Participant information sheet – Phase I interviews

Title	Developing a core outcome set for research and assessment of Immunoglobulin Replacement Therapy in haematological malignancies (Phase I interviews)
Principal Investigator	Dr Catriona Parker, Monash University
Associate Investigators	Prof Erica Wood, Monash University Prof Zoe McQuilten, Monash University

Part 1 What does my participation involve?

1. Introduction

You are invited to take part in this research project "Developing a core outcome set for research and assessment of Immunoglobulin Replacement Therapy in haematological malignancies (Phase I interviews)".

You are being asked to consider participating in this research project because you have personal or professional experience or expertise based in immunoglobulin replacement for blood cancers.

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

Participation in this research is voluntary. If you don't wish to take part, you do not have to. This will not impact on your current care or employment.

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 someone else.

If you decide you want to take part in the research project, you will be asked to provide consent by visiting think link: https://monash.az1.qualtrics.com/jfe/form/SV_57ndVdmY92g4oOG By doing so, you are telling us that you:

• Understand what you have read
• Consent to take part in the research project
• Consent to the use of your personal information as described

2. What is the purpose of this research?

Australia is the world's largest consumer per head of population, of immunoglobulin (Ig), a product made from donated blood, administered via intravenous (IVIg) or subcutaneous (subcut or SCIg) routes. This precious national resource costs upwards of $1 billion (AUD), and the demand for Ig replacement therapy is outpacing the growing clinical need. Ig replacement therapy is an effective treatment to prevent infections in people with blood cancer whose own Ig supplies have been depleted due to disease and treatment. However, little evidence exists as to how to best use Ig, how long it should be used, how often it should be given, what dose to use and the optimal time to start and stop Ig replacement therapy. Additionally, we have no system to capture any undesired side effects (adverse events) and therefore, we do not know how common or serious these are for patients. Research and routine data collection in health services is needed to answer these pressing questions.

Core outcome sets (COS) are an agreed-upon list of outcomes that encourage the reporting of the same things across different research studies or care settings. In research, having the same outcomes reported across different studies allows for direct comparison between the different studies and the pooling of results from multiple studies to generate more robust evidence. COS can also be used in routine clinical practice to collect the same information across health services, allowing for an understanding of current practices, variations in practice, adverse events, and patient outcomes.

The current study is the second phase of a larger research project aimed at developing two COS – one for use in research (COS-research) and one for use in healthcare services (COS-clinical).

The research has been initiated by the investigators listed at the front of this information sheet and is funded through a National Health and Medical Research Council (NHMRC) – Centre of Research Excellence (CRE) grant (APP2024876). A multi-disciplinary project team, made up of doctors, nurses, researchers, government representatives and patients, also oversees the research to provide advice and guidance on the broader project. More

information about the CRE and the broader work is available here:
https://www.optimalcre.org/

3. What does participation in this research involve?

If you decide to take part in this study, you will be asked to participate in an interview with a researcher online or by phone. However, you do not need to have a camera or turn your camera on for the interview. The interview will be audio recorded so the researchers can consider your responses in relation to other interviews. It is expected that the interview take between 30-45 minutes of your time.

During the interview, the researcher will explain more about core outcome sets, the concept of outcomes in research and routine care and ask you questions about your own ideas and beliefs about which outcomes are important based on your own knowledge and experiences. If you're a health care professional, we will also ask you about potential enablers and barriers to the routine collection of data for COS-clinical.

4. What do I have to do?

To participate in this research you must:

- Read all sections of this Participant Information Sheet
- Visit the provided link to provide your consent to take part
- After you provide consent, you will be contacted by a researcher to schedule a mutually convenient day and time for your interview.

5. Do I have to take part in this research project?

No. 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. You will have a copy of this Participant Information Sheet to keep and refer back to.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your relationship with the investigators, your employer or your relationship with your hospital or care team.

If you agree to participate in this research but later decide you wish to withdraw and not have your interview included in the research, you may do so within two months of your interview by contacting Dr Catriona Parker (Catriona.parker@monash.edu).

6. What are the possible benefits of taking part?

You will not receive any direct benefit from participation in this study. However, the development of core outcome sets will harmonise outcome reporting from research and identify current clinical practise which may benefit future patients.

7. What are the possible risks and disadvantages of taking part?

Aside from giving up your time, we do not expect that there will be any risks or costs associated with taking part in this study.

8. What happens when the research project ends?

We expect the findings will be presented in peer-reviewed journals, at professional meetings and at conferences. A summary of the findings will be made available to participants who opted for this information during the consent process.

Part 2 How is the research project being conducted?

9. What will happen to information about me?

By providing your consent, you are agreeing to us collecting information about you for the purposes of this study. Any recordings made from the interview will be transcribed, and the original recording will be destroyed within three months of the interview. All information you provide us or we collect about you will be stored securely and we will only disclose identifiable information with your permission unless we are required by law to release information. You will not be individually identifiable in any presentations or publications of the research findings.

The researcher(s) approved as part of the study will have access to the data. On study completion, all retained data will be kept for at least five years.

10. What if I would like further information?

If you still have questions or need something clarified after you have read this information, you may contact the following researcher:

Dr Catriona Parker, Research Fellow, catriona.parker@monash.edu

11. 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 Monash University. 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.

12. Who should I contact is I have a complaint or a concern?

Should you have any concerns or complaints about the conduct of the project, you are welcome to contact the Monash University Human Research Ethics Committee through any of the below contact details.

Executive Officer
Monash University Human Research Ethics Committee (MUHREC)
Office of Research Ethics and Integrity
Room 116, Administration Building B (3D)
26 Sports Walk, Clayton Campus
Monash University VIC 3800
Tel: +61 3 9905 2052 Email: muhrec@monash.edu