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| Human Research Ethics Committee **VARIATION FORM**  For Approved Research Involving Humans |

**What is a variation?** A variation is any change made to your originally approved research protocol. Variations may include, but are not limited to, extensions of time, changes of project titles, additions to the research, changes to researcher personnel, the study population, recruitment of participants, acquisition of human tissue, access to personal records, research instruments, or participant information and consent documentation.

**Variations must be approved by the HREC before they are implemented.**

**When you should use this form?** To request approval for a proposed variation to your original research project which has previously been approved by the University of New England’s Human Research Ethics Committee (HREC).

**Completing the form:**

* Care should be taken in the preparation of the variation, ensuring that you only answer the questions that are relevant to varying the existing, approved protocol.
* **Enable Editing** and **Enable Content** if prompted when you first open this form. This will enable you to select your answers using the tick boxes.
* Responses to questions must be:
* Entered into the spaces provided – these can be expanded if you require more room, although answers should be kept as concise as possible while at the same time providing the required detail. **Do not** answer questions with “see attached”.
* Questions requiring a Yes/No/N/A answer should be answered by **selecting** the relevant check box
* Answered in **plain English**. Where it is necessary to use technical terms, these must be explained in the first instance.

**Before you submit:**

* **Incomplete** variations **will not** be accepted; nor will variations submitted on **old** **versions of the form**. It is your responsibility to ensure that your variation is complete and on the latest version. The latest version can be downloaded from the HRE webpage (<https://www.une.edu.au/research/ethics-and-grants/human-research-ethics/apply-for-human-ethics-approval>)
* The variation must be signed by the Principal Researcher and any new or removed personnel listed on this form.
* Variations should be submitted electronically either as a word document or as a colour pdf.
* Please ensure that any new or varied supporting documents are submitted along with your application. All amendments in your original application or public documents should be highlighted so that they are easily identifiable.

**Submit variation by email to:** [humanethics@une.edu.au](mailto:humanethics@une.edu.au)

**Questions can be directed to:**

Research Ethics Officer - 02 6773 3115 OR [humanethics@une.edu.au](mailto:humanethics@une.edu.au)

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| **Please DELETE this page.** |

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| Human Research Ethics Committee **VARIATION FORM** For Approved Research Involving Humans |

**1. ADMINISTRATION**

|  |  |  |
| --- | --- | --- |
| **1.1** | **Approval Number:** | HE |
| **Project Title:** | |  |
| **Expiry date of this project:** | |  |
| **Principal Investigator’s or Supervisor’s Name:** | |  |
| **Phone (work/mobile):** | |  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **1.2** | **Type of Variation Requested**  Please **only** answer the questions relevant to the box below in questions 2-7. | | | |
| **Time extension (2)** | |  | **Changing procedure (5)** |  |
| **Additional participants (3)** | |  | **Other (6)** |  |
| **Change of personnel (4)** | |  |

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| **1.3** | **Please explain why the variation is required including a justification for its requirement.** |
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**2. EXTENSION OF TIME**

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| **If an extension of time is required, please indicate the new end date and why the project has been prolonged.** |
|  |

**3. ADDITIONAL PARTICIPANTS**

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| **Outline why you need more participants, where will be from (organisations, the general public, etc.), including the locations and how you will contact and recruit them.** |
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**4. CHANGE OF PERSONNEL**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **4.1** | **Provide details of any additional personnel to be listed on the protocol:** | | | | | |
| **Title and full name** | |  | **UNE staff/ student no.** |  | | |
| **Work mailing address** | |  | **School/ Employer** |  | | |
| **Email address** | |  | | | | |
| **Work phone no.** | |  | **Role in this project** | Choose a role | | |
| **Qualifications relevant to this project** | |  | | | | |
| **Please detail the relevant experience you have (including the number of years)** | | | | | | |
|  | | | | | | |
| **Are potential participants in dependent or unequal relationship with the researcher/s?** | | | | | **YES** |  |
| **NO** |  |
| *If* ***Yes****, provide details (e.g. how the recruitment process will deal with the dependent relationship):* | | | | | | |
| **Is there any possible conflict of interest for either the researcher(s) or participant(s)?** | | | | | **YES** |  |
| **NO** |  |
| *If* ***Yes,*** *provide details (Max 300 words):* | | | | | | |

*Copy this table and repeat for any additional personnel.*

|  |  |
| --- | --- |
| **4.2** | **Removal of personnel listed on the approved protocol:**  *List all personnel to be removed from the protocol and their date of departure. Personnel being removed from the project are required to sign the declaration below.* |
|  | |

**5. CHANGE TO THE PROJECT**

|  |  |  |  |
| --- | --- | --- | --- |
| **5.1** | **Describe the Procedural Modification. Please include the question number on the original application that the change relates to and the original wording from the answer to that question**. | | |
| **Question No.** | | **Previous submission wording** | **Proposed amendment** (in Plain English) |
|  | |  |  |

**6. OTHER**

|  |  |
| --- | --- |
| **6.1** | **Other changes not specified above**. Provide details and justification. |
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| --- | --- | --- | --- |
| **6.2** | **Will this variation require permissions or approvals from other authorities?** (if **yes**, provide a copy of the permissions/approval) | **YES** | *(give details below)* |
| **NO** |  |
| **N/A** |  |
|  | | | |

**7. DECLARATION OF REMOVED PERSONNEL:**

In signing this variation, I understand that I am being removed as a researcher from this project.

|  |  |  |
| --- | --- | --- |
| **Print Name** | **Signature** | **Date** |
|  |  |  |

*(Add rows as necessary)*

**7A. DECLARATION OF NEW PERSONNEL:**

In signing this variation request, I declare that I have read the original application nominated above and approval notice for this approved protocol. I agree to abide by the requirements of the Declaration and that the variation will not be implemented until approval has been received from the HREC.

|  |  |  |
| --- | --- | --- |
| **Print Name** | **Signature** | **Date** |
|  |  |  |

*(Add rows as necessary)*

**8. DECLARATION OF PRINCIPAL INVESTIGATOR/SUPERVISOR:**

In signing this variation, I accept responsibility for all procedures detailed in the approved application, and for supervising all personnel performing those procedures.

|  |  |  |
| --- | --- | --- |
| **Print Name** | **Signature** | **Date** |
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