Government of Western Australia
WA Country Health Service

Ethical Review Levels for Research at WACHS

What human research requires ethics approval?

Ethics approval must be sought for all research involving human participants, including their data and biospecimens. This includes WACHS patients, their carers and staff.

What are the levels of ethical review at WACHS?

WACHS has three levels of ethical review in order to streamline the review of applications for human ethics approval. The level of ethical review is dependent on the level of risk to participants involved in the research project and guided by the National Statement on Ethical Conduct in Human Research 2007 (National Statement) and the WA Health Research Governance Policy & Procedures (2012).

Level	Risk	Reviewed by
1. Exemption from ethical review.	Negligible risk	HREC Chairperson or Deputy Chairperson
2. Expedited ethical review for low risk research projects.	Low risk	Low Risk Subcommittee
3. Ethics review by a Human Research Ethics Committee (HREC).	More than low risk	Full HREC

Risk	National Statement Guide	Examples
Negligible risk	Where there is no foreseeable risk of harm or discomfort; and foreseeable risk is no more than inconvenience.	Common examples of inconvenience include filling in a form, participating in an anonymous self-administered short survey or in a short interview involving a structured set of questions where the research topic and questions are not sensitive and will not induce feelings of anxiety or have the potential to introduce emotional or reputational risks. There is no collection of identifying information from participants, and the participant must not be (or potentially be) identifiable in publications. Observational studies (with no form of intervention) of people undertaking non-sensitive, benign activities in a public space that will not be recorded or photographed and will not (or have the potential to) identify individuals is another example.
Low risk	Where the only foreseeable risk is one of discomfort.	Discomfort may be physical, psychological, emotional, social or financial. Common examples of discomfort include minor side-effects of medication (non-experimental), measuring blood pressure, anxiety induced by an interview and research examining sensitive personal or cultural issues.

What research can be exempt from ethical review?

Research projects can be exempt from ethical review where they are no more than negligible risk and involve the use of existing collections of data or records that contain only non-identifiable data about human beings.

The Research Governance Unit can provide written notification of exemption from ethical review where this is required for publication. Written notification of exemption cannot be provided if the project has commenced as retrospective ethical review is not possible.

What research is eligible for expedited ethical review?

Research projects are eligible for expedited review by the Low Risk Subcommittee must be **no more than low risk**. The project must be assessed by the WACHS Ethics Coordinator as either low or negligible risk. Where the risk, even if unlikely, is more than low or the Ethics Coordinator believes the overall project requires it, then the project will be allocated for HREC level review.

Gauging risk involves considering the kinds of harm, discomfort or inconvenience that may occur and the likelihood of these occurring as well as the severity of any harm that may occur. Judgement is based on the available transparent evidence.

What research is not eligible for the low risk pathway?

Research that includes any of the following, irrespective of risk, is not eligible for the low risk pathway.	
Waiver of consent	Use of personal information in medical research, or personal health information, without explicit or implied consent.
Interventions and therapies, including clinical and non-clinical trials and innovations or new treatment modalities	An intervention can be a drug or device (licensed or not); a surgical, diagnostic, or therapeutic procedure; a public health or mental health intervention; the collection of fresh bio specimens in children or the collection of bio specimens in adults where the foreseeable risk is more than discomfort.
Aboriginal people	Where Aboriginality is a key determinant; data collection is explicitly directed at Aboriginal people; Aboriginal people, as a group, will be examined in the results; the information has an impact on one or more Aboriginal communities (by geographic location or disease/health burden).
Limited disclosure that involves active concealment or planned deception of participants or that aims to expose illegal activities	Examples include: observation in public spaces of everyday behaviour; covert observation, for example of the hand-washing behaviour of hospital employees; undisclosed role-playing by a researcher to investigate participants' responses; telling participants the aim of the research is one thing when it is in fact quite different.
Paediatric research that involves direct interaction with children	Research involving participants aged less than 18 years old.
Use or disclosure of personal information from the Department of Health data collections and data linkage	Full HREC approval by the Department of Health WA HREC is required under WA Health policy.
Using organs or tissues derived from post-mortems	Research involving access to coronial material and information must be referred to the Coronial Ethics Committee for ethical and legal approval.
Human biospecimens prospectively collected for research purposes (including biobanks)	As per paragraph 3.2.3 of the National Statement, if the research involves only the use of stored biospecimens and involves no more than low risk, then the project may be suitable for review under a low risk pathway.
Multi-centre research projects (accessing sites outside of WACHS)	These projects require HREC level review in order to enable single ethical review under the NMA scheme or Lead WA Health HREC scheme.

Research that includes any of the following, irrespective of risk, is not eligible for the low risk pathway, [except where the project uses existing collections of non-identifiable data and involves only negligible risk, and may therefore be exempted from ethical review]:	
Women who are pregnant and the human foetus	Includes research on the woman who is pregnant and the foetus in utero, and the separated human foetus or on foetal tissue.
People highly dependent on medical care who may be unable to give consent	Examples include; patients who are receiving intensive care, terminal care, or emergency care.
People with a cognitive impairment, an intellectual disability, or a mental illness	People with a cognitive impairment, an intellectual disability, or a mental illness are entitled to participate in research, however the capacity of a person with any of these conditions to consent to research, and the ability to participate in it, can vary for many reasons. Even when capable of giving consent and participating, people with these conditions may be more-than-usually vulnerable to various forms of discomfort and stress.
People who may be involved in illegal activities	Research that is intended to study or expose illegal activity or that is likely to discover it.
Human genomics	Research generating, gathering, collecting, conveying or using genomic data or information that has hereditary implications and/or is predictive of future health in research involving participants, relatives and other family members.
Human stem cells or their products	Research involving human embryos and gametes, including the derivation of human embryonic stem cell lines.

How do I submit an ethics application to the low risk subcommittee?

You are strongly encouraged to contact the WACHS Ethics Coordinator to discuss your research project prior to submitting an application.

All ethics applications must be submitted via **WA Health's Research Governance Service (RGS)**. The application must include the WA Health Ethics Application Form (or Human Research Ethics Application Form), a Research Protocol and other documents specific to the research design, such as surveys, focus group questions and Participant Information and Consent Forms.

The WACHS Ethics Coordinator reviews all submitted applications and if they meet the eligibility criteria, the project will be allocated to the expedited ethical review stream and you will be notified that it will be reviewed by the low and negligible risk subcommittee.

If you believe your research project meets the criteria to be **exempt from ethical review**, please contact the WACHS Ethics and Quality Improvement Coordinator to discuss you project prior to submitting via RGS.

Contact Us

For more information or assistance in determining the appropriate level of ethical review for your research project, how to submit an ethics application and what tis involved in the review process, please contact the WACHS Ethics and Quality Improvement Coordinator.

WACHS Ethics and Quality Improvement Coordinator
WACHS.HREC@health.wa.gov.au
(08) 6553 0814

Published on 4 March 2020.
Version 1 05032020 ED-CO-20-2238

To provide feedback on this publication, email WACHS.HREC@health.wa.gov.au