ACT AEC Accelerating Clinical Trials / Accélérer les Essais Cliniques

Day 1 Breakout Summary

Discussion Leads:

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4th ACT Canada Consortium Meeting
Cape Breton
September 25th, 2025

General Structure

- Discussion leads have reviewed breakout notes they received from each group
- Discussion leads will summarize feedback by theme
- After each theme, we invite the audience to use the standing mics for additional discussion

Consent Modification Guidelines

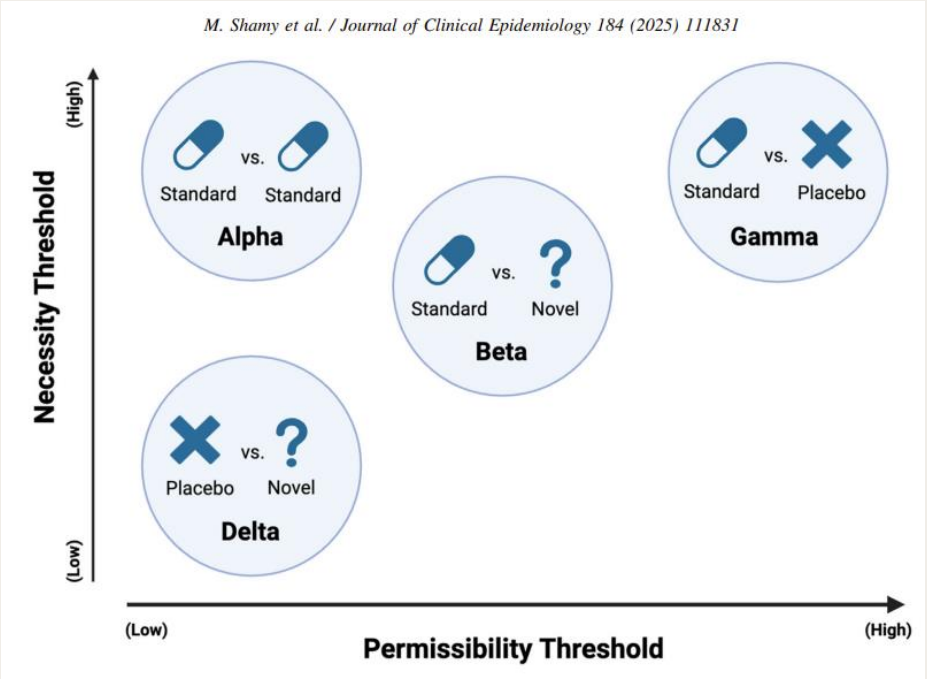
- Minimal Risk
- Participant Welfare
- Impracticability
- Routinely Collected Data for Minimal Risk
- Debriefing

Groups 01-03

MINIMAL RISK

[3.7A] Minimal risk research is defined as: research in which the ***probability and magnitude*** of possible harms implied by participation in the research are ***no greater than*** those encountered by participants in those aspects of their ***everyday life*** that relate to the research.

Figure: Four Quadrants Framework



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MINIMAL RISK

Audience Discussion

Groups 04-06

PARTICIPANT WELFARE

In the TCPS2, ***concern for welfare of participants*** is a core principle that requires researchers and research ethics boards to aim to ***protect the welfare of participants***, and, in some circumstances, to ***promote that welfare*** in view of any foreseeable risks associated with the research.

[3.7A] Welfare is defined as: the ***quality of a person's experience of life in all its aspects***. Welfare consists of the ***impact on individuals and/or groups of factors*** such as their physical, mental, and spiritual health, as well as their physical, economic, and social circumstances.

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PARTICIPANT WELFARE

Audience Discussion

Groups 07-09

IMPRACTICABILITY

It is **impossible or impracticable** to carry out the research and to address the research question properly, given the research design, if the ***prior consent of participants*** is required.

[3.7A] Impracticable is defined as: incapable of being put into practice due to a degree of ***hardship or onerousness that jeopardizes the conduct of the research***; it does not mean mere inconvenience.

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IMPRACTICABILITY

Audience Discussion

Groups 10-12

USE OF ROUTINELY COLLECTED HEALTH DATA FOR MINIMAL RISK STUDIES

[5.5A] Researchers who have not obtained consent from participants for secondary use of identifiable information shall only use such information for these purposes if they have satisfied the REB that:

a) identifiable information is ***essential*** to the research
b) the use of identifiable information without the participants' consent is ***unlikely to adversely affect the welfare*** of individuals to whom the information relates
c) the researchers will take ***appropriate measures to protect the privacy*** of individuals and to safeguard the identifiable information
d) the researchers will ***comply with any known preferences*** previously expressed by individuals about any use of their information
e) it is ***impossible or impracticable*** to seek consent from individuals to whom the information relates
f) the researchers have ***obtained any other necessary permission*** for secondary use of information for research purposes.

[5.5B] Researchers shall seek REB review, but are not required to seek participant consent, for research that relies exclusively on the secondary use of non- identifiable information.

USE OF ROUTINELY COLLECTED HEALTH DATA FOR MINIMAL RISK STUDIES

Audience Discussion

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Groups 13-15

DEBRIEFING

Debriefing in the Context of Alterations to Consent Requirements

a) Debriefing must be a part of ***all research*** involving an alteration to consent requirements **[3.7A]** whenever it is possible, practicable and appropriate.

b) Participants in such research must have the ***opportunity to refuse consent and request the withdrawal*** of their data and/or human biological materials whenever possible, practicable and appropriate **[3.1]**

In cases where participants were not asked for their consent prior to collection of data and/or human biological materials, researchers must explain why this exception to consent requirements was necessary. Researchers must give ***details about the importance of the research*** and the ***necessity of having to use alterations to consent requirements***, and ***address any concerns*** raised by participants. In order to address any misconceptions that may have arisen, researchers must explain ***why these research procedures were necessary to obtain scientifically valid findings.***

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DEBRIEFING

Audience Discussion

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Thank you for your participation!