School of Health and Social care

Amendment to Approved Application

**Amending an Approved Application**

Should you wish to make an amendment to an approved study, you will need to submit an ‘amendment request’ for the consideration of the Chair of the School Research Ethics Committee. Applications can only be amended **after** ethical approval has been granted.

You will need to apply for an amendment approval if you wish to:

1. Add a new participant group;
2. Add a new research method or make a change to existing methods;
3. Ask for additional data from your existing participants;
4. Remove a group of participants or a research method from the project, and have not yet commenced that part of the project;
5. Apply for an extension to your current ethical approval.
6. Change in PI

If you need to apply for an amendment approval, please complete the Amendment Approval Request Form on the next page.

When completing the form, please ensure you do the following:

* Clearly explain what the amendment you wish to make is, and the justification for making the change.
* Insert details of any ethical issues raised by the proposed amendments.
* Include all relevant information regarding the change so that the Chair can make an informed decision, and submit a copy of the sections of your application that have changed with all changes highlighted/underlined for clarity.
* You do not need to submit your original application in full again. However, if the changes you wish to make alters several sections of your application form, you are advised to submit this.

One signed hard copy of the form (and any amended documents), as well as an electronic copy of these same documents must be submitted to the REC Administrator to the address detailed below:

Administrator School of Health and Social Care Ethic Committee: Hilary Sawers

Email: SHSCethics@napier.ac.uk

Amendment requests are generally considered within 5-7 days of submission.

**School of Health and Social Care** ****

**Ethics Committee**



# Amendment Approval Request Form

|  |  |  |
| --- | --- | --- |
| **1** | **Project ID Number:**  | **Name and Address of Principal Investigator:** |
|  |  |        |
| **2** | **Project Title:**       |
| **3** | **Type of Amendment/s (tick as appropriate)** |
|  | Research procedure/protocol (including research instruments) [ ] Participant group [ ] Sponsorship/collaborators [ ] Extension to approval needed (extensions are given for one year) [ ] Information Sheet/s [ ] Consent form/s [ ] Other recruitment documents [ ] Principal researcher/medical supervisor\* [ ] Other [ ] \* |
|  | \*Additions to the research team other than the principal researcher, student supervisor and medical supervisor do not need to be submitted as amendments but a complete list should be available upon request. |
| **4** | **Justification** (give the reasons why the amendment/s are needed)      |
| **5** | **Details of Amendments** (provide full details of each amendment requested, state where the changes have been made and attach all amended and new documentation)      |
| **6** | **Ethical Considerations** (insert details of any ethical issues raised by the proposed amendment/s)       |
| **7** | **Other Information** (provide any other information which you believe should be taken into account during ethical review of the proposed changes)      |

|  |  |
| --- | --- |
|  | **Declaration** (to be signed by the Principal Researcher)* I confirm that the information in this form is accurate to the best of my knowledge and I take full

responsibility for it.* I consider that it would be reasonable for the proposed amendments to be implemented.
* For student projects I confirm that my supervisor has approved my proposed modifications.

Signature:       Date:       |
|  |  |  |
|  | FOR OFFICE USE ONLY:Amendments to the proposed protocol have been ………………… by the Research Ethics Committee. |
|  | Signature of the REC Chair: ………………………….Date: ……………………  |