**NSW Population & Health Services Research Ethics Committee**

**Request for an Amendment to an Approved Research Project**

CI NSW Study Reference Number:

AU RED Study Reference Number:

***Please note: Amendments will not be considered without tracked and clean versions of all changed documentation.***

1. **Title of the Project**

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1. **Date of Approval by HREC**

When was this project given approval by the HREC?

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| **/** **/**  |

1. **HREC Approval Expiry Date**

When will HREC approval for the study expire (including any approved extensions)?

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1. **Principal Investigator**

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| --- | --- | --- |
| Title (eg Prof/Dr/Mr/Ms/Mrs) | First Name | Surname |
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| Institution (include school/faculty if applicable) / Organisation |
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| Telephone (Business Hours) | Facsimile |
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| Email |
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1. **Single site / Multi-site study**

Is the study: [ ]  Multi-site (within NSW) or [ ]  Single site?

1. **Project Status**

Please provide a one paragraph lay summary of your project and its current status.

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**7. Have amendments previously been approved for this study?** **[ ]  Yes** **[ ]  No**

If yes, briefly list the amendment(s) with identifying version control.

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1. **Nature and reasons for current amendment(s):** (E.g. changes to the protocol, Investigator Brochure, Participant Information Sheet and Consent form, or other study documentation; or the addition of new sites).

***Please note: All amendments MUST also be updated in the study protocol. New version numbers and dates should be provided on all documents.***

Please provide details of the changes to the project and why they are necessary.

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1. **Do these amendments introduce new risks to participants? [ ]  Yes [ ]  No**

If yes, please outline any new risks that the changes you propose may create for participants (e.g. changes to confidentiality provisions, physical or psychological risks, increased time commitments etc).

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1. **Do these amendments necessitate changes to the Participant information sheet and consent** **form?** **[ ]  Yes [ ]  No**

*If yes, please attach tracked and clean versions of all revised documents with identifying version control.*

1. **Do the amendments represent any new ethical issues for participants?**

**[ ]  Yes [ ]  No**

If yes, please outline the ethical issues

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1. **Implications for compliance with legislative requirements:**
2. **Does the amendment involve the collection, use or disclosure of personal health information which is identified, or from which the identity of the person can be reasonably obtained?**

**[ ]  Yes [ ]  No**

If yes, please attach the NSW Health Privacy form.
<http://www.cancerinstitute.org.au/research-grants-and-funding/ethics/nsw-population-health-services-research-ethics-committee>

1. **Do you currently have an approved waiver of consent? [ ]  Yes [ ]  No**

**Declaration**

I certify that the above information is accurate and that the project will continue to be carried out in accordance with the original HREC approved protocol and any approved amendments.

Name:

Position:

Signature (Principal Investigator): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date:       /       /

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| **Please upload and submit 1 signed copy via** [**REGIS**](https://regis.health.nsw.gov.au/)**. Instructions for this can be found in the** [**Quick Reference Guide**](https://regis.health.nsw.gov.au/how-to/) **titled “Ethics Amendment – Completing and Submitting”.** Refer to the Guidelines for submission to the NSW Population and Health Services Research Ethics Committee for electronic and/or scanned signature requirements. For any questions please contact the Ethics team at cinsw-ethics@health.nsw.gov.au. ***Please note: If the amendment relates to a change in the research team, please also submit a Notification of Change in Personnel form.*** |