised to. The confidence scale survey and competency questionnaire will assess your confidence and competence when providing care for patients with Haemophilia. These assessments will take approximately 10-20 minutes to complete.

4. How long will I be in the study?
Approximately 2 months.

5. Can I stop being in the study?
You may leave the study at any time. If you decide to stop participating in the study, there will be no penalty to you.

6. What risks, side effects or discomforts can I expect from being in the study?
No foreseeable risks for participants of this study have been identified by the investigator.

7. What benefits can I expect from being in the study?
The educational intervention will contribute towards 1 staff Continuing Professional Development (CPD) hours. The educational outcome may result in improved patient/client outcomes by facilitating quality nursing evidence-based care of Haemophilia patients/clients.

8. What other choices do I have if I do not take part in the study?
You may choose not to participate without penalty or loss of benefits to which you are otherwise entitled.

9. What are the costs of taking part in this study?
There is no cost to participate in this study nor will you be paid.

10. Will I be paid for taking part in this study?
There is no cost for participation in this study, nor will you receive payment.

11. What are my rights if I take part in this study?
If you choose to participate in the study, you may discontinue participation at any time without penalty or loss of benefits. By signing this form, you do not give up any personal legal rights you may have as a participant in this study.

You will be provided with any new information that develops during the course of the research that may affect your decision whether or not to continue participation in the study.

You may refuse to participate in this study without penalty or loss of benefits to which you are otherwise entitled.

An Institutional Review Board responsible for human subjects research at SLHD reviewed this research project and found it to be acceptable, according to applicable state and federal regulations and University policies designed to protect the rights and welfare of research participants.

12. Will my de-identified information be used or shared for future research?
The data collected in this project may also be used in future research studies. The results of this study and de-identified data may be shared in the future with national and international collaborators, any stored data that is used for related or future research, will first be reviewed and approved and approved by an appropriately constituted Ethics Committee. You indicate your agreement to this by signing the REDCap Participant eConsent Form. You will be made aware of the results upon study completion via the email address you provided during enrolment.

13. Will my study-related information be kept confidential?
All the information collected from you for the study will be treated confidentially and will be stored on a SLHD REDCap database. Only the Principal Investigator will have access to it.

The data will be analysed at Royal Prince Alfred Hospital. All data for use in journal publications and presentations will be de-identified (de-identified data means that you/your information will not be identifiable). All participants will be assigned a unique study identifier upon study enrolment. The files will be retained for 7 years from the day the study is completed. Once the retention period expires, the files will be disposed of.

14. May I withdraw or revoke (cancel) my permission?
Yes. If you decide to withdraw from the study, we will not collect any more study-related information from you. If you want to withdraw please let us know and tell us what you would like us to do with the information we have collected from you up till then. If you wish, your information will be removed from our study records. It will not be included in the study results, unless we have analysed and published the results.

15. Who can answer my questions about the study?
For questions, concerns, or complaints about the study, or if you feel you have been harmed as a result of study participation, you may contact the Principal Investigator, Miles Kenny on (02) 9515 8453 or via email Miles.Kenny@health.nsw.gov.au.

16. Ethics Approval and Complaints

This study has been approved by the Ethics Review Committee (RPAH Zone) of the Sydney Local Health District. Any person with concerns or complaints about the conduct of this study should contact the Executive Officer on 02 9515 6766 and quote protocol number [X23-0325].

Signing the consent form
I have read (or someone has read to me) this form and I am aware that I am being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to participate in this study.

I am not giving up any legal rights by signing this form. I will be given a copy of this consent form.

I voluntarily agree to participate in this study. ◯ Yes ◯ No

Participant first name _____

Participant last name _____

Signature _____

E-mail _____

Date and time _____

INVESTIGATOR/RESEARCH STAFF

Investigator/Research Staff

There are no blanks in this document. A copy of this form has been given to the participant or his/her representative.

Printed name of person obtaining consent

_____

Signature of person obtaining consent

_____

Date and time

_____

Adapted from Combined Consent & HIPAA Authorization Template

(http://orrp.osu.edu/irb/investigator-guidance/consent/)