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 (2023) (NS) and carefully consider each answer. 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.

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Part A: Checklist

Does the research include recruitment of:

|  |  |  |
| --- | --- | --- |
| Women who are pregnant and the human foetus | NS 4.1 |  |
| People under the age of 18\* *(see footnote)* | NS 4.2 |  |
| People highly dependent on medical care who may be unable to give consent | NS 4.4 |  |
| People with a cognitive impairment, an intellectual disability, or a mental illness | NS 4.5 |  |
| People who may be involved in illegal activities | NS 4.6 |  |
| Aboriginal and Torres Strait Islander Peoples | NS 4.7 |  |
| People in other countries | NS 4.8 |  |

Does the research involve:

|  |  |  |
| --- | --- | --- |
| 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 |  |

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 |  |
| 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

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

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*Footnote:*

\**Lower risk research could potentially include young people between 14/15-17 based on the National Statement 4.2 ‘levels of maturity’ (page 67). If researchers wish to take this approach, this needs to be justified using National Statement 4.2.2 and 4.2.7(a).*