

Purpose

This form has been designed to identify if a research project meets the requirements for a lower risk review.

To request a lower risk review, applicants must complete this form and attach it in the eProtocol application. Any request for lower risk review that does not have this form included or is incomplete will be returned to the investigator. Please review all sections below and tick any relevant boxes.

Please refer to Bellberry guidance LER G1 Review pathways – Higher Risk and Lower Risk Research and the *National Statement on Ethical Conduct in Human Research (2025)* (NS) and carefully consider each answer.

Part A: Checklist

If any of the following considerations are relevant, the research cannot be reviewed via the Lower Risk pathway and must undergo review by a full HREC:

Request for a waiver of consent from the HREC for research using personal information in medical research or personal health information.	NS 2.3.9	☐
Opt-out consent, if so, do the s95 or 95A Privacy Act guidelines apply	NS 2.3	☐
Active concealment or planned deception or, aims to expose illegal activity	NS 2.3.4	☐
The prospective collection of biospecimens for research purposes	NS 3.2.1	☐
The research involves the use of stored human biospecimens for research and there is more than low risk to participants	NS 3.2.2	☐
Any genetic testing, except where information used cannot identify an individual and no linkage of data is planned	NS 3.3	☐
Animal-to-human xenotransplantation	NS 3.4	☐

Please indicate if the research includes recruitment of any of the following groups. Research in the following areas may require full HREC review; however, the risk level will be considered within the context of the research in determining the appropriate pathway.

Women who are pregnant and the human foetus	NS 4.2	☐
People under the age of 18* (<i>see footnote</i>)	NS 4.3	☐
People experiencing physical or mental ill-health, or disability	NS 4.5	☐
Aboriginal and Torres Strait Islander peoples and communities	NS 4.7	☐
Research that may uncover illegal activity	NS 4.9	☐

Discomfort vs harm

Discomfort is considered less serious than harm and can involve physical or psychological impacts, for example, minor side-effects of medication, discomfort related to non-invasive examinations or tests (such as measuring blood pressure), and mild anxiety associated with an interview. Where a person's reactions might exceed discomfort and become distress, this should be viewed as the potential for harm.

Is there a risk to the participant, either individually or collectively (consider groups, communities or non-participants such as family members) of:

Physical harm	NS 2.1	☐
Psychological harm (distress, guilt, anger, fear, re-traumatisation, etc.)	NS 2.1	☐
Psychological harm that is more than discomfort from questions asked in questionnaires or surveys	NS 2.1	☐
Devaluation of personal worth	NS 2.1	☐
Cultural harm	NS 2.1	☐

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Social harm	NS 2.1	☐
Societal harm (e.g., potential standard of care changes, informing policies)	NS 2.1	☐
Economic harm	NS 2.1	☐
Legal harm	NS 2.1	☐

Use of collections of data

Complete each section above, review NS Chapter 3.1, Element 4 and include any considerations below.

Part B: Justification

Non-clinical research can still pose potential risks to participants. Does your research involve any topics, questions, participant groups, or data collection processes that might create risks greater than discomfort? If yes, please explain:

- The nature of the potential risks
- Why these risks may arise
- How they will be minimised or managed to retain a lower risk status

Please justify why you consider your research to be lower risk, referring to the National Statement as required.

Footnote:

**Lower risk research could potentially include young people between 14/15-17 based on the National Statement 4.3 'levels of maturity'. If researchers wish to take this approach, this needs to be justified using National Statement 4.3.8.*

Reference

LER G1 Review Pathways – Higher Risk and Lower Risk Research
BA F1.1.7 HREC Application Review Flowchart