

Amendment Request Form

**Is an amendment appropriate?**

Amendments to approved projects generally request a change to the conduct of the project in a way that deviates from the approved protocol, but still adheres to the overall project scope and intent. Changes beyond that require a new application to be made.

The committee will consider whether the research intent will be substantially altered by the amendment. For proposed more substantial amendments it is the researcher’s responsibility to explain why a new application isn’t required.

Possible indicators of when a new application should be made include that the:

* research question is altered
* new activity has funding attached that suggests the funder sees the project as ‘new’
* changes warrant a name change for the project – either the whole project or the new activity
* risk level of the project is changed by the amendment
* research team needs to be substantially changed to accommodate the new activity
* project was established as a student project but wants to continue past the student’s completion
* activities or participant groups introduced by the amendment means the project now requires ethics review from another ethics body. For a list of all Australian NHMRC accredited HRECs see

<https://www.nhmrc.gov.au/health-ethics/human-research-ethics-committees-hrecs>

A project which intends to run many nested or subprojects within it needs to be approved in this way in the original ethics application. In most cases such projects will be first reviewed by the HREC, irrespective of the risk level.

When making an amendment request you must provide sufficient information for the committee to have a full understanding of the changes and their impact on the approved protocol.

**If you are unable to use the tick boxes on this template, please delete the option/s which do not apply.**

# Section 1: Overview

**If this form is being completed by a HDR candidate, please ensure that the form is completed in consultation with the supervisor.**

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| **1.1.** Project Title: |  |
| **1.2.** HREC Approval Number: | **H** |
| **1.3.** Chief Investigator/Principal Supervisor: |  |
| **1.4:** Chief Student (if applicable): |  |

**1.5.** **Indicate the nature of the Amendment**

**Sections 1 and 9 are MANDATORY.** *Sections 2 – 8 should only be completed when relevant.*

Mark all relevant amendment types:

[ ]  Extension of Time – **Complete Sections 1, 2 and 9**

[ ]  Change to the research team – **Complete Sections 1, 3 and 9**

 [ ]  Add student/investigator/professional staff

 [ ]  Remove student/investigator/professional staff

 [ ]  Change Western researcher to external researcher

[ ]  Change to site (including new sites) – **Complete Sections 1, 4 and 9**

[ ]  Change to Participant Groups/Numbers – **Complete Sections 1, 5, 6 and 9**

[ ]  Change to Research Design – **Complete Sections 1, 6 and 9**

[ ]  Change to Recruitment Procedure – **Complete Sections 1, 6 and 9**

[ ]  Administrative/Other – **Complete Sections 1, 6 and 9**

[ ]  Change to Funding – **Complete Sections 1, 7 and 9**

[ ]  Change to reimbursement (including new reimbursement) – **Complete Sections 1, 8 in and 9**

[ ]  Change to Information Sheet, Consent Form or Flyer - **attach**

[ ]  Change to research tools (surveys, questionnaires, etc) – **attach**

**1.6.** Provide a brief summary of what the specific amendments are.

Provide a summary as you would like it to appear on the amendment approval letter.

Note: if the change is not summarised here, it will not be considered by the ethics committee.

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**1.7.** Explain why this change to the project is needed.

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**1.8.** Which of the original study aims and objectives does this amendment align with?

(Refer to your project description)

Explain how the proposed changes adhere to the overarching aims/hypothesis of the original project.

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**1.9.** What ethical principles have you considered? Reference to the Elements section of the National Statement will assist here.

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**1.10.** What are the new risks and burdens associated with the change, and how will they be managed?

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**1.11.** List all supporting documentation which has been attached.

Consider which documents will need to be revised or added because of the proposed amendment.

Eg: Information sheets, consent forms, recruitment texts, data collection tools.

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# Section 2: Extension of study duration

**2.1.** Current Approval Expiry Date:

**2.2.** Proposed Expiry Date:

If not sure see – [Western Sydney University Researcher Portal](https://research-report.uws.edu.au/wpubs/Portal.asp)

If a Progress Report is due for this project please ensure you submit a Progress Report with this Amendment.

