

Participant Information and Consent Form

Short Name of Project	Beyond the Form
Full Name of Project	Beyond the Form: Engaging Participants Throughout Clinical Research
Principal Investigator	Dr Lisa Eckstein
Project Sponsor	CT:IQ and Victorian Comprehensive Cancer Care Alliance



What am I being invited to do?

We, the Beyond the Form project team, invite you to take part in a project that assessing the ways in which current participants communicate with researchers and other study staff in Australian clinical research projects. You have been invited to take part because you currently work in clinical research in Australia as a clinical researcher, study staff member or sponsor representative.

If you take part, we will conduct a half hour interview with you to talk about your experience communicating with clinical research participants.

Around 25 people will take part in this project. They will be from clinical research organisations around Australia.

Please read this information and ask us any questions by emailing beyondtheform@ctiq.com.au. You can take some time to make up your mind. You get to decide whether this project is right for you.



What is the purpose of this project?

In this project we will identify and assess ongoing participant communication strategies that are being used in Australian clinical research. We hope that the results from this project will inform future clinical research practices in Australia and around the world.



Do I have to take part and can I change my mind?

Taking part is up to you

You get to decide whether you take part in this project. You can say yes or no.

If you choose to stop taking part in the project, you can withdraw at any time. If you withdraw after having completed an interview, we will remove and destroy your interview data. It will be possible to remove this data until the time of publication.



What do I have to do if I take part?

If you agree to take part in this project, you will participate in an online video interview. You will be asked about your experiences of communicating with current participants in clinical research. This will take about 30 minutes. At the end of the interview, you will be offered a \$50 gift card in recognition of your time.



What are the benefits of taking part?

There may be no direct benefit to you for taking part in this project; however, we hope that you will be helping to establish better clinical research practices in Australia in the future. We will email a summary of the study results to you once they are available, which may be useful for your clinical research practices in the future.



What are the risks and discomforts of taking part?

The only foreseeable risks of this research are to your privacy. To minimise this risk, we will take steps to keep your information secure:

- To capture your responses, we will record your interview on Zoom or a similar video platform. The recording will be deleted as soon as a transcript has been developed. The transcript will contain only pseudonymised (coded) data. Only Investigators Eckstein and Wells will have access to identifying information.
- We will store your coded interview transcript electronically on a secure, password-protected server for a total of 5 years from the completion of this project. After this time, your transcript will be deleted from our servers.
- We will store your name and email address along with your interview code separately on a secure, password-protected server. At the end of the project, we will delete this file.

We will not identify you in any publications.



Who is running and paying for this project?

This project is being organised and funded by CT:IQ and the Victorian Comprehensive Cancer Centre Alliance.



Who has reviewed and approved this project?

The Central Adelaide Local Health Network (CALHN) Expedited Review Panel has approved this project (ref: 18126).

This committee makes sure that this project meets Australian ethical standards for research that involves people.

Comments or complaints about how this project is being run

If you have any comments or complaints about this project, please contact beyondtheform@ctiq.com.au.



Where can I find more information?

Thank you for taking the time to read this information about our project. You can contact a member of the project team at any time to ask questions.

Gudrun Wells Research Officer [email], [phone number]

You can find out more information about the larger Beyond the Form project by visiting <https://ctiq.com.au/current-projects/project-9/> or emailing beyondtheform@ctiq.com.au.

Signature Page

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Consent to take part in this project: This means you can say NO

By signing this consent form, I acknowledge that:

- I freely agree to take part in this project
- I understand that I can stop taking part in the project at any time
- I have read, or have had read to me, the information provided about this project and understand what is involved including the use of my personal information
- I have had the opportunity to consider the information, ask questions and am satisfied with the answers I received

Person taking part in the project

Signature: _____ Date: _____

Name: _____

You must sign and personally date this consent form