Project Name	Clinical Research Data Sharing Frameworks – Ethics Review Body Benchmarking Shared Ethical Decision Making
Principal Investigator	Dr Lisa Eckstein, CT:IQ
Project Sponsor	Australian Research Data Commons (ARDC)

What am I being invited to do?

We, the Clinical Research Data Sharing Frameworks project team, invite you to take part in a project that explores common barriers and enablers to sharing clinical research data for future research, including ethical review processes. 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, Ms Vanessa Warren and Dr Rebekah McWhirter.

We are looking for ethics review bodies that deal with ethics applications involving the secondary sharing of human research data. If you agree to take part, we will ask you to:

Part 1

Complete a short online survey about barriers and enablers when assessing ethics applications dealing with secondary data sharing.

You will not be paid for your time participating in this survey.

Part 2

Participate in a shared ethical decision-making benchmarking exercise. This will involve:

a) reviewing a hypothetical research proposal that involves the use of secondary data with your Committee,

b) sharing the de-identified minutes of the Committee's review discussion for analysis and comparison across participating ethics review bodies, and;

c) completing a short online survey about your experience reviewing the hypothetical research proposal, and any support that may assist future reviews of this nature.

You (Executive Officer or Chair) may also opt to:

d) participate in a brief interview to explore specific decision-making processes, priorities, and expectations to support best-practice research applications and ethical review in the future.

Your ethics review body will receive a $100 gift card honorarium for participation in the review exercise (Part 2), in recognition of the time involved.

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 any).

You can choose to participate in the survey (Part 1) only OR you can choose to participate in both Part 1 and Part 2.

You can change your mind at any time. If you decide to take part in the survey or the review exercise, you can change your mind about participating at any time, including prior to, during or after completing Part 1 or Part 2. You do not have to tell us the reason. If you have already completed a survey or review exercise, we won't analyse the information that you gave us.

What are the benefits of taking part?

There may be no direct benefit to you for taking part in this project; however, you will be helping to identify the enablers and barriers that ethics review bodies experience when assessing applications involving secondary data. By doing so you will be helping to set up better clinical research data sharing practices in Australia in the future.

We will email a summary of the study results to you once they are available. This may help to inform your ethical review practices.

What are the risks and discomforts of taking part?

The only foreseeable risks of this research are to the privacy of your ethics review body. To minimise this risk, we will:

- De-identify the survey, review minutes, and online interviews so that both the participating ethics review bodies and participating individuals are anonymous. 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 or your ethics review body in any publications.

In accordance with relevant Australian and/or South Australian privacy and other relevant laws, you have the right to request access to your information collected and stored by the research team. You also have the right to request that any information with which you disagree be corrected. Please contact the study team member named at the end of this document if you would like to access your information.

We will share certain information from the survey and review exercise so that others can use it and understand the study findings. This information does not identify you individually. We will make this project information available through journal articles, presentations, and the CT:IQ and ARDC website. **By participating in this project, you agree to us sharing de-identified information for these purposes**.

Your participation in this study shall not affect any other right to compensation you may have under common law.

Who is running and paying for this project?

This project is being run and funded by CT:IQ and 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 (HREC number 20447).

Where can I find more information?

You can visit our website to find more information about the project: https://ctiq.com.au/current-projects/clinical-research-data-sharing-frameworks/

If you have any questions concerning this project or your participation, please contact:

Research Contact

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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
Phone	(08) 7117 2229
Email	Health.CALHNResearchEthics@sa.gov.au

By continuing with Part 1 and/or Part 2, 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.