OFFICIAL

Department for Health and Wellbeing Human Research Ethics Committee

Determining the level of risk for research projects

Chapter 2.1 of the National Statement on Ethical Conduct in Human Research 2023 (National Statement) clearly defines risk, harm and burden. Please consider this information when assigning the level of risk associated with each research project. The DHW full ethics committee must review projects that have more than a low risk of harm to participants or, in some cases, non-participants (National Statement 2.1).

The table below is from the National Statement, Chapter 2.1, figure 1 and defines the risk profiles of research.

Lower risk		Higher risk (Individual, group, community, societal or global)	
Minimal	Low	Greater than low	High
No risk of harm or discomfort; potential for minor burden or inconvenience*	No risk of harm; risk of discomfort (+/- foreseeable burden)	Risk of harm (+/- foreseeable burden)	Risk of significant harm (+/- foreseeable burden)

In addition, projects which are of lower risk but which have either or both of the following characteristics must be reviewed by a full HREC:

- > Projects which involve Aboriginal and Torres Strait Islanders peoples; OR
- Projects with request a waiver of consent for research using personal information in medical research or personal health information

The HREC will advise if the appropriate level of risk has been assigned to each project.

For more information

Executive Officer Office for Research Department for Health and Wellbeing Telephone: (08) 7117 6635 <u>Health.HumanResearchEthicsCommittee@sa.gov.au</u>





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