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| Office for Research Governance and Development |

Pre-submission (Peer) review Proforma

The purpose of the review is to identify areas for improvement which will ensure the project is scientifically valid. Please also see [Pre-submission (Peer) Reviewer Process](https://www.publications.qld.gov.au/dataset/gold-coast-health-research-documents/resource/221a262a-5823-4f0e-a2dc-6e73af0a8b12) for more information.

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| **PROJECT TITLE** |  |
| **Version number & date of Protocol under review** |  |

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| **PRINCIPAL INVESTIGATOR** |  |
| **Position Title** |  |
| **Department / Group** |  |
| **Institution** |  |

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| **PEER REVIEWER NAME** |  |
| **Position Title** |  |
| **Department / Group** |  |
| **Institution** |  |

**PEER REVIEWER DECLARATION:**

* I agree to maintain confidentiality of all matters and documents regarding this project; and
* I am independent of this project; and

I agree that I have no potential conflicts of interest in reviewing this research protocol; **OR**

I declare I have the following potential conflicts of interest:

*Please disclose any actual or potential conflict of interest in the research being reviewed, including any:*

1. Personal involvement or participation in the research
2. Financial or other interest or affiliation, or
3. Involvement in competing research

**Brief summary of the project**

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**Please explain any ‘No’ response and record any comments regarding required changes or suggestions which could improve the project in the relevant section on the last page of this form.**

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| **CRITERIA:** *Using the right column please indicate if each criteria has been addressed, in your opinion* | | **YES**  **NO**  **N/A** |
| **Project details:** Has all appropriate information been included?  (Investigator details and project title, protocol version number, and date) | |  |
| **Research question:** Is there a clearly and precisely defined, answerable question?  Is there a clear aim and objective/s? Is the research question an important one? | |  |
| **Background:** Does the background information provide a good rationale for why the project is being done? Is the study useful to clinical practice? Is there a real problem/knowledge gap that needs filling? | |  |
| **Plan of Investigation:** | | |
| 1 | **Design:** Is the design appropriate to the aim? Will the study address the question being asked and is it likely to produce an answer? |  |
| 2 | **Bias and confounding**: Has the study been designed to minimise the risk of bias? Have the investigators adequately accounted for the influence of potential confounders? |  |
| 3 | **Randomisation and blinding:** Where applicable, is enough detail provided on exactly how randomisation and blinding will be achieved, including who is responsible? |  |
| 4 | **Sampling issues:** Will the proposed study group be large enough to provide sufficient statistical precision or power, where appropriate? Is there a reasonable justification for the proposed sample size? Will the sample collected be reasonably representative of the population in question?  \*There should be justification for sample size in both qualitative and quantitative research, and in the case of quantitative research, this should be supported by a statistical calculation with stated power and P value, and/or named expert statistical advice |  |
| 5 | **Feasibility:** Is there sufficient evidence to indicate that it will be possible to obtain the numbers required for the study? Is the study feasible in terms of funds, time, and other resources? |  |
| 6 | **Participants:** Are the criteria for eligibility clear and justified? Have the methods used to identify, approach, recruit and consent participants been clearly and completely described? |  |
| 7 | **Intervention or exposure:** Is the intervention or exposure factor clearly described in adequate detail, where appropriate? If the intervention is a drug, are details of dose, delivery, preparation, handling, and compliance provided? |  |
| 8 | **Procedure plan:** Has an appropriate plan of the study been detailed? Is the estimated duration of the project stated and appropriate? Is it clear how a participant will progress through treatments, procedures, assessments, and visits? |  |
| 9 | **Outcome measures:** Are these appropriate and achievable? Are definitions sufficiently detailed? Are the relevant data being collected on the proposed outcomes? |  |
| 10 | **Adverse events:** Is there an appropriate plan for detecting, managing, recording, and reporting defined adverse events? |  |
| 11 | **Data collection:** Are the proposed data collection tools and data management systems appropriate for the project? |  |
| 12 | **Analysis:** Is there an adequate indication of what analysis will be done on outcome measures to answer the research question? Are the proposed analyses appropriate? |  |
| **Project management:** Have adequate arrangements been specified for conduct and oversight? | |  |
| **Expertise:** Does the research team include (or have access to) all the necessary expertise for the project? | |  |
| **Ethical issues:** Have any potential ethical issues been addressed? Are risks to participants minimised? | |  |

**Each question, comment, suggestion, or requirement should be separately bulleted.**

**Where applicable please reference the section and page number.**

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| **General Comments** (Remarks that the investigator does not need to respond to) |
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| **Required Changes** (Points that the investigator must address by either making the required change, or producing a cogent argument against the change) |
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| **Suggested Changes** (Points that the reviewer thinks may improve the project. They are not of such importance that they would render the project scientifically invalid/unethical if the investigator did not address the issues) |
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| **Pre-submission (peer) review outcome:** (reviewer to circle or highlight) | |
| **A** | **No changes required:** take the study forward to submission. |
| **B** | **Changes suggested:** at the discretion of the investigator; take the study forward to submission. |
| **C** | **Changes required:** decision about acceptability of subsequent changes at the discretion of the HREC representative. A peer reviewer does not need to review the amended protocol prior to submission. |
| **D** | **Changes and further peer-review required:** decision about acceptability of the subsequent changes at the discretion of the reviewer following a pre-submission peer review of the amended protocol. An additional review and proforma should be completed to document the review of the amended protocol. |

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| **Peer Reviewer**  **Signature** |  | **Date** |  |