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# Participant Information and Consent Form

## Adult providing own consent

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| **Title:** | **The MAIN project:** Meeting Access and Inclusion Needs in the informed consent process for clinical research. |
| **Protocol Number:** | Version 2.0 dated 29 June 2024 |
| **Principal Researcher:** | Fleur O’Hare |
| **Project Sponsor:** | Centre for Eye Research Australia (CERA) |

## 1. What does my participation involve?

You are invited to take part in this research project that is being done to learn more about how research organisations can improve the way information is provided to people. This is because you have either recently participated, or are currently participating, in a study or clinical trial. The research project is aiming to collect feedback from people on the ways researchers can provide information to people when considering participating in studies and trials.

This Participant Information Sheet/Consent Form tells you about the research project. It explains the steps 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. You can take some time to make up your mind and decide if this project is right for you.

Participation in this research is voluntary. If you don’t wish to take part, you don’t have to. You will receive the best possible care whether or not you take part.

If you decide you want to take part in the research project, you will be telling us that you:

* Understand what you have read.
* Consent to take part in the research project.
* Consent to the research that is described.
* Consent to the use of your personal and health information as described.

By completing the online survey, you are consenting to your anonymous responses being used for the research purposes described. Following the survey, you will be asked if you would like to be involved in other parts of this research project.

## 2. What is the purpose of this research?

* The MAIN project is looking at ways to enhance how information about clinical research can be provided to people.
* We hope to gather feedback on how information can be best presented, so that it is helpful to reading and understanding the key elements of research participation.
* We hope to develop a set of guidelines and tools that researchers can use to make sure information is accessible, easy to read and use.
* We are inviting people who would like to share their ideas about ways to improve how information can be provided to people. This includes ways to provide information so that people with sensory impairments, such as vision loss, can access the information provided.

The results of this research will be used by the researcher Fleur O’Hare to obtain a doctorate degree with the University of Melbourne. The research is being sponsored by the Centre for Eye Research Australia.

## 3. What does participation in this research involve?

You can choose to be involved in one part of the project or multiple parts of the project.

The levels of involvement are as follows:

* **Level one involves completing a survey**. The first section of the survey asks you questions about you, such as your age, as well as questions about how much information you generally prefer when being told about a study or clinical trial. The second section of the survey asks you about your most recent experience in receiving information about a clinical study or clinical trial. We want to know your views about the information quality and the process you went through before deciding whether to participate or not.

The survey can take around 25 minutes to complete, depending upon how much information you would like to share. It can be completed on paper or online, with or without assistance from a member of the study team. If online, a secure platform hosted by the University of Melbourne will be used called Qualtrics.

There is also the option of providing feedback over the phone or on email if this is preferred.

* **Level two involves attending a single group discussion,** also called a focus group or workshop meeting. These group sessions are aimed at exploring topics and sharing ideas together. They are semi-structured meetings and will run for approximately 60 to 90 minutes. They will be conducted online, for example via ZOOM teleconferencing, with instructions and support provided.
* **Level three involves attending group meetings on a more regular basis.** There may be the opportunity to be involved in multiple discussion group meetings or workshops depending on your interest and expertise. The project aims to take note of feedback to develop tools and templates for clinical researchers to consider using in their practice. Involvement in ongoing meetings will be in an advisory capacity where members of the group work together to co-design the tools and templates for use. Training and support will be provided.

Meetings will be audio recorded and will be conducted online using ZOOM videoconferencing. This is so people located in various locations can be included. The option of face-to-face meetings will be considered as needed.

There are no costs associated with participating in this research project. Interpreters and other communication services will be provided as needed.

## 4. Other relevant information about the research project

* We hope to enrol up to 200 people in this study.
* The project is open to anyone who has either been invited to take part in a research study or clinical trial before.

## 5. 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.
* 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 the Centre for Eye Research Australia.

## 6. What are the possible benefits of taking part?

* There will be no direct benefit from being involved in this project. However, your contribution is valuable in giving us a better understanding of how we can improve engagement with clinical research services.
* Importantly, we want to ensure that everyone considering being involved in research is given an equal chance of reading and understanding the information provided to them by researchers.
* Your feedback will ensure we take a considered approach to enhancing the experience and journey that people have when considering to be involved in research.
* Your valued feedback will help us take steps to promote a set of recommendations, tools and templates for use by clinical research organisations and researchers to improve their service delivery.

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

It is not expected that there would be any significant risks from being in this research program, other than an impact to your time in taking part.

Risk to confidentiality.

There may be a possible risk to confidentiality. This study will be capturing some information about you that includes identifiable, personal information, like your age and whether you have any vision loss. This information will be collected as part of the study to confirm your consent and to also allow general characteristics of the project participants to be grouped together and reported. See point 11 on how we will protect your information.

Group discussions.

Whilst all care will be taken to maintain privacy and confidentiality, you may experience embarrassment if one of the group members were to repeat things said in a confidential group meeting.

## 8. What if I withdraw from this research project?

* If you do consent to participate, you may withdraw at any time.
* If you do decide to leave the research project, no additional information will be collected from you.
* If possible, the information collected up to that time you withdraw will form part of the research project. This includes any survey responses as it will be difficult to identify which responses are yours as they are anonymous.

## 9. Could this research project be stopped unexpectedly?

* We might need to stop the project while you are taking part. If this happens, we will explain the reasons to you.

## 10. What happens when the research project ends?

Participants in the advisory group meeting will be consulted about what findings are important and how best to present them. This may include producing a summary of the main findings. It will also likely include important findings being shared in respected journals and presented at national and international conferences. No personal information that could identify you will be shared. See point 11 below for more information.

