Participant Information Sheet/ Consent Form

Title	*Development of evidence-based guidelines for the management of medical device alarms that aim to improve patient safety within Australian intensive care units*
Short Title	*Explore, understand, and synthesise current practices of alarm management by nurses working in ICU.*
Project Number	*AU HREC 4944*
Project Sponsor	*Not applicable*
Principal Investigator	*Ms Vivienne Leigh*
Associate Investigator(s)	*A/Prof Lemuel Pelentsov* *Emeritus Prof Carol Grech* *A/Prof Allison Roderick*

Part A: Project Overview

1. What is the purpose of the research project?

   The aim of this research project is to understand current practice in medical device alarm management used in Level II and III Intensive Care Units (ICUs) across Australia. This part of the overall project is to explore, understand and synthesise current practices of alarm management by nurses working in ICU (Level II and III) to gain a deeper understanding of the relationship that nurses have with medical devices. It is anticipated that a draft set of recommendations for the management of medical device alarms will evolve from this project.

2. Who is undertaking this project?

   This project is led by Ms Vivienne Leigh, a PhD candidate within Adelaide University, and a lecturer in postgraduate nursing. Semi-structured focus group interviews form part of the overall research project.

3. Who is guiding and supervising this project?

   The project is co-supervised by Emeritus Prof Carol Grech, A/Prof Allison Roderick along with A/Prof Lemuel Pelentsov as principal PhD supervisor.

4. Is this project funded?

   This research has not received any specific grants from funding agencies in the public, commercial or not-for-profit sectors.

5. Who has reviewed and approved this project and focus group interview?

   The ethical aspects of this research project have been approved by the Human Research Ethics Committee (HREC) of Adelaide University HREC (AU 4944). This research is conducted in accordance with the Australian government research requirements, specified in the National Statement on Ethical Conduct in Human Research (2025). This statement has been developed to protect the interests of people who agree to participate in human research studies.

Part B: Project Participation

6. What does participation in the focus group interviews involve?

   Participants are invited to talk with the PhD candidate about their experience in the management of medical device alarms in the critical care environment. The interview may be via Microsoft Teams or Zoom, depending on what participants feel most comfortable with or where they are located. Prompt questions will be used to guide the interview which should take approximately 60 minutes of your time.

   All participants who take part in a focus group interview will be asked to maintain the confidentiality of the focus group discussions and preserve the anonymity of the focus group participants. Please note, however, that given the public nature of focus groups, this cannot be guaranteed.

   The PhD candidate will record the interview and analyse the transcript to identify emerging themes. A copy of the final report will be offered to you.

7. Where will the focus group interviews be held?

The focus groups/ interviews will be held either online via Microsoft Teams or Zoom at times that is in agreement with you. These semi-structured sessions will be run is small groups to generate a more enriching conversation.

8. Is there any additional work required of the study participants?

There is no preparation that will be asked of you and nothing to bring to the focus group sessions.

9. Can I withdraw?

Participation is voluntary. If you do not wish to take part, you do not have to. If you decide and consent to take part and later change your mind, you are free to withdraw from the focus group at any stage by clicking on the “leave” button at the bottom of the page. Your decision to take part or not to take part, or to take part and withdraw will not affect your relationship with the University or the PhD candidate who is conducting the focus group interviews. If you decide to take part in this focus group, you will be asked to sign the consent section. By signing it, you are telling us that you:

- Understand what you have read
- Consent to take part in the focus group interview
- Consent to be involved in the research described
- Consent to the use of your de-identified information and interview responses as described

You will be provided with a copy of this Participant Information and Consent Form to keep.

10. What are the benefits of taking part in this focus group interview and project?

You will receive no personal benefits from this research however; participation may contribute to the development of recommendations in the management of medical device alarms in the Australian ICU context. Additional benefits may be through raising awareness in the importance of alarm management in the clinical setting.

11. What possible risks or disadvantages are there in taking part in this focus group interview?

Participants may disclose sensitive information or experience discomfort during the focus group interviews.

Parameters for engagement in the focus groups interviews will be communicated by the PhD candidate at the beginning of the focus group interview session to include, that participants:

- can leave the focus group interview at any time should they wish to do so;
- counselling support is available should you require;
- follow up (member checking) will be offered;
- contact with the PhD candidate post the focus group interview is available should they wish to do so; and
- the use of cameras with online focus group interviews will be at the discretion of the participants

12. Who do I contact if I am feeling distressed during or following the focus group interview and feel I need assistance?

In the event that you become distressed or experience discomfort during or following the focus group interview and require assistance:

- Counselling support is available should you require.
- A follow up (member check) from the PhD candidate will occur post the focus group interview.
- You are also welcome to contact the PhD candidate should you wish to do so.

Counselling contacts

Name	Nurse Midwife Health Program Australia
Telephone	+61 1800 001 060
Website URL	Contact - Nurse Midwife Health Program Australia

Name	Nurse & Midwife Support
Telephone	+61 1800 667 877
Website URL	Get Support | Support for Nurses & Midwives

13. What will happen to information about me?

By signing the consent form, you consent to the research team collecting and using information about you for the research project. Any identifiable information collected from the focus group interviews will be de-identified by the PhD candidate by assigning a code to the participant. Codes will be stored separate to any participant names on a password protected network on the secure Adelaide University server that will only be accessible by the PhD candidate. Any data collected as part of this project will be treated as confidential and securely stored.

14. What happens with the information collected from the focus group interviews?

The focus group interviews will be audio recorded and transcribed verbatim. The transcribing of the collected data will be undertaken by the PhD candidate. A qualitative template analysis will be conducted following data collection that will set about constructing a preliminary set of themes from emerging findings from the preceding phases of the project. The likely themes will be reworked, shaped, and refined with further emergence of the data.

It is anticipated that the results of these focus groups will be published and/or presented in a variety of forums. The findings will be used to inform a final report which will make recommendations about clinical alarm management in ICU. The de-identified information from the focus group interviews will be included within the PhD candidate's thesis and associated publications. No identifying information will be used in any written work, and your responses will remain anonymous.

15. What happens when the research project ends?

The data developed or collected as part of the project will be stored on the Adelaide University storage infrastructure. On completion of the project the research data will

be transferred to Adelaide University Research Data Storage and retained for five years as required by South Australian legislation before being permanently deleted.

Part C: Concerns, Complaints and Issues

16. Who do I contact if I have any concerns or something goes wrong?

If you want any further information concerning this project or if you have any problems which may be related to your involvement in the project, you can contact any of the following people:

Research contact person

Name	Vivienne Leigh
Position	PhD candidate
Telephone	+618 8302 7810 or 044 962 2731
Email	vivienne.leigh@adelaide.edu.au

Name	A/ Prof Lemuel Pelentsov
Position	PhD Principal Supervisor
Telephone	+618 8302 1038
Email	lemuel.pelentsov@adelaide.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, please contact:

Reviewing HREC approving this research and HREC Executive Officer details

Reviewing HREC name	Adelaide University Human Research Ethics Committee
HREC Executive Officer	Human Ethics Officer
Telephone	+618 8302 6330
Email	hrec@adelaide.edu.au