Participant Information Sheet: Part A Consumer Focus Group/ Semi-Structured Interview

HREC No:	71834
Project Title:	The impact of a clinically led innovation of the ieMR for stroke on integrated care, interprofessional practice and real-time data analytics.
Principal Investigator:	Ms Samantha Robertson
Associate Investigators:	Prof Sandy Brauer, Prof Andrew Burton Jones, Dr Rohan Grimley, Dr Ingrid Rosbergen

What does your participation involve?

You are invited to take part in this research project because you are involved in a consumer group within a Queensland Hospital and Health Service or within the Statewide Stroke Clinical Network. This research project is titled: ***"The impact of a clinically led innovation of the ieMR for stroke on integrated care, interprofessional practice and real-time data analytics."***

You are asked to participate in providing feedback about the newly designed implementation and education package for the stroke ieMR enhancement. Your feedback will be used to assist in co-designing the ieMR education package to enhance interprofessional practice within acute stroke teams and enhance patient centred care. The Princess Alexandra Hospital (PAH) will act as the pilot site (Part A) with further sites being Sunshine Coast University Hospital, Gold Coast University Hospital and Mackay Base Hospital (Part B).

This Participant Information Form contains detailed information about this research project especially in relation to Part A of the study in which you are invited to participate. Its purpose is to explain to you as openly and clearly as possible all the procedures involved in this project before you decide whether or not to take part in it.

Please read this Participant Information Form carefully.
Feel free to ask questions about any information in this document. You may also wish to discuss the project with a relative or friend. Feel free to take adequate time for this. Your participation in this study is voluntary. This study will not affect your relations with the Queensland Health, the Statewide Stroke Clinical Network or the University of Queensland if you decide not to take part.

Once you understand what the project is about, and if you agree to take part in it, you will be asked to sign the consent section. By signing the consent section, you indicate that you:

- Understand the information provided.
- Give your consent to participate in the research project,
- Consent to the procedures described, and
- Consent to the use of your personal information regarding the consumer group (e.g., length of time as a consumer representative).

You will be given a copy of this Participant Information and Consent Form to keep as a record.

Purpose and background:

In recent years, Queensland Health has undergone significant digital transformation. Integrated electronic Medical Records (ieMR) have now been implemented across 14 sites in Queensland, aiming to deliver digital health care services that improve safety, efficiency and quality in clinical workflow processes. The ieMR is a constantly evolving system in hospitals that has the potential to improve clinical communication and documentation. However, the opposite effect is also reported, with disconnected teams and information 'overload'. Currently, limited research exists in the effect of the ieMR digital transformation in Queensland, with a large gap in our knowledge of how digital health effects teams, and how we utilise routine clinical assessment data in a streamlined and timely fashion.

The Queensland Statewide Stroke Clinical Network in collaboration with Queensland Health developed an ieMR innovation to enhance the visibility of patient information to support patient care and allow automatic data extraction from routine documentation. The innovation is a stroke specific single-entry point into the ieMR summarising key multidisciplinary aspects of the patient. Built in widgets allow clinical indicator data uploads to a national clinical registry aiding in real time service evaluation. The project is a pre-post implementation study across multiple sites using a mixed methods study design. Our aim is to assess the impact of a stroke ieMR enhancement on integrated care, interprofessional practice and real-time data analytics and develop a transferable evidenced based education and training package for digital health implementation. Results of this project and evaluation will be used to inform future digital transformations across clinical areas.

The study will be completed in two parts: Part A, a pre-post pilot study and Part B, a multisite staged pre-post implementation study. The study will investigate two interventions, the stroke ieMR enhancement itself and the effect of a tailored education and implementation package.

Part A of the study will act as the pilot site for the study. In Part A of the study, we will investigate the uptake of the ieMR enhancement and its effect on teamwork and interprofessional practice pre and post the ieMR enhancement rollout. We will obtain staff feedback at the pilot site on the implementation and education of the stroke ieMR enhancement to design an implementation and education package.

