Participant Information Sheet

Project Name	Clinical Research Data Sharing Frameworks
Principal Investigator	Dr Lisa Eckstein, CT:IQ
Project Sponsor	Australian Research Data Commons (ARDC)

We, the Clinical Research Data Sharing Frameworks project team, invite you to take part in a project that explores common barriers and enablers to accessing and sharing clinical research data for future research. The project is being run through CT:IQ, which is a not-for-profit Australian clinical research improvement organisation. This part of the project is being conducted by Dr Lisa Eckstein, Vanessa Warren and Dr Rebekah McWhirter.

What am I being invited to do?

We are looking for people who have experience with accessing and sharing clinical research data in Australia as a researcher, study coordinator, site staff member, or a study sponsor. If you take part, we will ask you to join one 60-minute online focus group (via Teams or Zoom). During the focus group, you will be asked to share your feedback on current barriers to secondary sharing of clinical research data, and tools and resources that may help improve sharing practices. Each focus group will include up to eight participants.

You will not be paid for your time in participating.

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

Taking part is up to you. Participation in this study is entirely voluntary. You have the right to refuse to participate or withdraw from the study at any time without any consequences. Your decision will not affect your relationship with CT:IQ. If you decide to take part, you can schedule participation through the project website. At the start of the focus group, you will be asked to verbally confirm your consent to participate.

You can change your mind at any time. If you decide to register for a focus group, you can change your mind about participating at any time, including prior to, during, or after the focus group. You do not have to tell us the reason. If you have already attended a focus group, we won't analyse the information that you gave us at that focus group.

What are the benefits of taking part?

There may be no direct benefit to you for taking part in this project such as monetary payment; however, we hope that you will be helping to set up better clinical research data sharing practices in Australia in the future, which will benefit researchers, HRECs, research institutions and consumers. We will email a summary of the study results to you once they are available.

What are the risks and discomforts of taking part?

The only foreseeable risks of this research are to your privacy. We will record the focus groups using Teams, so that we can re-watch it to make sure that the transcript is accurate. To minimise this risk, we will:

- Delete the recording as soon as we have checked it. Only Investigators Eckstein, Warren and McWhirter will have access to any identifying information.
- Store all information on a secure, password-protected server for a total of 5 years from the completion of the project, and then delete it. Your name, email and focus group code will be stored separately from the focus group data.
- Not identify you in any publications.

Australian privacy law (or rules) requires us to tell you how we handle your private information, and you can ask us to give you more information about that and you can find out what information we have about you and you can fix it if it is wrong.

We will share certain information from these focus groups so that others can use it and understand the study findings. This information will not identify you individually. We will make this project information available through journal articles, presentations, and the CT:IQ and ARDC website. **By being in this project, you agree to us sharing focus group information for these purposes**.

Who is running and paying for this project?

This project is being run by CT:IQ and the Australian Research Data Commons (ARDC). The project is being funded by the ARDC.

Who has reviewed and approved this project?

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

study has been approved by the Central Adelaide Local Health Network Human Research Ethics Committee.

Where can I find more information?

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

If you have any questions concerning this project or your participation, contact the following person:

Research Contact

Name	Dr Lisa Eckstein
Position	CT:IQ Director
Phone	0409 274 167
Email	lisaeckstein@ctiq.com.au

If you wish to speak to someone not directly involved in the study about your rights as a volunteer, or if you have any complaints about any aspect of the project or about the conduct of the study, you may contact:

Reviewing HREC approving this research, HREC Executive Officer details and Complaints Contact

HREC Name	Central Adelaide Local Health Network Human Research Ethics Committee (CALHN HREC)
Contact	HREC Support Officer
Telephone	(08) 7117 2229
Email	Health.CALHNResearchEthics@sa.gov.au

By registering for this focus group, you indicate that you have read and understood the information provided in this Participant Information Sheet. Your participation in this study is voluntary, and you consent to take part under the conditions outlined above.