PARTICIPANT INFORMATION SHEET AND CONSENT FORM

Understanding the impact of statutory duty of candour and new legislation on the management of serious adverse patient safety events (SAPSE) in Victorian health services

You are invited to participate in an interview for a research study examining knowledge, effectiveness and impacts of a Statutory Duty of Candour (SDC) in public and private hospitals. Statutory Duty of Candour requires healthcare providers to give an honest account of what has happened and how they intend to prevent furture recurrence in instances of serious harm to patients that are a result of the healthcare they have received which are described as serious adverse patient safety events (SAPSE). The study is being led by Professor Reema Harrison at the Australian Institute of Health Innovation, Macquarie University.

Before you decide whether or not you wish to participate in the interview, it is important for you to understand why the research is being conducted and what it will involve. Please take the time to read the following information carefully and discuss it with others if you wish.

1. 'What is the purpose of this study?'

The purpose of the interview is to obtain information from you on your understanding and perspective of the statutory duty of candour legislation, what it means for you, and its impact on health service based on your own experiences in the Victorian health system.

2. 'Why have I been invited to participate in this study?'

You are eligible to participate in this study because of your role as a healthcare provider in the hospital or a patient, or healthcare consumer.

3. 'What if I don't want to take part in this study, or if I want to withdraw later?'

Participation in this study is voluntary. It is completely up to you whether or not you participate. If you decide not to participate, it will not affect your role at the hospital, nor will it affect your treatment or relationship with the hospital conducting this research.

If you wish to withdraw from the study once it has started, you can do so at any time without having to give a reason by contacting the research team using the information provided below.

4. 'What does this study involve?'

If you agree to participate in this study, you will be asked to sign the 'Participant Consent Form.' Your involvement in the study will include answering questions in a semi-structured interview that will last approximately 25-30 minutes. The interview will be conducted online or telephone or in person at your convenience.

5. 'How is this study being paid for?'

The study is funded by Safer Care Victoria as part of an evaluation of the impact of the statutory duty of candour legislation.

6. 'Are there risks to me in taking part in this study?'

There are no foreseeable risks to taking part in this study. However, if you do experience any form of psychological distress from participating, please contact either Lifetime (13 11 14), Beyond Blue (1300 224 643) or your GP for further assistance. You can also contact us, and we will discuss this with you, and if needed, we will provide suggestions for referral to professional support.

7. 'Will I benefit from the study?'

There is no direct benefit to you from participating in this study, but this study aims to further our understanding of the role of SDC and its impact in health service system. In doing so, it is hoped to inform a discussion around minimising any barriers to the provision of SAPSE legislation and to establish SDC role in hospitals for any patients. Furthermore, it will help to improve health service's accountability and transparency between healthcare providers and, patients and their families.

8. 'Will taking part in this study cost me anything, and will I be paid?

Participation in this study will not cost you anything. Consumers will be reimbursed for their time and participation by e-gift card to the amount of $25 for each interview.

9. 'How will my confidentiality be protected?'

By signing the consent form you consent to the research team recording and collecting information about you in the course of the research that you provide via the interview process. Any information obtained in connection with this research that can identify you will remain confidential. All participant information will be de-identified. Your information will only be used for the purpose of this research project, and it will only be disclosed with your permission, except as required by law. If you do not wish to be recorded, written notes will be taken.

All data collected will be de-identified, any personal information provided will be non-identifiable. Professor Reema Harrison will be responsible for the data storage, security, and retention of the data extracted at the Australian Institute of Health Innovation (AIHI) at Macquarie University. All information will be stored electronically on a password protected secure server located at the AIHI at Macquarie University. Only the named researchers will have access to the secure computer folder where the information is stored. It is anticipated that the results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that you cannot be identified, except with your express permission. Once the recorded interview has been transcribed, original recordings will be deleted.

10. 'What happens with the results?'

Participants can request the available results of the study by contacting the research team directly. Contact information, such as email addresses or phone numbers, will be provided to the participants at the beginning of the study or upon their initial enrollment. We intend to discuss and publish the results with stakeholders through a range of methods and outlets. In all instances, only aggregated data will be provided, and you will not be identified in any of these reports. We will share the results through academic publications to increase knowledge of the topic area, of SDC

and SAPSE legislation. Presentations will be prepared for staff and consumers via social media post (e.g., LinkedIn, Twitter), scientific conferences and other meeting fora.

11. 'What should I do if I want to discuss this study further before I decide?'

If you would like to know more at any stage, please do not hesitate to contact Corey Adams (Clinical Research Officer) on corey.adams@mq.edu.au.

12. 'Who should I contact if I have concerns about the conduct of this study?'

This study has been approved by the Macquarie University Human Research Ethics Committee. Any person with concerns or complaints about the conduct of this study should contact the Ethics Secretariat who is nominated to receive complaints from research participants. You should contact them on 02 9850 4194 and quote HREC reference number (to be obtained).

Thank you for taking the time to consider this study.
If you wish to take part in the study, please sign and return the consent form.

CONSENT FORM

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1. I, ...
   of.....
   agree to participate as a subject in the study described in the 'Participant Information Sheet' set out above **(or: attached to this form).**

2. I acknowledge that I have read the 'Participant Information Sheet,' which explains why I have been selected, the aims of the study and the nature and the possible risks of the investigation, and the statement has been explained to me to my satisfaction.

3. Before signing this consent form, I have been given the opportunity of asking any questions relating to any possible physical and mental harm I might suffer as a result of my participation, and I have received satisfactory answers.

4. I understand that I can withdraw from the study at any time without prejudice to my relationship with my employer or with the investigators or the Australian Institute of Health Innovation, Macquarie University.

5. I agree that research data gathered from the results of the study may be published, provided that I cannot be identified.

6. I understand that if I have any questions relating to my participation in this research, I may contact Professor Reema Harrison, 02 9850 2425 who will be happy to answer them.

7. I acknowledge receipt of a copy of this Consent Form and the Participant Information Sheet.

Complaints may be directed to:
Ethics Secretariat, Research Services
Human Research Ethics Committee
Macquarie University NSW 2109
Phone 02 9850 4194 | email ethics.secretariat@mq.edu.au

Signature of participant **Please PRINT name** **Date**

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Signature of investigator **Please PRINT name** **Date**

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REVOCATION OF CONSENT

I hereby wish to **WITHDRAW** my consent to participate in the study described above and understand that such withdrawal **WILL NOT** jeopardise any treatment or my relationship with Australian Institute of Health innovation at Macquarie University or my medical attendants.

Signature Date

Please PRINT Name

The section for Revocation of Consent should be forwarded to:

PRINCIPAL INVESTIGATOR DETAILS

Professor Reema Harrison (PH: 02 9850 2425 or email: reema.harrison@mq.edu.au)
Australian Institute of Health Innovation, Macquarie University
Level 6, 75 Talavera Road
Macquarie University NSW 2109.