# WESTERN HEALTH LOW RISK ETHICS PANEL

###### Amendment Request Form

In the event that a project ethically approved by the Western Health Low Risk Ethics Panel (WH LREP) research project requires amendment, this form must be submitted to the Western Health LREP by the Principal Investigator (PI).

**An amendment must not be implemented at a site until it has been approved by the WH LREP.**

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| 1. **RESEARCH PROJECT DETAILS**
 |
| **Date of this Form:** | Select date |
| **Project Number:** | E.g. 41234; HREC/18/WH/123; QA2018.123 |
| **Project Title:** | Enter text |
| **Principal Investigator:** | Enter text |
| **Study Contact/Coordinator:** | Enter text |
| **Study Site/s approved:**Sunshine Hospital[ ]  Footscray Hospital [ ]  Williamstown Hospital [ ] Sunbury Day Hospital [ ]  Drug Health Services [ ]  Hazeldean Transition Care [ ] Sunshine Radiation Therapy Centre [ ]  |
| **Date of Original Approval:** | Select date |
| **Provide a brief summary of the approved project, including a brief statement of the main objective of the project and the methodologies (*up to 150 words*)** |
| Enter text |
| 1. **AMENDMENT DETAILS**
 |
| 1. **Explain the changes that have occurred or are intended (may include changes in procedure, direction of project, source/manner of recruitment, number of participants or changes to research personnel)**
 |
| Enter text |
| 1. **Reason for the changes (include a comment on the impact on the research project and the participants at sites)**
 |
| Enter text |
| 1. **Do these changes raise any ethical issues?**

If Yes, identify the issues below. | [ ]  No [ ]  Yes  |
| Enter text |
| 1. **Does the amendment also involve a change of personnel on the research team?**

If Yes, provide details below and please also complete a WH Change of Personnel Form – please see this form for other submission requirements. If the amendment only involves a change of personnel, please complete the WH Change of Personnel Form only. | [ ]  No [ ]  Yes |
| Researchers Leaving the Project: | Enter text |
| Researchers Joining the Project: | Enter text |
| 1. Does the amendment involve a re-activation/extension of the approval?

If Yes, provide details below.  | [ ]  No [ ]  Yes |
| Original expected completion date: | Select date |
| New expected completion date: | Select date |
| Reason for the re-activation/extension: | Enter text |
| 1. **Annual Progress Report provided?**
 | [ ]  Yes*- attach WH LREP Annual Progress Report Form*[ ]  No - *please give reasons:* Enter text |
| 1. **Does the amendment involve changes to Participant Information, Consent Forms or letters of invitation?**

If Yes, provide amended versions of the relevant documents and, if feasible, an original version showing tracked changes.  | [ ]  No [ ]  Yes |
| 1. **Does the amendment involve changes to other documents, such as surveys or questionnaires**

If Yes, provide amended versions of the relevant documents and, if feasible, an original version showing tracked changes. | [ ]  No [ ]  Yes |
| 1. **Does the amendment have privacy implications?**

If Yes, complete Section 2 of the Victorian Specific Module for the new information that is to be collected, used or disclosed. | [ ]  No [ ]  Yes |
| 1. **DOCUMENTS FOR REVIEW**

**Include Document Title, version number and date. Attach one copy of each amended document to this form; all changes must be clearly indicated on the document(s) – please provide tracked and clean copies of amended documents** |
| **Name** | **Version** | **Date** | Office use only |
| Name of document | Insert Number | Select date | [ ]  |
| Name of document | Insert Number | Select date | [ ]  |
| Name of document | Insert Number | Select date | [ ]  |
| Name of document | Insert Number | Select date | [ ]  |
| Name of document | Insert Number | Select date | [ ]  |
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| Name of document | Insert Number | Select date | [ ]  |
| Name of document | Insert Number | Select date | [ ]  |
| Name of document | Insert Number | Select date | [ ]  |

*If more documents required, please attach a list on a separate page.*

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| 1. **SUPPORTING DEPARTMENT**
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| **Does this amendment impact the type or frequency of service provided by a supporting department?**If Yes, indicate the relevant departments below and please provide updated Statement of Approval Forms for these departments. | [ ]  No [ ]  Yes |
| Enter text |
| 1. **DECLARATION**
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| I confirm that the information provided is accurate and true and that this project is being conducted as originally approved by the Western Health Low Risk Human Research Ethics Panel. I confirm that the project is being conducted in compliance with the NHMRC National Statement on Ethical Conduct in Human Research (NHMRC, 2007) and the Western Health Research Code of Conduct (2018) or as amended.Amendments requested will not be implemented until approval has been granted by the Western Health Low Risk Ethics Panel. |
| **Principal Investigator (or delegate):** | Enter text |
| **Signature:** | **Date:** |
| **Email:** Enter email address |
| **Telephone:** Enter contact number |

Please send a signed electronic copy of this Amendment Request Form with signature and relevant documents via email to ethics@wh.org.au.

**Mandatory electronic file name convention:**

To ensure the electronic copies submitted are easily identifiable, the format outlined below must be used for all electronic files. As shown in example below, include version numbers (if applicable) and dates in the file name.

Projects submitted with documents that do not follow the below naming convention/format will not be considered and will be returned via email to sender.

**Convention**: [Reference Number/ERM Project ID] [Document Name] [version number] [Date DDMMMYY]

E.g. 41234 Amendment Request Form 01Jan19; QA2018.123 Protocol v3 Clean 01Jan19; HREC18WH123 Advertisement v3 Tracked 01Jan18