You will have the option of requesting a summary of the findings from this study. To do so, please contact the Principal Researcher, Fleur O’Hare on her email: fohare@cera.org.au

## 11. What will happen to information about me?

Collecting your information.

By agreeing to take part, you are consenting to the research team collecting and using information you provide for the research project. Any information obtained in connection with this research project that can identify you will remain confidential.

Information we collect may be recorded on paper, online or recorded during a teleconference. Survey responses collected online will be recorded using the University of Melbourne’s Qualtrics Research system. All data is stored securely and can only be directly accessed by the study team.

Survey participation is anonymous. There is the option of contacting the Principal Researcher directly should you wish to be involved in group meetings or workshops. If this is the case, we will remove names, initials, and other information from the stored files so that it would make it harder to identify you. If attending group meetings, these will be audio recorded via ZOOM teleconferencing and audio information will be digitally transcribed and saved as text files to a secure database.

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.

It is anticipated that the results of this research project will be published and presented in a variety of forums. In any publication or presentation, information will be provided in such a way that you cannot be identified.

In accordance with relevant Australian and/or Victorian 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. This excludes survey responses as they are anonymous. Please inform the research team member named at the end of this document if you would like to access your identifiable 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.

Keeping your information safe.

To keep your information safe, we will follow the following steps.

* Follow all relevant privacy requirements.
* Always keep it in a secure location in a locked research office.
* Take steps to prevent anyone from accessing information that identifies you unless they need to, for example, to check it in an audit.
* Give it a code and keep it separate from anything that could easily identify you, like your name or contact information.

Information we collect and record from you will be kept for 5 years, then destroyed securely by shredding paper files and deleting electronic files. Information we collect on digital recording systems will also be deleted 5 years after the completion of the study. Backup data files stored on the CERA network can’t be permanently deleted.

Sharing your information with others.

Research data will be shared with CERA as the Sponsor of the study. CERA is co-located with Cerulea Pty Ltd (‘Cerulea’), a related entity of CERA. As CERA and Cerulea share clinical space and software your information will be shared with Cerulea.

We may also share information summaries with other research organisations that have an interest in the project findings. We may also share information that is required by law or regulation to any review board that oversees human protections or any federal agency that oversees research. We will only share information that has been aggregated (that is, joined together with information from others before sharing) to ensure anonymisation. We will remove names, initials, and other information from the stored files so that it would make it harder to identify you.

If you would like to know more about how we will collect, store, and share your information as part of this project, please contact the Principal Researcher, Fleur O’Hare on her email fohare@cera.org.au

12 Complaints and compensation

If you suffer any negative consequences from participating in this research project, you should contact the study team as soon as possible and you will be assisted in arranging appropriate care. There are no compensation arrangements in place for participating in this project. See the contact for complaints under point 15.

## 13. Who is organising and funding the research?

This project is being run by the Principal Researcher, Fleur O’Hare, who is employed by the Centre for Eye Research Australia and is also undertaking post-graduate studies with the University of Melbourne. The research is being sponsored in Australia by the Centre for Eye Research Australia. No member of the research team will receive a personal financial benefit from your involvement in this research project (other than their ordinary wages).

If you choose to take part in meetings or workshops you will be offered a $100 gift card, for each meeting, to thank you for your time. Gift cards can be distributed electronically, to your email address, or a hard card can be provided.

## 14. 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 St Vincent’s Hospital Melbourne.

This project will be carried out according to the National Statement on Ethical Conduct in Human Research (2007, updated 2023). This statement has been developed to protect the interests of people who agree to participate in research studies.

## 15. Further information and who to contact

The person you may need to contact will depend on the nature of your query. You can contact the Principal Researcher at any time to ask questions about the MAIN project.

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| Position | Principal Researcher – Fleur O’Hare |
| Telephone | 03 9959 0113 |
| Email | fohare@cera.org.au |

**Complaints about how this project is being run.**

If you have any complaints about how this project is being run, please contact:

|  |  |
| --- | --- |
| Position: | CERA Research Governance Office |
| Telephone: | 03 9959 0028 |
| Email: | cera-rgo@cera.org.au |

**Reviewing HREC Approving this Research and HREC Executive Officer Details**

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| --- | --- |
| Reviewing HREC Name: | St Vincent’s Hospital Melbourne |
| Position: | HREC Executive Officer |
| Telephone: | (03) 9231 6970 |
| Email: | research-ethics@svhm.org.au |

# Consent to take part - Adult providing own consent

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## Declaration by Participant

* I have read the Participant Information Sheet or someone has read it to me in a language that I understand.
* I understand the purposes, procedures and risks of the research described in the project.
* I have had an opportunity to ask questions and I am satisfied with the answers I have received.
* I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the project without affecting my future care.
* I understand that my responses may be audio recorded if participating in meetings.
* I understand that the data from this research project will be stored at the Centre for Eye Research Australia and will be destroyed 5 years after project completion and publication.

By completing the online survey, you are consenting to your anonymous responses being used for the research purposes described in this document.

Following the survey, you will be asked if you would like to be involved in other parts of this research as described in this document.

# Withdrawal Form - Adult providing own consent

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## Declaration by Participant

* I wish to withdraw from participation in the above research project and understand that such withdrawal will not affect my routine treatment, my relationship with those treating me or my relationship with the Centre for Eye Research Australia.

### **Person withdrawing from the project.** Please insert name, date and signature in the fields in the table below.

|  |  |
| --- | --- |
| Name: |  |
| Date: |  |
| Signature: |  |

In the event that the participant’s decision to withdraw is communicated verbally, the Researcher will need to provide a description of the circumstances below:

**Declaration by Researcher.** I have explained what is involved in withdrawing from the project to the participant and I believe they have understood that explanation.

|  |  |
| --- | --- |
| Name: |  |
| Date: |  |
| Signature: |  |