We will use a co-design methodology (staff and consumer feedback) with information from the pilot site (Part A) to design the implementation package. We will conduct a literature review to assist in the development of the education package and utilise an implementation framework to guide its development. The education and training package may involve multi-modal elements such as face-to-face computer-based learning, e-learning modules or simulation and may include targeted strategies based on staff turnover, level of team based care, acceptability and feasibility.

Part B of the study will be a pre-post phased study design measuring the uptake of the stroke ieMR enhancement across multiple sites at staged timepoints. Again, we will investigate the uptake of the ieMR enhancement by staff and its effect on teamwork and interprofessional practice pre and post the ieMR enhancement rollout. These sites will receive the newly designed implementation and education package and we will compare its effects in relation to teamwork and interprofessional practice. The completeness of clinical indicator data collection will be measured at all sites.

The study 'The impact of a clinically-led innovation of the ieMR for stroke on integrated care, interprofessional practice and real-time data analytics has four aims:

Part A

Aim 1: Understand the experience of individuals, teams and disciplines on use of the stroke ieMR enhancement and to use this information to optimise development of the implementation and education package

Aim 2: Develop an education and training package for implementation of the stroke ieMR enhancement

Part B

Aim 3: Investigate the impact of a stroke ieMR enhancement and implementation package on interprofessional practice and integrated care

Aim 4: Investigate the impact of a stroke ieMR enhancement on clinical indicator data extraction and real-time data analytics

Procedures:

Your participation in this study can include partaking in one or more elements of the study – a focus group and/or semi-structured interview. Two separate consent signatures will be obtained for each element of the study.

After you have consented to participate in this study your participation involves the following:

1. Participation in a **focus group** session together with other clinicians held at a local Queensland Hospital site. If necessary, participants can participate in the focus groups via web conferencing e.g., TEAMS/Zoom.
    - Eligible participants will be consumer representative of a Queensland Health Hospital and Health Service or the Statewide Stroke Clinical Network.
    - We will conduct 1 focus group of 5-7 participants
    - We will conduct consumer focus groups after the data from staff has been analysed and the new education and training package has been developed. The purpose of this focus group is to gather consumer feedback on the stroke ieMR enhancement and education and training package to ensure patient centred care is at the forefront. Each focus group is estimated to take around 60-75 minutes.
    - The focus groups will be audio recorded, transcribed and de-identified during the transcription process. Only one member of the research team will need to listen to the original recordings to check the accuracy of the transcription. No other researcher will listen to the recordings. The focus group will be led by the Principal Investigator. All questions in the focus groups are entirely optional and you are under no obligation to answer any question.

2. Participation in a **semi-structured interview** held at a local Queensland Hospital site. If necessary, participants can be involved in interviews via web conferencing e.g., TEAMS/Zoom.
    - Eligible participants will be consumer representative of a Queensland Health Hospital and Health Service or the Statewide Stroke Clinical Network.
    - We will conduct 1-2 semi-structured interviews to provide further detail to the focus group data
    - Each interview is estimated to take 45-60 minutes

- The interviews will be audio recorded, transcribed and de-identified during the transcription process. Only one member of the research team will need to listen to the original recordings to check the accuracy of the transcription. No other researcher will listen to the recordings. The interview will be led by the Principal Investigator. All questions are entirely optional and you are under no obligation to answer any question.

Alternatives to Participation

Your participation in this research is voluntary.

Possible benefits

We cannot guarantee or promise that you will receive any direct benefit from your participation in this research. However, you will be assisting us to gather information that may improve stroke care, provide better outcomes for stroke teams and patients, and enhanced knowledge about digital health in Queensland Health.

Possible risks

We do not foresee there to be any personal risks associated with any tasks outlined in this description of research. You are free to withdraw your participation from the project at any time should you wish to, or should you experience any distress.

Confidentiality and Privacy

Your privacy and confidentiality will be maintained at all times during this research. Any information that is obtained in this study will be maintained in a secure and confidential manner.

