

Aboriginal Health and Medical Research Council of NSW

HREC Statement Amendment requests V1.0 March 2021



**Aboriginal
Health & Medical
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of NSW**

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Background

The AH&MRC Human Research Ethics Committee (The HREC) reviews proposals to conduct Human Research in accordance with the National Statement on Ethical Conduct in Human Research (2007 updated 2018) and the Ethical Conduct in Research with Aboriginal and Torres Strait Islander Peoples and Communities: Guidelines for researchers and stakeholders (2018). These National Guidelines provide a framework for a thorough review of applications for HREC approval.

Amendment Requests

Once an application has been approved, the HREC has an ongoing responsibility to ensure that research that is approved by the HREC continues to operate in an ethically acceptable manner (NS 5.5.1, 5.7.3 (a) and (b)). The HREC considers that researchers should consider and account for any future intention to amend a research proposal. All proposals to amend the project must be designed in a manner that ensures the project continues to meet the National Ethical criteria. For large scale amendments, this often requires a re-review of the application in its entirety. It is for this reason, that the HREC has determined that it will not accept large scale protocol amendments for review within (12) twelve months of a project receiving the HREC approval. In instances where the HREC receives substantial amendments for a project, either as individual or collective requests, the HREC will need to determine whether the amendments delineate from the original proposal significantly. If the request proposes to significantly alter the methodology, aims or objectives or if the request does not align with the original aims and objectives, it will not be accepted as an amendment. If the proposed changes are necessary, the project will need to be resubmitted for full ethical review and approval. The HREC recognises that there will be exceptions to this mandate.

If you are seeking further information regarding this statement, please contact the Ethics Secretariat at ethics@ahmrc.org.au