**The purpose of pre-submission peer review is to determine if a proposed research activity has merit, is scientifically and methodologically sound, and contains all elements required for ethical review. Research design must safeguard the health and safety of the participants and must ensure valid and reliable results that address the research aims and research questions. Peer reviewers may take the opportunity to suggest changes that will improve the methodology and/or conduct of the project. Peer reviewers may also assist the ethical review process by identifying ways to minimise participant risk or burden.**

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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 agree that I have the appropriate skills, knowledge and experience to determine whether

 the proposed research activity has merit and is scientifically and methodologically sound,

[ ]  I am independent of this project; and

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

[x]  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. *c)Involvement in competing research*

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| **CRITERIA:** *Using the right column please indicate if each criteria has been addressed, in your opinion***Please explain any ‘No’ response and record any comments regarding required changes or suggestions that could improve the project, in the relevant section on the last page of this form** | **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 or objective? |  |
| **Background:** Is the research question an important one? Does the background information provided give 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? |  |
| 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, where applicable? |  |
| 9 | **Outcome measures:** Are these appropriate and achievable? Are definitions sufficiently detailed? Is 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, where applicable? |  |
| 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 and therefore unethical if the investigator did not address the issues) |
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| **Pre-submission review outcome:** |
| [ ]  | **No changes required:** take the study forward to submission. |
| [ ]  | **Changes suggested:** at the discretion of the investigator; take the study forward to submission. |
| [ ]  | **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. |
| [ ]  | **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 & proforma should be completed to document the review of the amended protocol. |

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