For the purpose of this study, you will be provided a Project Person Identification which will replace your name and any identifying details for the focus groups. No data collected will be linked or associated with any of your personal details. Data that is collected from you (including audio recordings from focus groups and survey information) will be converted to electronic files and stored in a safe and secure research data manager program. Voice recordings will be deleted once the transcription process occurs and transcripts will be deidentified. After the study is finished, any paper records and electronic data will be kept for a minimum of at least 5-7 years from date of publication in accordance with the NHMRC guidelines until its confidential destruction. If you give us permission by signing the consent form, we plan to publish the results in international scientific journals. Your identity will not be disclosed in any publication or presentation.

The study team members will preserve the privacy of participants taking part in this study and are bound by agreements of patient and data confidentiality. If you wish to participate in the study however do not wish to participate in a focus group session, please notify the Principal Investigator and we will offer the opportunity for feedback one-on-one. If you experience any problems or have any questions or concerns during the study, you can contact the Principal Investigator Ms. Samantha Robertson on the telephone number provided. At your request, we can provide a summary of the overall results and conclusions at the completion of the study. You can also be directed to any publications arising from this research.

Withdrawal from the research

Your participation in this research is voluntary. If you wish to withdraw your consent during the research project, the study team will not collect additional information from you. Personal and study information collected to that point will be retained and will form part of the study results to ensure that results of the research project can be measured and to comply with law.

If you wish to withdraw consent from this study, the Principal Investigator Ms. Samantha Robertson, should be contacted as early as possible. Withdrawal from the study should be indicated verbally to the study investigator, via mail/email or completion of the Withdrawal of Participation Form. Withdrawal from this study will not affect your relationship with Queensland Health or the University of Queensland.

Complaints

If you experience any problems as a result of this research project, you should contact the Principal Investigator Ms. Samantha Robertson as soon as possible.
Phone (07) 5202 8430
Email: samanthat.robertson@health.qld.gov.au or samantha.robertson@uq.edu.au
If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact the Metro South Ethics Committee on: (07) 34438049 or email: MSH-Ethics@health.qld.gov.au.

Organisation of Research and Funding

This study is a partnership between researchers at the School of Health and Rehabilitation Sciences and School of Business at the University of Queensland and researchers within Queensland Health. Samantha Robertson is completing her PhD and is leading this research project. No incentive payments will be available to participants.

Ethics Approval

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). This study has been reviewed and approved by Metro South Hospital and Health Service, Human Research Ethics Committee.

Further Information and Contacts

We would like to thank you for your interest in the research titled: "The impact of a clinically led innovation of the ieMR for stroke on integrated care, interprofessional practice and real-time data analytics." If you would like more information about the study or if you wish to discuss any other concerns, please feel free to contact:

Samantha Robertson
Phone: (07) 5202 8430 or
Email: samanthat.robertson@health.qld.gov.au or samantha.robertson@uq.edu.au

Participant Consent Form: Part A Consumer Focus Group/ Semi-Structured Interview

HREC No:	71834
Project Title:	The impact of a clinically led innovation of the ieMR for stroke on integrated care, interprofessional practice and real-time data analytics: Part A.
Principal Investigator:	Ms Samantha Robertson
Associate Investigators:	Prof Sandy Brauer, Prof Andrew Burton Jones, Dr Rohan Grimley, Dr Ingrid Rosbergen

Declaration by participant:

- I have read the Participant Information Sheet or someone has read it to me in a language that I understand.
- I understand the purposes, procedures and risks of the research described in the project.
- I have had an opportunity to ask questions and I am satisfied with the answers I have received.
- I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the study without affecting my care or relationship with Queensland Health, the Statewide Clinical Stroke Network or the University of Queensland.
- I understand that I will be given a signed copy of this document to keep.

Consent for Focus Group

Name of participant: .....

Signature: ..... Date:
DD / MM / YYYY

Consent for Semi-structured interview

Name of participant: .....

Signature: ..... Date:
DD / MM / YYYY

Declaration by Study Investigator:

- I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

Name of Investigator: .....

Signature: ..... Date:
DD / MM / YYYY

Note: all parties signing the consent form must date their own signature