Participant Information Sheet

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| **Title** | *Patients’ perception of qualitative and quantitative risk in anaesthetic consent.* |
| **Principal Investigator** | *Dr Rachel Smith* |
| **Associate Investigators** | *Dr Michelle Lau, Dr Phillip King, Dr Allan Cyna*  |
| **Location**  | *Nepean Hospital* |

**Part 1 What does my participation involve?**

**1 Introduction**

You are invited to take part in this research project, which is called ‘patients’ perception of qualitative and quantitative risk in ‘anaesthetic consent’. You have been invited because you are a person who is presenting for a pre-anaesthetic consultation.

This Participant Information Sheet tells you about the research project. It explains the processes involved with taking part. Knowing what is involved will help you decide if you want to take part in the research.

Please read this information carefully. Ask questions about anything that you don’t understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or local health worker.

Participation in this research is voluntary. If you don’t wish to take part, you don’t have to.

If you decide you want to take part in the research project, you will be asked to fill out the survey. By completing it you are telling us that you:

• Understand what you have read

• Consent to take part in the research project

• Consent to be involved in the research described

• Consent to the use of your personal and health information as described.

You will be given a copy of this Participant Information to keep.

**2 What is the purpose of this research?**

This project is looking at two different ways doctors can explain the level of risk to their patients, for example by using numbers or words. This project aims to explore how these numbers and words match each other so that doctors can learn to communicate risk in a more understandable way.

**3 What does participation in this research involve?**

If you decide to take part in the research project, you will be randomly assigned one of two possible questionnaire asking about some basic questions regarding information about yourself and your proposed surgery. Then you will be given different ways of describing risks of anaesthesia, words or numbers and asked them to match them to each other. The surveys differ in the order in which these are presented. Completing the questionnaire will take approximately 10 minutes. There are no costs associated with participating in this research project, nor will you be paid. We aim to recruit approximately 200 participants from the Nepean Hospital Readmission Clinic.

**4 Do I have to take part in this research project?**

Participation in any research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage.

If you do decide to take part, you will be given this Participant Information to keep.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your routine care, your relationship with professional staff or your relationship with Nepean Hospital.

**5 What are the possible benefits of taking part?**

We cannot guarantee or promise that you will receive any benefits from this research; however, possible benefits may include You may benefit from obtaining a greater understanding of the way in which doctors describe risks before an anaesthetic and this study may lead to improving the way we describe risk to patients so that understanding is improved for future patients.

**6 What are the possible risks and disadvantages of taking part?**

You may feel that some of the questions we ask are stressful or upsetting. If you do not wish to answer a question, you may skip it and go to the next question, or you may stop immediately.

**7 What if I withdraw from this research project?**

If you do consent to participate, you may withdraw at any time. If you decide to withdraw from the project, please notify a member of the research team before you withdraw. A member of the research team will inform you if there are any special requirements linked to withdrawing. If you do withdraw, you will be asked to complete and sign a ‘Withdrawal of Consent’ form; this will be provided to you by the research team.

**8 Could this research project be stopped unexpectedly?**

No.

**9 What happens when the research project ends?**

Should you wish to be provided with a copy of the final results of the research, please contact the lead researcher.

**Part 2 How is the research project being conducted?**

**10 What will happen to information about me?**

By filling out the survey you consent to the research team collecting and using personal information about you for the research project. Any information obtained in connection with this research project that can identify you will remain confidential and de-identified at analysis. All digital information will be kept on a password protected computer at the NBMLDH and hardcopy documents will be kept in a locked filing cabinet in a locked room in the department of anaesthetics. Your information will only be used for the purpose of this research project only and it will only be disclosed with your permission, except as required by law.

The personal information that the research team collect and use is information from the questionnaire you complete.

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.

In accordance with relevant Australian and/or NSW privacy and other relevant laws, you have the right to request access to the information about you that is collected and stored by the research team. You also have the right to request that any information with which you disagree be corrected. Please inform the research team member named at the end of this document if you would like to access your information.

Any information obtained for the purpose of this research project that can identify you will be treated as confidential and securely stored. It will be disclosed only with your permission, or as required by law.

**11 Complaints and compensation**

If you suffer any distress or psychological injury as a result of this research project, you should contact the research team as soon as possible. You will be assisted with arranging appropriate treatment and support.

**12 Who is organising and funding the research?**

This research project is being organised by Dr Rachel Smith. No member of the research team will receive a personal financial benefit from your involvement in this research project (other than their ordinary wages).

**13 Who has reviewed the research project?**

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC).

The ethical aspects of this research project have been approved by the HREC of NBMLHD.

This project will be carried out according to the National Statement on Ethical Conduct in Human Research (2007). This statement has been developed to protect the interests of people who agree to participate in human research studies.

**14 Further information and who to contact**

The person you may need to contact will depend on the nature of your query. 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 the researcher.

 Research contact person

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| --- | --- |
| Name | *Rachel Smith* |
| Position | *Junior Medical Officer* |
| Email | *rachel.harrison11@hotmail.com* |

For matters relating to research at the site at which you are participating, the details of the local site complaints person are:

Complaints contact person

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| --- | --- |
| Name | *Ms Felicity Lindfield,* |
| Position | *Nepean Hospital Patient Representative* |
| Telephone | *(02) 4734 3228* |
| Email | *Felicity.Lindfield@health.nsw.gov.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:

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| --- | --- |
| Reviewing HREC name | *NBMLHD HREC* |
| Telephone | *(02) 4734 1998* |
| Email | NBMLHD-ResearchOffice@health.nsw.gov.au |

**Thank you for your participation in this project.**