|  |
| --- |
| **Cabrini project number** (if known): |
| **Project title**:  |
| *Indicate YES or NO to each question in the far right columns* | **YES** | **NO** |
| **Publication** |
| 1 | Do you wish to publish your results outside of Cabrini? |  |  |
| **Burdens and risks**  |
| 2 | Does the proposed activity impose a burden or inconvenience on participants beyond that experienced in their routine care e.g. completing a questionnaire or interview? |  |  |
| 3 | Does the proposed activity involve the possibility of discomfort beyond that experienced in their routine care e.g. non-invasive examinations or tests, mild anxiety? |  |  |
| 4 | Does the proposed activity pose any risks (harm) for participants beyond those of their routine care e.g. intervention outside of routine care?  |  |  |
| **Privacy and confidentiality** |
| 5 | Does the proposed activity risk breaching the confidentiality of any individual’s personal information beyond that experienced in the provision of routine care e.g. providing identified or potentially identifiable data to a third party not involved in the individual’s routine clinical care? |  |  |
| **Waiver of Consent** |
| 6 | Will the proposed activity make use of personal / health information for a purpose which is un-related to the original purpose of collection without consent of persons to whom the information relates?\* |  |  |
| **Overlap with research** |
| 6 | Does the proposed activity involve any clinically significant departure from the routine clinical care provided to the participants? |  |  |
| 8 | Does the proposed activity involve randomisation or the use of a control group or a placebo? |  |  |
| 9 | Does the proposed activity seek to gather information about the participant beyond that collected in routine clinical care? |  |  |
| **Broader implications** |
| 10 | Does the proposed activity potentially infringe the rights, privacy or professional reputation of carers, health care providers or institutions? |  |  |
| **Is the research MINIMAL or LOW RISK?** |  |  |
| 11 | Is the foreseeable risk more than inconvenience. Yes = **more than Minimal Risk**. *Where the risk, even if unlikely, is more than minor burden or inconvenience, the research is not minimal risk (Figure 1: Risk profiles of research, National Statement 2023).* |  |  |
| 12 | Is the risk more than simple discomfort? Yes = **more than Low Risk** *Where the risk, even if unlikely, is greater than discomfort, the research is not low risk (Figure 1: Risk profiles of research, National Statement 2023).* |  |  |
| **Does the research activity target the following PARTICIPANT GROUPS?** |  |  |
| 13 | Women who are pregnant and the human fetus |  |  |
| 14 | Children and young people |  |  |
| 15 | People in dependent or unequal relationships |  |  |
| 16 | People highly dependent on medical care who may be unable to give consent |  |  |
| 17 | People with a cognitive impairment, an intellectual disability, or a mental illness |  |  |
| 18 | People who may be involved in illegal activities |  |  |
| 19 | Aboriginal and Torres Strait Islander Peoples |  |  |
| 20 | People in other countries |  |  |
| **HOW TO SUBMIT AND LEVEL OF REVIEW REQUIRED** |
| **If ‘Yes’ to question 1 only, you need to complete and submit a Low Risk & Governance Review Application Form (**[**Attachment 2**](http://cabrini.com.au/research-and-education/research-ethics/)**).** **If ‘Yes’ to question 2 and ‘No’ to all question(s) from 3 onwards, seek advice from CRGO Administration regarding level of review required.****If you answer ‘Yes’ to any question from 3 onwards, you must seek a NHMRC-certified HREC approval elsewhere and then seek Governance review by submitting a completed Low Risk & Governance Review Application Form (**[**Attachment 2**](http://cabrini.com.au/research-and-education/research-ethics/)**)**. **Refer to the** [**CRGO Handbook**](http://cabrini.com.au/research-and-education/research-ethics/) **for further instruction on Cabrini-specific requirements.**  |

\*[Australian Privacy Principle (APP) 6](https://www.oaic.gov.au/assets/privacy/australian-privacy-principles/the-australian-privacy-principles.pdf) states that:

*‘*6.1 If an APP entity holds personal information about an individual that was collected for a particular purpose (the ***primary purpose***), the entity must not use or disclose the information for another purpose (the ***secondary purpose***) unless:

1. the individual has consented to the use or disclosure of the information; or
2. subclause 6.2…

6.2 This subclause applies in relation to the use or disclosure of personal information about an individual if:

(a) the individual would reasonably expect the APP entity to use or disclose the information for the secondary purpose and the secondary purpose is:

(i) if the information is sensitive information — directly related to the primary purpose; or

(ii) if the information is not sensitive information — related to the primary purpose;…’

An example of ‘secondary purpose’ is ***quality assurance*** (QA) activity. If the project involves access to identified data, by clinicians or administrative staff who normally have access to that data, to conduct QA activity, question 6 should be answered ‘No’. If the purpose goes beyond QA i.e. research, or access is by someone who would not normally have access to that data, question 5 must be answered ‘Yes’. In this case, a *waiver of the requirement for consent* must be sought from an NHMRC-certified HREC, justifying the reasons by addressing [2.3.10 of the National Statement.](https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2023)

Review the [NHMRC’s Ethical Considerations in Quality Assurance and Evaluation Activities](https://www.nhmrc.gov.au/about-us/resources/ethical-considerations-quality-assurance-and-evaluation-activities) to learn about the types of studies that qualify as ***QA or evaluation activities***.

Refer to Chapter 5.1 sections 5.1.15 to 5.1.17 to understand the types of studies that qualify as being ***exempt from review*** – exemptions can only be granted by the responsible institution.

*…………………………………………………… …………………………………………… ..…………………………………*

Principal Investigator (print name) Signature Date