# Guidance on Low/Negligible Risk Research

Human research involves a wide range of studies that have different levels of risk and potential benefits. All human research must be conducted ethically, in accordance with the [National Statement on Ethical Conduct in Human Research](https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018), but not all research requires the same level of ethical oversight. While some types of research must be reviewed by a full Ethics Committee, many research projects can be reviewed and approved via the low/negligible risk pathway.

## Low and negligible risk research

The [National Statement](https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018#toc__155) defines a risk as “a potential for harm, discomfort or inconvenience”.

Research is “low risk” where the only foreseeable risk is one of discomfort. Where the risk, even if unlikely, is more serious than discomfort, the research is not low risk. (National Statement 2.1.6)

Research is “negligible risk” where there is no foreseeable risk of harm or discomfort; and any foreseeable risk is no more than inconvenience. Where the risk, even if unlikely, is more than inconvenience, the research is not negligible risk. (National Statement 2.1.7)

**If your project involves greater than low risk, you must submit a** [**Human Research Ethics Application**](https://hrea.gov.au/) **for review by the full Ethics Committee (see the Ethics page on Connect for more information).**

## Harm, discomfort and inconvenience

Consider the impact of your research on participants. Could the research cause inconvenience, discomfort or harm to participants?

The [National Statement](https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018#toc__155) identifies the following examples of harm:

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| Kinds of potential harms | Examples |
| Physical harms | Injury, illness or pain |
| Psychological harms | Feelings of worthlessness, distress, guilt, anger or fear related, for example, to disclosure of sensitive or embarrassing information, or learning about a genetic possibility of developing an untreatable disease |
| Devaluation of personal worth | Being humiliated, manipulated or in other ways treated disrespectfully or unjustly |
| Social harms | Damage to social networks or relationships with others; discrimination in access to benefits, services, employment or insurance; social stigmatisation; and findings of previously unknown paternity status |
| Economic harms | Imposition of direct or indirect costs on participants |
| Legal harms | Discovery and prosecution of criminal conduct |

Less serious than harm is discomfort – for example, minor side-effects of medication, the discomforts related to measuring blood pressure, and anxiety induced by an interview.

Less serious again is inconvenience – for example, filling in a form, participating in a street survey, or giving up time to participate in research.

**If your project involves any risk of harm, even if unlikely, you must submit a** [**Human Research Ethics Application**](https://hrea.gov.au/) **for review by the full Ethics Committee (see the Ethics page on Connect for more information).**

## Research that must be reviewed by the full Ethics Committee

Certain types of research require review by the full Ethics Committee, regardless of the level of risk:

* Research falling under the following chapters of the National Statement (except where research on collections of non-identifiable data under these chapters satisfies the conditions for exemption from review):
	+ [Chapter 4.1](https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018#toc__1123): Women who are pregnant and the human fetus
	+ [Chapter 4.4](https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018#toc__1288): People highly dependent on medical care who may be unable to give consent
	+ [Chapter 4.5](https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018#toc__1354): People with a cognitive impairment, an intellectual disability, or a mental illness
	+ [Chapter 4.6](https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018#toc__1390): People who may be involved in illegal activities (if the research is intended to study or expose illegal activity or likely to discover it)
	+ [Chapter 4.7](https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018#toc__1428): Aboriginal and Torres Strait Islander Peoples
	+ [Chapter 4.8](https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018#toc__1491): People in other countries.
* Research involving the use of human biospecimens that may reveal information that could be important for the health of the donor(s), their relatives or their community. Researchers should prepare an ethically defensible plan to describe the management of any proposed disclosure or non-disclosure of that information, which must be approved by the full Ethics Committee ([NS 3.2.15](https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018#toc__826));
* Research involving a waiver of consent for the use of personal information in medical research or personal health information ([NS 2.3.9](https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018#toc__296));
* Research that involves active concealment or planned deception, or aims to expose illegal activity ([NS 2.3.4](https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018#toc__296));
* Research involving development of immortalised cell lines;
* Research involving sensitive personal or cultural issues, such as ethnic identity, gender identity, sexuality or mental health;
* Research of a nature that Lifeblood donors might not be comfortable to support.

**If your project involves any of the above types of research, you must submit a** [**Human Research Ethics Application**](https://hrea.gov.au/) **for review by the full Ethics Committee (see the Ethics page on Connect for more information).**

## Examples of low/negligible risk research

* Research using existing biospecimens collected with unspecified or extended consent for research (for example, blood and blood products obtained from Lifeblood Biological Resources), where the research will not reveal information that may be important for the health of the donor(s), their relatives or their community
	+ Note: genetic research can be approved under the low risk pathway if is only uses previously collected and non-identifiable samples. If the samples can be re-identified, the research must be reviewed by the full Ethics Committee.
* Surveys, questionnaires, interviews or focus groups where the questions are not overly sensitive;
* Analysis of de-identified, routinely collected data;
* Trials of marketing interventions or communications;
* Clinical trials involving low risk interventions, such as applied muscle tension.

## Further information

If you have any questions or would like advice on whether your project may be considered low or negligible risk, please contact the Ethics Secretary at ethics@redcrossblood.org.au.

# Low/Negligible Risk Application Form

If you are satisfied that your project meets the criteria for low or negligible risk research according to the guidance above, use this form to apply for ethical approval. Low/negligible risk applications may be submitted at any time to ethics@redcrossblood.org.au.

