

Considering Sex and Gender in Research Ethics and Responsible Conduct of Research

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Overview

- Current guidance
 - Ethics
 - Integrity
- Considerations for improvement
 - Policy
 - Education
 - Enforcement

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Ethics guidance - TCPS 2

- Fundamental value
 - Respect for human dignity
- Expressed through three core principles
 - Respect for persons
 - Concern for welfare
 - Justice



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Core principle – Respect for Persons

Moral obligation to respect autonomy

- Based on requirement of free, informed and ongoing consent
- Informed consent requires understanding of research risks and potential benefits



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Core principle – Concern for Welfare

Obligation on researchers and REBs to protect welfare of participants

- Consider impact of research on participant
- No exposure to unnecessary risks
- Attempt to achieve most favourable balance of risks and potential benefits



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Core principle - Justice

- Obligation to treat people **fairly** and **equitably**
 - Fairness : treating all people with equal respect and concern
 - Equity: no undue burden or denial of benefits to one segment of population



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Chapter 4 - Fairness and Equity

“Particular individuals, groups or communities should neither bear an unfair share of the direct burdens of participating in research, nor should they be unfairly excluded from the potential benefits of research participation”



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Appropriate Inclusion - Article 4.1

“Taking into account the scope and objectives of their research, researchers should be inclusive in selecting participants. Researchers shall not exclude individuals from the opportunity to participate in research on the basis of attributes such as culture, language, religion, race, disability, sexual orientation, ethnicity, linguistic proficiency, **gender** or age, unless there is a valid reason for the exclusion.”



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Appropriate Inclusion (cont'd)

- Participation should be based on inclusion criteria that are justified by the research question
- Researchers have a duty not to exclude individuals or groups from participation for reasons that are unrelated to the research



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Inappropriate Exclusion - Article 4.2

“Women shall not be inappropriately excluded from research solely on the basis of gender or sex.”



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Inappropriate Exclusion – Article 4.3

“Women shall not be inappropriately excluded from research solely on the basis of their reproductive capacity, or because they are pregnant or breastfeeding”



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Guidance on responsible conduct of research

Objectives of RCR Framework include:

“promote and protect the quality, accuracy, and reliability of research funded by the Agencies”

(Art. 1.3.c)



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Research Integrity Policy

Rigour:

“Scholarly and scientific rigour in proposing and performing research; in recording, analyzing, and interpreting data, and in reporting and publishing data and findings.”

(Article 2.1.2.c, RCR Framework)



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Considerations for improvement

- Policy gaps?
- Need for clarification, interpretation?
- Need for better implementation, enforcement?



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Other Guidelines / Guidance

- Health Canada
 - Considerations for Inclusion of Women in Clinical Trials and Analysis of Sex Differences (2013)
- Canadian Institutes of Health Research
 - Criteria for Integration of Sex & Gender – Biomedical Research
- European Association of Science Editors
 - SAGER Guidelines

CONCLUSION

Good science is necessary for good ethics

Good ethics requires good science

Please get in touch



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