

Submitting a new research proposal for ethical review by the WA Health Central Human Research Ethics Committee

The WA Health Central Human Research Ethics Committee (Central HREC) undertakes the review, approval and monitoring of research involving humans, their tissue and/or data to ensure scientific rigour and compliance with the ethical standards outlined in the <u>National Health and Medical Research Council (NHMRC) National Statement on Ethical Conduct in Human Research 2023</u>. The Central HREC is currently registered with the NHMRC and will be seeking certification to enable participation in the National Mutual Acceptance (NMA) scheme.

All applications to the Central HREC must be submitted via the <u>Research Governance Service</u> (RGS). They must be clear, concise, and complete. Applications that do not comply with the required standard will not be added to the committee's meeting agenda. The Central Office for Research Ethics (CORE) recommends applicants utilise the proportional review toolkits to determine which review pathway is appropriate for their project.

The Central HREC is comprised of up to six separate committees: 4 generalist committees that will review most types of human research and two specialist committees that will consider proposals requiring access to WA Health Datasets and/or Data linkage and proposals involving Mothers, Infants, Children, Adolescents and the foetus (MICA) The Central HREC meets to review ethics applications up to six times each month, except January. Please refer to the Meeting Calendar for specific meeting dates and application deadlines set for 2024. Once the Central HREC is fully operational, there will be no application deadline and your proposal will be tabled at the next available and appropriate committee meeting. If you are submitting a response to a review or making a resubmission it will be reviewed by the committee that first reviewed your proposal.

Note:

 Research involving the staff, patients, data, or resources of any WA Health Service Provider (HSP) or the Department of Health will require Site Authorisation from each institution where the project is being conducted.

Applications for Site Authorisation should be submitted via the <u>RGS</u>. This review process can take place concurrently to the Central HREC review process; however, authorisation will not be granted until ethics approval is granted. For more information, please contact the relevant Research Governance Office via the <u>contact details listed on the RGS</u>.

 Research explicitly involving Aboriginal people or Aboriginality as a key determinant in WA will require an additional HREC approval from the WA Aboriginal Health Ethics Committee (WAAHEC). It is strongly advised that researchers initiate the WAAHEC review process at the earliest opportunity. This review process can take place concurrently to the Central HREC's review of your proposal. However, the Central HREC will not grant ethical approval until they are provided with evidence that WAAHEC has provided their approval. For more information, please contact WAAHEC at ethics@ahcwa.org or refer to their website.

- Research involving access to data held within the WA Department of Health's data collections, including linked data, must first undergo a <u>Feasibility Assessment</u> by the Client Services Team based in the Department of Health's Information and System Performance Directorate (ISPD)
 - This feasibility assessment must be completed **before** a submission can be made to the Central HREC. For more information, please contact ISPD Client Services at DataServ@health.wa.gov.au or refer to their website.
- Research involving access to linked health data held by PeopleWA must undergo a review process with PeopleWA via the <u>PeopleWA application system</u>
 - The PeopleWA review process must be completed before making a submission to the Central HREC If accessing WA health data via PeopleWA and not requiring data from the Department the research proposal will not require a Feasibility Assessment from ISPD Client Services. For more information, please contact PeopleWA at PeopleWA@dpc.wa.gov.au or refer to their website.
- Research projects seeking to obtain ethics approval under the NMA scheme must ensure that
 the project complies with the institutional and jurisdictional requirements of the sites where
 the research will be conducted.

Applicants seeking ethical approval to conduct their project at sites outside of WA under the NMA scheme should direct their application to either the Child and Adolescent Health Service HREC, Sir Charles Gairdner and Osborne Park Health Care Group HREC, or the South Metropolitan Health Service HREC.

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Submission checklist

Submissions requesting ethical review of a new research proposal should include the following:

		Yes	No	N/A
1.	Relevant ethics application form			
	For projects involving only WA entities:			
	 WA Health ethics application form (WAHEAF) 			
	For projects seeking access to WA Health data sets that have gained HREC approval from an HREC based in another Australian Jurisdiction:			
	 Health research ethics application (HREA) form, and 			
	Western Australian specific module form			
2.	Research protocol			
3.	Supporting documentation (as relevant to the project)			
	 Participant facing documents such as surveys, invitation letters, telephone scripts, posters, social media and website texts, advertisements, emails, text messages etc. 			
	Participant and/or guardian information sheet and consent forms			
	Investigator brochure			
	Radiation safety officer/Radiological council report			
	Evidence of HREC approval for the project from:			
	 A specialist HREC such as WAAHEC 			
	 A HREC based in another Australian jurisdiction that has granted the project approval under NMA: 			
	WA Health student research and confidentiality declaration forms for each student whose work on the project will contribute to attaining their qualification.			
	Template can be accessed on RGS			
	Other relevant documentation for review			
4.	ISPD client services/PeopleWA approved feasibility assessment documents (as relevant to the project)			
	These forms can be accessed on the <u>Data Linkage</u> and <u>PeopleWA</u> websites as applicable			
	In-principal support letter			
	Application form			
	Variable list forms			
	Data management plan			
	Data services forms (ISPD client services only)			

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For further information please contact:
The Central Office for Research Ethics Phone: (08) 9222 4214 email: hrec@health.wa.gov.au
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