

**APPLICATION FOR AMENDMENT OF AN APPROVED PROJECT**

1. **PROJECT DETAILS**

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| --- | --- |
| **HREC Approval Number** |  |
| **Title of Approved Study** |  |
| **Ethics Approval Date** |  |
| **Date of Amendment** |  |

1. **PRINCIPAL INVESTIGATOR**

|  |  |
| --- | --- |
| **Title** |  |
| **Initials** |  |
| **Surname** |  |
| **Faculty** |  |
| **Supervisor Name and Surname** |  |
| **Contact number** |  |
| **Email address** |  |

1. **TYPE OF AMENDMENT**

Amendments are planned changes to an approved study and may be classified as either major or minor. Please refer to the definitions below to categorise your amendment accordingly.

|  |  |
| --- | --- |
| Minor |  |
| Major |  |

**Amendments are planned changes to an approved study and may be classified as either major or minor.**

**Examples of Major amendments:**

* **Increasing the inclusion criteria**
* **Reducing the exclusion criteria**
* **Emergence of new and/or serious risks and/or significant risks to either participants and/or researchers**
* **Requirement for new and/or additional study documentation to be distributed to or viewed by participants that include information and/or data collection items significantly different to that in materials previously approved (i.e Revision of informed documents or questionnaire or interview).**
* **Principal investigator changed during the study**

**Example of Minor amendments:**

* **Any modification that would not significantly affect the assessment of the risks and/or benefits of the study.**
* **Any change that does not significantly affect the aims and/or design of the protocol for the study.**
* **A decrease/increase in sample size, supported by relevant statistical motivation.**
* **Administrative changes such as researcher contact details, the removal/addition/replacement of research personnel and/or study sites;**
* **Reducing the inclusion criteria;**
* **Increasing the exclusion criteria.**
* **Change in study title.**
* **Modifying data collection points or volume of data collected if any safety regulations/constraints are retained.**
* **Changes in compensation and/or reimbursement with adequate rationale.**
* **Any editorial modifications that serve to clarify but not alter a document's meaning.**
* **Any translations of documents previously reviewed and approved.**

**Unless there are extenuating circumstances, continuous applications for amendments to a particular study will not be viewed in a favourable light**

**ITEMS REQUIRED FOR AMENDMENT IN THE FOLLOWING FORMAT**

|  |  |
| --- | --- |
| **Amendment Requested** | **Highlight in protocol**  **Submit protocol on Converis for future reference** |
| **Reason For Amendment** |  |
|  |  |
| **Impact on Participants** |  |
|  |  |

* **If a new site is being added, submit the gatekeeper permission letter to this application.**
* Include all supporting documents relevant to your amendment request, for example updated consent forms or questionnaires if you amending the previously approved or amended questionnaires.
* **Highlight all changes in the protocol.**
* **Submit the protocol on Converis**

Signature of Principal Investigator:

If the PI is a student, the supervisor’s signature is required on this amendment form:

Signature of supervisor: