**Cabrini Research Submission Checklist**

The Cabrini Research Governance Committee is responsible for establishing procedures for the ethical review of human research. That review can be undertaken at various levels, according to the degree of risk involved in the research, which is outlined in the National Statement on Ethical Conduct in Human Research 2023 <https://www.nhmrc.gov.au/research-policy/ethics/national-statement-ethical-conduct-human-research>.

Any research with a greater than low level of risk must be reviewed by an NHMRC-certified Human Research Ethics Committee (HREC). Research involving no more than low risk must be reviewed by the Cabrini Research Governance Committee by submitting a Cabrini Low Risk & Governance Application. The checklist below should clarify the risk in most cases. There may be “grey areas”, and if so, we suggest you contact the Research Governance Office for clarification via researchgovernance@cabrini.com.au.

A judgement that a human research proposal meets the requirements of the National Statement and is ethically acceptable must be made by the Cabrini Research Governance Committee before research can begin and, if funded, before full funding for the proposal is released.

**Definition of Risk** (Section 2.1:National Statement on Ethical Conduct in Human Research 2023)

A risk is a potential for harm or discomfort (discussed below). It involves:

* the likelihood that a harm or discomfort will occur, and
* the severity or magnitude of the harm or discomfort, including their consequences.

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| --- | --- |
| **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)  |

Potential harms - While no list of harms can be exhaustive, one helpful classification identifies the following types of potential harms in or from research:

* physical harm: including injury, illness, pain or death;
* psychological harm: including feelings of worthlessness, distress, guilt, anger, fear or anxiety related, for example, to disclosure of sensitive information, an experience of re-traumatisation, or learning about a genetic possibility of developing an untreatable disease;
* devaluation of personal worth: including being humiliated, manipulated or in other ways treated disrespectfully or unjustly;
* cultural harm: including misunderstanding, misrepresenting or misappropriating cultural beliefs, customs or practices;
* social harm: including damage to social networks or relationships with others, discrimination in access to benefits, services, employment or insurance, social stigmatisation, and unauthorised disclosure of personal information;
* economic harm: including the imposition of direct or indirect costs on participants;
* legal harm: including discovery and prosecution of criminal conduct.

Any of these types of harm can be experienced individually or collectively.

**Vulnerable Groups** (Section 4: National Statement on Ethical Conduct in Human Research 2023)

Ethics review by an HREC is required for any research that involves the following groups, no matter the risk:

1. Pregnant woman and the foetus in utero
2. Children and young people
3. People in dependent or unequal relationships
4. People highly dependent on medical care who may be unable to give consent
5. People with cognitive impairment or an intellectual disability, or a mental illness
6. People who may be involved in illegal activities
7. Aboriginal and Torres Strait Islander People
8. People in other countries

**Opt-out Approach or Waiver of Consent**

The [National Statement](http://www.nhmrc.gov.au/guidelines-publications/e72) says that you should respect people's capacity to make their own decisions. This normally means that people should give express consent to take part in your project. Sometimes it may be justifiable to use an alternative approach. You may be able to use an opt-out approach or a [waiver of consent](http://rch.org.au/ethics/informed_consent_and_plain_language/Waiver_of_consent_projects/). This might be appropriate if you are running a large scale, low risk project and it is not feasible to get express consent from each person.

Using an opt-out approach means that participants are included in the research unless they give their express decision to be excluded. Their decision must be informed. Therefore, you still need to give them information about your project. Once you have done this, you can assume that they are willing to take part in your project **unless** they have advised they do not want to.

If you want to use an opt-out approach, you must get permission from a HREC. You need to make a strong argument that:

* your project poses little or no risk to participants and
* the risk of not seeking express consent is outweighed by the public benefit or interest of the research.

This is only appropriate if people can make an informed choice about participation. An opt-out approach requires that:

* you give people written information about the project
* people receive this information, and are able to read and understand it
* people are able to act on the information to decline participation.

**A waiver of consent must be approved by a HREC where you will need to justify your request by addressing the National Statement 2.3.10 (a) to (i).**

|  |  |
| --- | --- |
| **Project Title:** |  |

|  |  |  |
| --- | --- | --- |
| **Does the research project involve ANY of the following? (Tick all that apply)** | **YES** | **NO** |
|  | **A)** Use of a product (drug, device or technology) that is not registered with the Therapeutic Goods Administration (TGA) | [ ]  | [ ]  |
| **B)** Use of a drug, device or technology in a clinical trial, when the product is being used in the trial for an unapproved indication, in an unapproved age group or at an unapproved dose  | [ ]  | [ ]  |
| **C)** Use of a drug, device or technology in a clinical trial, when such use in the trial is to gain further information about an approved use (e.g. pharmacokinetic or pharmacodynamic research) | [ ]  | [ ]  |
|  | A randomised and/or control group trial assessing an intervention(s) i.e. drug/device, clinical, surgical, diagnostic, public health or mental health | [ ]  | [ ]  |
|  | Any risk (or the potential for risk) of physical or psychological harm to the participant, beyond that imposed in routine clinical care | [ ]  | [ ]  |
|  | Targeted recruitment of Aboriginal or Torres Strait Islander people | [ ]  | [ ]  |
|  | Targeted recruitment of vulnerable groups e.g. children in the ICU, people with mental illness or those who may have been involved in criminal activities | [ ]  | [ ]  |
|  | Invasive procedures outside of standard care e.g. collection of blood or tissue samples that are not part of standard-of-care | [ ]  | [ ]  |
|  | Establishment of a Register, Databank or [Biobank](https://intranet.mcri.edu.au/research-and-science/biobanking) | [ ]  | [ ]  |
|  | Genetic testing or use of Stem Cells | [ ]  | [ ]  |
|  | Examining potentially sensitive or contentious issues or deception of participants, concealment or covert observation | [ ]  | [ ]  |
|  | Any of the following: Xenotransplantation; Genetically Modified Organisms | [ ]  | [ ]  |
|  | Research which may show unknown disabilities; disease status or risk; or have the potential for the discovery of non-paternity | [ ]  | [ ]  |
|  | Request for a [Waiver of Consent](https://www.rch.org.au/ethics/informed_consent_and_plain_language/Waiver_of_consent_projects/) or Opt-out Approach*Note: Retrospective chart review by the clinician is able to be done without consent for the purposes of improvement or evaluation of health services as per Health Privacy Principles therefore a Waiver is not required in this instance* | [ ]  | [ ]  |
|  | Exposure to ionizing radiation additional to standard care | [ ]  | [ ]  |
|  | Multi-site projects | [ ]  | [ ]  |
|  | Research conducted in another country, where additional ethical considerations may arise. | [ ]  | [ ]  |
| If you ticked “Yes” to any item then **NHMRC-certified HREC review** is required. |
| If you ticked “No” to ALL items please submit a **Cabrini Low Risk & Governance Application** |