Quorum

Tri-Council Policy Statement: A Summary of the Second Edition Changes

This table **locates, evaluates, and summarizes the changes** in the revised version of the *2nd edition* of the **Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans**, issued by the Canadian Panel on Research Ethics on December 18, 2014. The revised version of the Policy represents the Tri-Council's continued commitment to promoting the ethical and useful conduct of research involving humans in Canada and incorporates feedback received from the research community and ethics professionals regarding aspects of the Policy that have demonstrated the need for further clarification, improved flexibility, and heightened transparency with human participants.

Topic	Ch.	Type	Impact	Affected	Summary
Research Definitions	2.1	Clarification	Minor	Researchers/ REBs	Research is defined as an undertaking intended to extend knowledge through a disciplined inquiry and/or systematic investigation. "Disciplined inquiry" should be defined according to expectations of the relevant research community.
Research Definitions	2.1	Clarification	Minor	Researchers/ REBs	In determining whether an activity meets the definition of research requiring review, the choice of methodology and/ or intent to publish are factors, but are not dispositive.
Identifiability	2.1, 5	Clarification	Minor	Researchers	The assessment of whether information is identifiable should be made in the context of the specific research activity.
Minors	3.3	Clarification	Minor	Researchers	Decision making capacity should drive the consent process whenever compatible with any laws governing research participation. Consent should be sought from children who mature sufficiently to make their own choices.

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Incidental Findings	3.4	Addition	Major	Researchers	Researchers may seek an exception to the obligation to disclose material incidental findings based on impracticability or impossibility. REBs should decide whether exceptions apply on a case-by-case basis.
Consent Alterations	3.7A	Revisions	Major	Researchers/ REBs	Precise nature and extent of any proposed alteration must be defined and may be available even in the context of a therapeutic intevention.
Consent Alterations	3.7A	Clarification	Minor	Researchers/ REBs	Alterations should be permitted only to the extent necessary and REBs should consider both the proposed alterations and the proposed plan for debriefing. Specific considerations provided for alteration of consent in general and for specific circumstances - partial disclosure, data and/or human biological materials, vulnerable populations, and public health.
Debriefing	3.7B	Clarification	Major	Researchers	Debriefing must be a part of all research involving an alteration whenever possible, practicable, and appropriate. Specific considerations provided for debriefing and the exception to the debriefing requirement.
Withdrawal	3.7B	Addition	Major	Researchers	Participants must have opportunity to refuse consent and request withdrawal of their data and/or human biological materials whenever possible, practicable, and appropriate. Specific considerations provided for offering withdrawal and how to confront concerns.
Secondary Uses	5.5B, 12.3	Addition	Major	Researchers/ REBs	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. Onus will be on researcher to establish that information to be used can be considered non-identifiable for all practical purposes.
REB Establishment	6.2	Clarification	Minor	REBs	The highest body of the institution establishes the REB. Institutions determine the highest body based on their individual governance structure and taking into consideration whether other responsibilities of those bodies may conflict with the responsibility for establishing an REB.
Requiring Review	6.12	Clarification	Minor	REBs	Theses or equivalent research projects involving human participants typically meet the definition of research.

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Delegated Review	6.12	Revisions	Major	REBs	Delegated review is available for annual renewal of more than minimal risk research where the remaining research-attributable risk is determined to be no more than minimal or there have been no significant changes to the research, no increase in risk to the participants since the most recent review by the full REB, and the REB Chair has determined that the delegated review process is appropriate.
Annual Review	6.14	Addition	Minor	REBs	Institutional ethics policies should include provisions that assist REBs, researchers, and institutions to determine when continuing research ethics review is no longer required.
Public Spaces	10.2	Clarification	Minor	Researchers	Observational studies may be undertaken in publicly accessible spaces (e.g., a stadium, library, museum, planetarium, beach, park), in virtual settings (e.g., Internet chat rooms), or in private or controlled spaces (e.g., private clubs or organizations).
Reporting Results	11.8	Clarification	Minor	Researchers	New information must be submitted to the publicly accessible trial registry along with reports of findings once the trial is completed. Where possible, this information can be reported earlier to the registry in descriptions of study design, intervention, or an equivalent data field.
Reporting Results	11.12	Addition	Major	Researchers	Any new information that has an effect on the welfare of participants that comes to light at, or after, the end of the trial should be reported in subsequent publications.
Reporting Results	11.12	Addition	Major	Researchers	Researchers are encouraged to make data available for further analysis and verification by peers. When sharing participant's data with peers, researchers must be mindful of their responsibility to safeguard participant privacy and confidentiality and may have to code or anonymize the data to do so.
Confidentiality & Publication Clauses	11.12	Clarification	Major	Researchers	Clinical trial research contracts must provide that all confidentiality and publication clauses include access to all trial data by principal investigators, access to all trial data by researchers at their respective site, and access to all trial data by all researchers in cases where no principal investigator is named.
Human Pluripotent Stem Cell Research	12.10 - 12.20	Addition	Minor	Researchers	Formally incorporated Canadian Institutes of Health Research guidelines for Human Pluripotent Stem Cell Research.

Contact us at BusDev@QuorumReview.com for more information.

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