

Amendments to Chapter 2.1 of the *National Statement on Ethical Conduct in Human Research, 2007*

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Science & Technology Australia is the peak body for the nation's science and technology sectors, representing 95 organisations and more than 90,000 scientists and technologists.

We connect science and technology with governments, business and the community to advance science's role in solving some of humanity's greatest challenges.

We thank the National Health and Medical Research Council for this opportunity to offer feedback on [the proposed amendments to Chapter 2.1 of the *National Statement on Ethical Conduct in Human Research, 2007*](#). This chapter deals with definitions of risk categories resulting from revisions to Section 5 following public consultation in 2020.

Ensuring human research is conducted in accordance with stringent and consistent ethical guidelines is important – research integrity, public trust in science and social licence depends on it. It's also important that a consistent set of robust principles are regularly reviewed to ensure they consider new issues raised in research and are fit for purpose.

Clarity of risk levels

The amended Chapter 2.1 largely streamlines and simplifies the content in the previous version, and redefines the concept of 'inconvenience' to one of 'burden'. It gives clarity that 'inconvenience' to research participants need not be considered as a potential 'harm' incurred by the research. This new chapter also simplifies the process and allows researchers and reviewers to focus on the more serious risks of 'discomfort' and 'harm'.

Online data

Another amendment highlights the importance of considering risks associated with using large collections of online data. Robust management and security of data gathered in research is important. However, the amended chapter does not offer any clarity on how this risk should be assessed or mitigated. If there are particular aspects of risk involved with online data, it would be useful to articulate these.

‘Impact’ of research

Another amendment replaces the existing text that describes the concept of harm and/or discomfort arising from research:

“Research may lead to harms, discomforts and/or inconveniences for participants and/or others.”

with this sentence:

“Research may lead to harm or discomfort for participants and/or others involved in the research or who experience the impact of the research”

The phrase “or who experience the impact of the research” potentially significantly alters the scope of risk that researchers and ethics reviewers must consider when designing or assessing a research project. It can be extremely difficult, if not impossible, to predict all potential impacts of a given research project, particularly over an indefinite timeframe.

If this new clause is interpreted strictly, literally and expansively by ethics approval bodies, it could be extremely challenging for researchers and ethics reviewers (in some fields of health and medical research especially) to predict and ultimately assess all those who may potentially ‘experience the impact of the research’. This poses a significant challenge for both researchers and reviewers – and may lead to excellent research being assessed negatively.

To avoid this complication, we recommend maintaining the wording in the current version of Chapter 2.1, and remove the reference to ‘the impact of the research’.

If ‘research impact’ is to be included, a clearer definition and limits upon the scope of ‘impact’ will be necessary to assist researchers and reviewers navigate the ethics review process. This would allow for sensible discretion to be used in designing and reviewing research proposals.

Recommendation: STA recommends maintaining the wording in the current version of Chapter 2.1, and removing the reference to ‘the impact of the research’.

Section 5 amendments

Additionally, although this consultation is about the Chapter 2.1 amendments, there is a section in the revised Section 5 that warrants further consideration.

Section 5.1.19 states

“5.1.19 Research that involves the use of information already in the public domain (such as information published in journals, newspapers or archives, including systematic reviews and meta-research (i.e. research on research) may need to be assessed to determine whether it qualifies as human research. If such investigations are not human research, then neither ethics review nor a decision to grant an exemption from review is required.”

This change implies that a project that includes already published work that is deemed to be ‘human research’ may need to obtain ethics approval.

This has implications for researchers conducting time-sensitive or comprehensive reviews of existing research – e.g. such as compilations of all available evidence regarding a virus during a pandemic – and could seriously delay or stymie valuable research.

Given any published work that would qualify as ‘human research’ would have gone through the required ethics review process, it is unnecessary that an additional ethics review be conducted simply to include the work in a research review.

This would place Australia as the only country requiring ethics review for systematic reviews of research.

The only consideration would be for work that has been published previously but may not have taken specific cultural considerations into account. For example, projects or reviews that include work done with or about Aboriginal and Torres Strait Islander people or communities should consider how republishing or promulgating the previous studies may further affect First Nations people. The [AIATSIS Code of Ethics for Aboriginal and Torres Strait Islander Research](#), which gives guidance for all research with and about Aboriginal and Torres Strait Islander peoples, notes:

“It should not be assumed that Aboriginal and Torres Strait Islander research involving the use of existing collections of data or records that contain only non-identifiable data automatically carries minimal or no risk and can be exempted from review.²¹ In addition, it cannot be assumed that desktop or archival research relating to Aboriginal and Torres Strait Islander people carries no risk to, or does not require engagement with Aboriginal and Torres Strait Islander peoples.” (p 7)

To ensure a workable approach for researchers and reviewers, Section 5.1.19 could be amended to remove the possibility that reviews of previously published research will be required to seek ethics approval. Rather, the importance of ensuring the work included in the review has previously passed ethics review could be noted. Additionally, this section could note that a review project that includes work of or about First Nations people or issues should refer to the AIATSIS Code of Ethics for Aboriginal and Torres Strait Islander Research for guidance.

Recommendation:

STA recommends amending Section 5.1.19 to remove the possibility that reviews of previously published research will be required to seek ethics approval.

STA recommends this section notes that a review project that includes work of or about First Nations people or issues should refer to the AIATSIS Code of Ethics for Aboriginal and Torres Strait Islander Research for guidance.

Please do not hesitate to contact us if we can assist as you consider the next steps in this process.

Professor Mark Hutchinson
President, Science & Technology Australia

Misha Schubert
CEO, Science & Technology Australia