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The I-DECIDED Study

A clinical decision-making tool for intravenous catheter assessment and safe removal in hospitals

PARTICIPANT INFORMATION SHEET

[name of hospital]

Chief Investigator:
Dr Gillian Ray-Barruel, RN, BSN, BA(Hons), Grad Cert ICU Nursing, PhD
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[insert name of hospital] Investigator:
Name, Qualifications
Position
Contact Phone:
Contact Email:

You are invited to take part in this research project, *I-DECIDED: A clinical decision-making tool for intravenous catheter assessment and safe removal in hospitals*. This is because you have been identified as a patient with a peripheral intravenous (IV) catheter at the [insert name of Hospital]. This phase of the research project aims to assess your IV catheter site and compare this assessment with the documentation in your medical chart. Participation is completely voluntary and you may refuse/withdraw your consent at any time.

This information sheet has been provided to you to allow you to give fully informed consent. You should keep a copy of this sheet for your future reference.

Why is the research being conducted?

Seven out of 10 hospital patients need an IV catheter for fluids or medicines. However, many IV catheters have painful complications or stop working before treatment is finished. Improved assessment could help prevention and early detection of complications. This study will test the effectiveness of an IV catheter assessment tool (I-DECIDED), developed by a Griffith University researcher, in improving IV care in hospital patients.

What you will be asked to do

1. You will be asked to consent to participate in this IV assessment and chart audit.
2. If you agree to participate, basic non-identifiable demographic details will be collected including: age, gender, previous history of IV catheters.
3. The researcher will spend 5–10 minutes with you, examining your IV catheter site and checking your medical record for evidence of IV assessment by hospital staff.
4. You are welcome to have a relative or friend present, if you choose.

The expected benefits of the research

We do not expect you to get any direct benefit by participating in the study. We do think that your participation may benefit patients, nurses, doctors and hospitals in the future, and you may feel satisfaction at your contribution to improving health care through research. You will be able to receive a report on the results of the research study by ticking the box on this form.

Risks to you

There are no foreseeable risks through participation in the study. Your participation is entirely voluntary. The researcher will treat you with courtesy and confidentiality at all times, and there is no right or wrong way to complete the questions.

Your confidentiality

Data collected during this study will be treated confidentially. The bedside interview will be led by an independent senior clinical researcher who has no authority or reporting relationship with the hospital. No individual person will be identifiable in any reports or publications arising from the study. All data generated will be de-identified and safely stored at the [insert name of Hospital] and Griffith University. Research records will be destroyed 5 years after the study.

Your participation is voluntary

Your participation is entirely voluntary and if you decide not to participate this will not affect your relationship with the hospital. If you choose to participate, you are free to withdraw your consent and to discontinue participation later, by telling the research nurse. If you choose to withdraw you will be given the opportunity to revoke the researcher's rights to keep any data collected, or otherwise consent to its use in the final results. This choice will not impact upon your relationship with the hospital in any way.

The ethical conduct of this research

This study has been reviewed and approved by The Prince Charles Hospital Human Research Ethics Committee (EC00168). Should you wish to discuss the study in relation to your rights as a participant, or should you wish to make an independent complaint, you may contact the Coordinator or Chairperson, Human Research Ethics Committee, The Prince Charles Hospital, Chermside, Qld, 4032 or telephone (07) 3139 4500,
email: ResearchTPCH@health.qld.gov.au

Griffith University conducts research in accordance with the National Statement on Ethical Conduct in Human Research. If potential participants have any concerns or complaints about the ethical conduct of the research project they should contact the Manager, Research Ethics on 3735 4375 or research-ethics@griffith.edu.au.

Who can I contact for further information?

If you would like further information or have any questions about this research or the study procedure, please contact

Dr Gillian Ray-Barruel
Chief Investigator, Griffith University
(07) 37358442
g.ray-barruel@griffith.edu.au

[Insert site logo]

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, you may contact:

Research Governance Officer:

[Insert site information]

[Insert site logo]

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PARTICIPANT CONSENT FORM

[name of hospital]

I have had the contents of this information sheet explained to me and I have been provided with a copy. I agree to participate in the IV assessment and chart audit phase of the I-DECIDED Study. I understand that this will involve the researcher assessing my IV catheter site and checking my medical record for evidence of IV assessment by hospital staff. I agree that my basic demographic data (non-identifiable) may also be collected.

Please read the following carefully, and sign below if you agree with these statements and are happy to participate in the study:

1. I have read and understood the information sheet and this consent form.
2. I have had the opportunity to ask questions about the study and these have been answered to my satisfaction.
3. I understand that this project is for research and that I may not benefit directly.
4. I have been informed that the information collected about me in this study will remain confidential and will be adequately safeguarded, and that when results are published, they will be presented in such a way that I cannot be identified.
5. I understand that if I do participate, I am free to withdraw my consent and to discontinue participation at any time without comment, and with no effect on my relations with the hospital in any way, but that I do need to tell the research staff if I wish to withdraw.
6. If I have any questions or comments about the study at any time I am free to contact Dr Gillian Ray-Barruel (07) 37358442 and the research nurses.

I would like a copy of the research results to be sent to me at the end of this study. ☐

Email or postal address for report to be sent: _____

_____

Name of Participant: _____

Signature: _____ Date: _____

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 Researcher: _____

Signature: _____ Date: _____

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WITHDRAWAL OF CONSENT FORM

I _____ no longer wish to participate in the research study named above

Name of Participant: _____

Signature: _____ Date: _____

Name of Researcher: _____

Signature: _____ Date: _____

This Revocation of Consent should be forwarded to:

[Insert local investigator details]