

Flowchart for determining appropriate level of ethical review for research involving humans

To enable this electronic form, you must first **SAVE** it then **REOPEN** as a PDF file (it will not function properly when used in a browser window).

Please complete the following questions to ascertain whether your research project should be submitted for review by the HREC or by your Faculty Human Ethics Committee (FHEC).

While FHECs typically review low risk research, some types of research are deemed by the [National Statement on Ethical Conduct in Human Research](#) (*National Statement* or NS) to require HREC review, rather than FHEC review (i.e. these types of research must go to the HREC for review even if you consider they only involve low risk).

The right hand column for each question indicates the relevant section/s of the [National Statement](#) - please refer to this document for additional information.

Student researchers must complete this form with their supervisors.

As soon as you select a response in the form that directs you to submit your project to the HREC, submit your project to the HREC for review (no need to complete the form).

There is no need to submit this form with your application - unless your first 'yes' answer is to Question no. 20. In that case, you should explain your reasoning in the space provided, and forward your application and this form to the HREC.

Definitions/explanations from the *National Statement*:

Low risk: "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" (2.1.6 emphasis added).

Discomfort: "... discomfort ... can involve body and/or mind. Discomforts include, for example, minor side-effects of medication, the discomforts related to measuring blood pressure, and anxiety induced by an interview" (p. 13).

Risk: "A risk is a potential for harm, discomfort or inconvenience It involves: the likelihood that a harm (or discomfort or inconvenience) will occur; and the severity of the harm, including its consequences" (p. 12).

Assessment of risk: "Assessment of risks involves:

- identifying any risks [including participants' perceptions of risks];
- gauging their probability and severity;
- assessing the extent to which they can be minimised;
- determining whether they are justified by the potential benefits of the research; and
- determining how they can be managed" (p. 12).

Questionnaire:

NS Reference

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| 1. Is your research being funded by an agency outside the University, which requires approval by a fully constituted Human Research Ethics Committee? | <input type="radio"/> Yes - your application must be submitted to the HREC | <input type="radio"/> No, go to Q2 | |
| 2. Is the project hosted/auspiced by an organisation other than CSU? | <input type="radio"/> Yes - your application must be submitted to the HREC | <input type="radio"/> No, go to Q3 | |
| 3. Are you using an opt-out approach (i.e. will people be considered to be participants unless they actively indicate otherwise)?
<i>NB: Opting-out is not the same as being able to withdraw participation.</i> | <input type="radio"/> Yes - your application must be submitted to the HREC | <input type="radio"/> No, go to Q4 | p.19 |
| 4. Does your research involve active concealment or explicit deception of, participants? | <input type="radio"/> Yes - your application must be submitted to the HREC | <input type="radio"/> No, go to Q5 | 2.3.1 - 2.34 |
| 5. Are you requesting a waiver of consent? | <input type="radio"/> Yes - your application must be submitted to the HREC | <input type="radio"/> No, go to Q6 | 2.3.9. Ch 3.3 |
| 6. Does your research involve human bio-specimens in laboratory based research? | <input type="radio"/> Yes - go to Q7 | <input type="radio"/> No, go to Q9 | Ch 3.4 |
| 7. Does your research involves any risks to the donors, their blood relatives or their community that are more serious than discomfort? | <input type="radio"/> Yes - your application must be submitted to the HREC | <input type="radio"/> No, go to Q8 | 3.4.8 (a) |
| 8. Might your research give rise to information that may be important for the health of the donors, their blood relatives or their community where the identity of the donors will be known to, or can reasonably be ascertained by, those conducting the research or with access to health or research data related to donors? | <input type="radio"/> Yes - your application must be submitted to the HREC | <input type="radio"/> No, go to Q9 | 3.4.8 (b) |
| 9. Does you research involve human genetics? | <input type="radio"/> Yes - your application must be submitted to the HREC | <input type="radio"/> No, go to Q10 | Ch 3.5 |
| 10. Does your research target, or make likely the recruitment of women who are pregnant, AND/OR the human foetus ex utero, AND/OR human foetal tissue after the separation of the foetus from the woman? | <input type="radio"/> Yes - your application must be submitted to the HREC | <input type="radio"/> No, go to Q11 | Ch 4.1 |
| 11. Does your research target, or make likely the recruitment of children and young people? | <input type="radio"/> Yes - Go to Q12 | <input type="radio"/> No, go to Q14 | Ch 4.2 |
| 12. Does your research involve the possible coercion of children or young people by parents, peers, researchers or others to participate in research? | <input type="radio"/> Yes - your application must be submitted to the HREC | <input type="radio"/> No, go to Q13 | p.50 |
| 13. Does your research involve the possibility of conflicting values and interests of parents and children? | <input type="radio"/> Yes - your application must be submitted to the HREC | <input type="radio"/> No, go to Q14 | p.50 |
| 14. Are potential participants in a dependent or unequal relationship with one or more members of the research team? | <input type="radio"/> Yes - your application must be submitted to the HREC | <input type="radio"/> No, go to Q15 | Ch 4.3 |

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| 15. Does your research target, or make likely the recruitment of people highly dependent on medical care who may be unable to give consent? | <input type="radio"/> Yes - your application must be submitted to the HREC | <input type="radio"/> No, go to Q16 | Ch 4.4 |
| 16. Does your research target, or make likely the recruitment of people with a cognitive impairment, an intellectual disability, or a mental illness? | <input type="radio"/> Yes - your application must be submitted to the HREC | <input type="radio"/> No, go to Q17 | Ch 4.5 |
| 17. Does your research target, or make likely the recruitment of people who may be involved in illegal activities? | <input type="radio"/> Yes - your application must be submitted to the HREC | <input type="radio"/> No, go to Q18 | Ch 4.6 |
| 18. Does your research target, or make likely the recruitment of Aboriginal and Torres Strait Islander peoples? | <input type="radio"/> Yes - your application must be submitted to the HREC | <input type="radio"/> No, go to Q19 | Ch 4.7 |
| 19. Does your research target, or make likely the recruitment of people in other countries? | <input type="radio"/> Yes - your application must be submitted to the HREC | <input type="radio"/> No, go to Q20 | Ch 4.8 |
| 20. Do you have any reason for thinking that your project is not suitable for review at the FHEC level? | <input type="radio"/> Yes - please explain below | <input type="radio"/> No | 5.1.19 (c) |

Explanation: