CT:IQ Clinical Trials: Thinking Smarter

Australian Research Data Commons

Clinical Research Data Sharing Frameworks
Ethics Review Body Benchmarking Activity

EXECUTIVE SUMMARY

Background

- Using data from completed clinical trials can help confirm previous results and allow researchers to explore new questions.
- Ethics review bodies (ERBs) play an important role in making decisions about the acceptable use of clinical trial data for secondary research projects in Australia. This is especially important where trial participants weren't asked at the time of consenting to the original trial whether they agree to their data being used for future research. To use these data, researchers must ask an ERB to authorise a waiver of the requirement for consent for data sharing.
- Waivers of the requirement for consent for data sharing require ERBs to balance the public benefits from data sharing with potential harms to participants, including privacy risks.
- This project investigated how ERBs are managing this complex decision-making responsibility.

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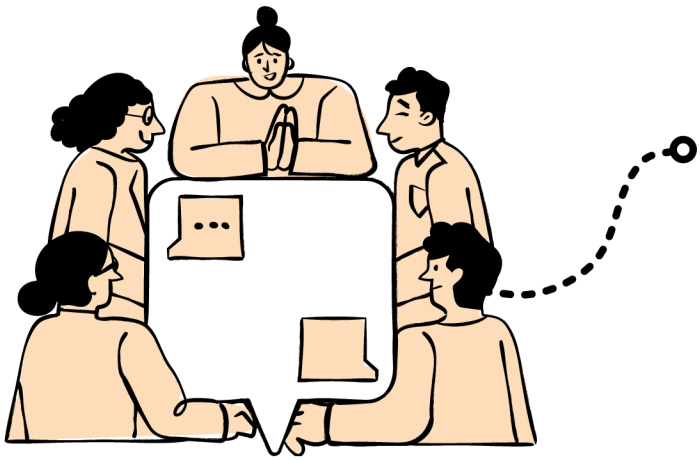
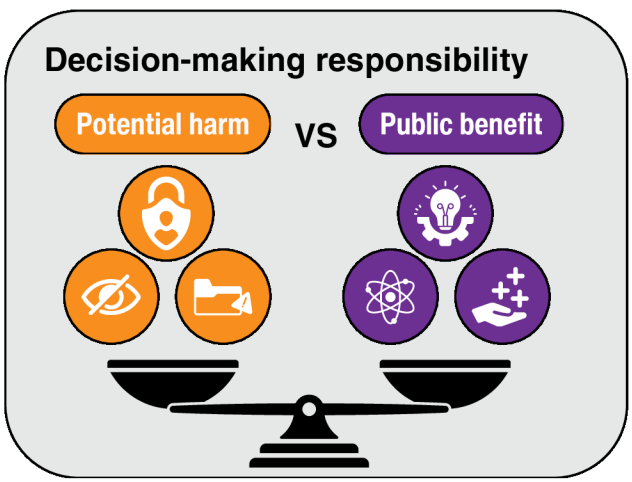




The Ethical Review Body Benchmarking Activity

We created a hypothetical application seeking to share data from a completed clinical trial to answer a new research question. We developed two versions of the application with just one difference—one version included a Participant Information and Consent Form (PICF) that was silent on future data sharing; the other had a PICF that gave participants an option to consent to 'related' data sharing activities.

Every ERB (n = 188) in Australia received an invitation to do a mock review of one of the two randomly assigned versions of the hypothetical application.

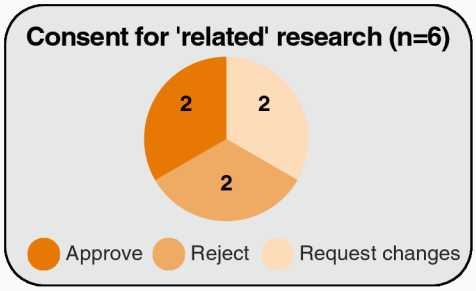
Eighteen (18) ERBs provided a review.

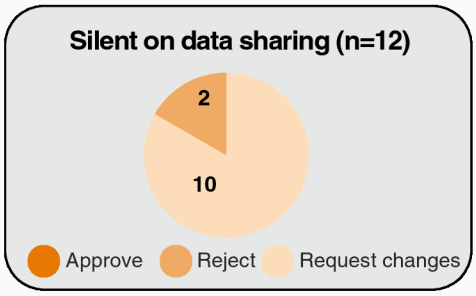
This included ERBs from most Australian states and territories, and ERBs based in public hospitals, private sites and universities.

Outcome

ERBs varied widely on their application of the National Statement on Ethical Conduct in Human Research (National Statement), both in the provisions of the National Statement on which they chose to focus and the way in which they interpreted its provisions.

- Of the six ERBs provided with the PICF that allowed participants to consent to their information being shared for 'related' studies, two outright approved, two outright rejected, and two asked for changes before they approved.
- Of the twelve ERBs provided with the PICF that was silent on future data sharing, none outright approved, two outright rejected, and ten asked for changes
- This variation highlights that ERBs were significantly less likely to approve data sharing outright when the original consent form did not mention future use of data.





ERBs expressed a broad range of views on:

- the potential benefits of the proposed secondary research,
- whether the data being requested were deidentified, and
- whether it would be practicable to seek reconsent from trial participants.

Some ERBs told us that they weren't always sure about the scope of their role.

Conclusions

Differences between ERBs highlight the need for more guidance on the legal and ethical criteria for the review of secondary data use to ensure sound research can be undertaken and trust in the ethics review process is maintained. This includes:

- Resources for researchers on planning and drafting clear and complete applications to re-use clinical trial data.
- Resources for ERBs on assessing the benefits of data sharing against potential risks to trial participants, including what constitutes personal and identifiable information, privacy risks and the role of ERBs as compared with other regulatory actors.