**Participant Information Sheet**

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| Short **Name of Project** | Beyond the Form  |
| Full Name of Project | Beyond the Form: Engaging Participants Throughout Clinical Research (Part C – participant workshops) |
| Principal Investigator | Dr Lisa Eckstein |
| Project Sponsor | CT:IQ and the VCCC Alliance |



### What am I being invited to do?

The Beyond the Form project team invite you to be part of a project exploring how clinical researchers communicate with research participants. The Beyond the Form project team is made up of members of CT:IQ and the VCCC Alliance. This part of the project is being conducted by Dr Lisa Eckstein, Gudrun Wells and Gillian Mason.

We are looking for up to 32 people who have participated in clinical research in Australia to take part in **two 2-hour workshops**, held two weeks apart. They will be either via videocall (on Zoom) or in-person in a community hall (for people who live in Tamworth, NSW). For the Zoom meetings you will need to have access to a computer or tablet device (like an iPad) that connects to the internet. You don’t need to be really good with computers – we’re happy to help you learn what to do with Zoom. The sessions will be held in English.



### What is the purpose of this project?

The connection between someone in a clinical research study and their study team is important. It can change how safe, supported, and informed the person may feel throughout their research experience. CT:IQ, the VCCC Alliance and the Hunter Medical Research Institute are doing the *Beyond the Form* project to find ways to improve communication between study teams and the people taking part in the studies.

We want to hear from people who have taken part (or have supported someone else to take part) in a clinical research study in Australia. We would like to explore how useful you think different communication strategies are, and what you think is important in how studies are set up.



### 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, and your decision won’t affect your relationship with anyone who suggested you might be interested.

**You can change your mind at any time**

If you do decide to take part in the workshops, you can still change your mind at any time. If you want to stop, please let us know. You do not have to tell us the reason. If you have already attended a workshop, we won’t analyse the information that you gave us at that workshop.



### What do I have to do if I take part?

If you take part in this project, you will attend **two 2-hour workshops** (either via Zoom or in-person), with some reading before each of the workshops. You will be sent a physical copy of the materials at least a week before the session to give you time to consider all the discussion questions before the first workshop.

A research team member will guide the discussion in the workshops, focussing on the questions sent out by the team, and ideas that you and other workshop members bring to the group.

Payment for your time and expenses

You will need to spend about 6 hours of time taking part in this project. This includes the preparation time before each workshop. To recognise your time, we will offer you $350.

For people in Tamworth who choose to come to the in-person workshop, we will also reimburse you for out-of-pocket expenses like parking or meals.



### 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 set up better clinical research projects in Australia in the future. We will email a summary of the study results to you once they are available.

### What are the risks of taking part?

The only foreseeable risks of this research are:

1. To your privacy. To minimise this risk, we will take steps to keep your information secure:
* We will record the workshops using Zoom, so that we can re-watch it to make sure that the transcript (written record) is accurate. The recording will be deleted as soon as we have checked it. Only Investigators Eckstein, Wells and Mason will have access to any identifying information.
* All information will be stored on a secure, password-protected server for a total of 5 years from the completion of the project, and then deleted. Your name, email and workshop code will be stored separately from the workshop data.
* We will not identify you in any publications.
1. Feeling distressed. Some people may feel distressed when recalling memories of health issues and the research studies they have been part of in the past.

To minimise this risk and make sure that people who take part are supported:

* The facilitators are experienced, and they will explain the scope of the workshop to you and the group before starting.
* The workshops and questions were designed together with people who have taken part in research themselves

Taking steps to cope with stressful situations is important. If you are experiencing high levels of stress, talk to your GP or a Counsellor. You can also get support by calling Lifeline on 13 11 14 (free call) or chat to a professional online at <https://online.beyondblue.org.au/#/chat/start>.

1. Breach of confidentiality.In this workshop, we will talk about sensitive topics. There is a chance that other people in the group could share information from the workshop with others outside of this project. We will remind everyone who takes part that they must keep what they hear in this workshop confidential and not share it with others.



### Who is running and paying for this project?

The Beyond the Form project is being run and funded by CT:IQ and the VCCC Alliance. The Hunter Medical Research Institute is assisting in running these participant workshops.



### Who has 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.

If you have any complaints about how this study is being run, please contact CALHN at

Health.CALHNResearchLNR@sa.gov.au or call (08) 7117 2224



### Where can I find more information?

If you would like more detailed information about how the project will be run and what taking part will involve, you can contact a member of the team at any time to ask questions: beyondtheform@ctiq.com.au. You can also visit our website to find more information about the project: [Project 9 – CT:IQ Clinical Trials (ctiq.com.au).](https://ctiq.com.au/current-projects/project-9/)