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| **1. PROJECT OVERVIEW** |
| **Project title:** | Click or tap here to enter text. |
| **Lifeblood R&D project number (if applicable):** | Click or tap here to enter text. |
| **Expected duration of the project:** | Click or tap here to enter text. |
| **Does the project have approval from another HREC?** | [ ]  Yes (please attach a copy of the approval letter)[ ]  No |
| **Will the project be submitted for further ethical review?** | [ ]  Yes[ ]  No |
| **If yes, please provide details:** | Click or tap here to enter text. |

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| **2. PROJECT TEAM** |
| **Details of Principal Investigator:** |
| **Name:** | Click or tap here to enter text. |
| **Institution:** | Click or tap here to enter text. |
| **Position:** | Click or tap here to enter text. |
| **Email address:** | Click or tap here to enter text. |
| **Telephone number:** | Click or tap here to enter text. |
| **Briefly describe the researcher’s role in this project:** | Click or tap here to enter text. |

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| **Details of Co-Investigator:** |
| **Name:** | Click or tap here to enter text. |
| **Institution:** | Click or tap here to enter text. |
| **Position:** | Click or tap here to enter text. |
| **Briefly describe the researcher’s role in this project:** | Click or tap here to enter text. |

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| **Details of Co-Investigator:** |
| **Name:** | Click or tap here to enter text. |
| **Institution:** | Click or tap here to enter text. |
| **Position:** | Click or tap here to enter text. |
| **Briefly describe the researcher’s role in this project:** | Click or tap here to enter text. |

(Copy and paste table for additional researchers)

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| **3. PROJECT DESCRIPTION** |
| **Provide a brief description of the project (approx. 100 words) in non-technical language:** | Click or tap here to enter text. |
| **Why is this project important?** | Click or tap here to enter text. |
| **What are the aims/objectives of this project?** | Click or tap here to enter text. |
| **What are the expected outcomes of this project?** | Click or tap here to enter text. |

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| **4. PARTICIPANTS** |
| **Provide details of the participants in this research (e.g. inclusion/ exclusion criteria, number required, sample size calculation)** | Click or tap here to enter text. |
| **How will you recruit participants for this research?**Attach a copy of any recruitment materials, e.g. emails, advertisements, telephone scripts. | Click or tap here to enter text. |
| **How will participants consent to this research?**Attach a copy of the Participant Information and Consent Form, if applicable. | Click or tap here to enter text. |
| **Will participants be reimbursed for participation?** | [ ]  Yes (provide details and justification below)[ ]  NoDetails: Click or tap here to enter text. |

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| **5. DATA COLLECTION** |
| **What methods of data collection will you use in this research?**Attach a copy of any questionnaires/surveys, interview/focus group guides etc. | [ ]  Questionnaire/survey[ ]  Interviews[ ]  Focus groups[ ]  Observation of participants[ ]  Extraction of data from databank (e.g. NBMS)[ ]  Analysis of human biospecimens (e.g. blood/blood products from Material Supply)[ ]  Other (describe below) |
| **Describe the methods of data collection (e.g. survey/interview topics; data fields; types of biospecimens):** | Click or tap here to enter text. |
| **How will the data be used and shared?** | Click or tap here to enter text. |

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| **6. RISKS AND BENEFITS** |
| **What are the potential risks of this project? (e.g. to participants, to Lifeblood and to the community)** | Click or tap here to enter text. |
| **What are the expected benefits of this research? (e.g. to participants, to Lifeblood and to the community)** | Click or tap here to enter text. |
| **Explain how the expected benefits outweigh any risks:** | Click or tap here to enter text. |

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| **7. DATA AND PRIVACY** |
| **Will you be collecting and/or using personal information, health information or sensitive information?** For definitions, [click here](https://www.oaic.gov.au/privacy/guidance-and-advice/what-is-personal-information). For guidelines on identifiability of data, see [NS 3.1 – Element 4](https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018#toc__556). | [ ]  Personal information[ ]  Health information[ ]  Sensitive information[ ]  None of the above |
| **How will you protect participants’ privacy?** | Click or tap here to enter text. |
| **Has a Privacy Impact Assessment (PIA) been completed for this project and reviewed by Lifeblood’s Legal team?** See Lifeblood Privacy Manual (POL-00160) for more information. | [ ]  Yes[ ]  No |
| **If yes, summarise key risks and mitigation.** | Click or tap here to enter text. |
| **If no, provide an explanation.** | Click or tap here to enter text. |

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| **8. LIST OF DOCUMENTS** |
| **Document Title** | **Version Number** | **Date** |
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| **9. DECLARATION** |
| ***“I confirm that the information in this form is accurate and complete.”*** |
| **Principal Investigator Name:** |  |
| **Signature:** |  |
| **Date:** |  |

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| **10.1. LIFEBLOOD AUTHORISATION** |
| **Authorisation by relevant Lifeblood Director or delegate:*****After careful consideration of the logistical implications and scientific merit of the above project, as outlined in this application, I authorise Lifeblood involvement.*** |
| **Name** | **Signature** | **Date** |
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| **10.2. OTHER INSTITUTIONAL AUTHORISATION** |
| **Authorisation by Head of Department of institution involved in the project and/or providing support/services to the project:*****After discussion with the researcher and careful consideration of both the support and services to be provided for the project and the project’s scientific merit, I authorise this institution to be involved in the above research project, as outlined in this application.*** |
| **Name** | **Signature** | **Date** |
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| **Institution** | **Position in Institution** |
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| **Authorisation by additional institution, if required:** |
| **Name** | **Signature** | **Date** |
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| **Institution** | **Position in Institution** |
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