# Section 3: Change to Research Team

What changes are you making?

[ ]  Adding an academic or professional person (go to 3.1)

[ ]  Adding a student (go to 3.2)

[ ]  Removing a person (go to 3.3)

**3.1. Adding an academic or professional person to an approved protocol**

Create a new table for each new person being added.

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| Name |  |
| School/Institute/Organisation |  |
| Organisation address: |  |
| Email Address: |  |
| Student/Staff ID |  |
| Role: | [ ]  Western Sydney U Investigator  |
|  | [ ]  Western Sydney U Professional Staff  |
|  | [ ]  Non-Western Sydney U Investigator |
| Summary of Qualifications and relevant expertise NS 4.8.7 NS 4.8.15: |  |
| Declare any general competing interests: |  |
| Name the site(s) for which this individual is responsible: |  |
| Role: | [ ]  Western Sydney U Investigator  |
|  | [ ]  Western Sydney U Professional Staff  |
|  | [ ]  Non-Western Sydney U Investigator |
| Describe the role/activities that will be conducted by the individual in this project: |  |
| Signature of new team member (or attach email confirmation) |  |

**3.2. Adding a student to an approved protocol**

Create a new table for each student being added.

Doctoral, MPhil and MRes students should usually submit a separate ethics application. Students should usually only be added as amendments to existing projects if:

* They are being employed as a Research Assistant and will be conducting already approved activities as per the original ethics application; or
* The addition of student researchers was indicated in the original ethics application.

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| Name: |  |
| School/Institute/University: |  |
| Email Address: |  |
| Student/Staff ID: |  |
| Role: | [ ]  Western Sydney U Student |
|  | [ ]  Non-Western Sydney U Student  |
| Enrolled in Course? |  |
| Non-WSU student:Why is the external student being added to this protocol and not applying for ethics approval at their home university? |  |
| Non-WSU student:Does the student’s home institution support the student being added to a WSU protocol?  | [ ]  Yes [ ]  No |
| Summary of Qualifications and relevant expertise NS 4.8.7 NS 4.8.15: |  |
| Declare any general competing interests: |  |
| Name the site(s) for which this individual is responsible: |  |
| Describe the role/activities that will be conducted by the individual in this project: |  |
| Did the original protocol indicate that students would be added to the project in the future?  | (See Project Description 3.6)[ ]  Yes [ ]  No |
| Will this student be conducting activities that have already been approved by the ethics committee? | [ ]  Yes [ ]  No |
| Is this research project part of the assessment of the student?  | [ ]  Yes [ ]  No |
| Is the student's involvement in this project elective or compulsory?  | [ ]  Elective [ ]  Compulsory |
| What training or experience does the student have in the relevant research methodology? |  |
| What training has the student received in the ethics of research? |  |
| Describe the supervision to be provided to the student. NS 4.8.8 |  |
| Provide the name(s) of the student’s supervisor(s) If the Student’s Supervisors are not already named on this project, add them via the academic section 3.1 above. |  |
| Signature of new team member (or attach email confirmation) |  |

**3.3. Remove a person from an approved protocol**

Create a new table for each person being removed.

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| Name: |  |
| School/Institute/Organisation: |  |
| Is the person being removed the Chief Investigator or Principal Supervisor?Note: If the CI is being changed, the declaration must be signed by both the old CI and the new CI | [ ]  Yes [ ]  No |
| If the person being removed is the CI/PS, who will assume this role?Note: If the new CI/PS is not already named on the project team, please add them at Section 3.1 above.  |  |
| Signature of outgoing CI/PS (or attach email confirmation) |  |

# Section 4: Change to site (including new sites)

# Copy and complete all the questions in Section 4 for each change.

**4.1.** Would you like to:

 [ ]  Add a new site in Australia (go to 4.2)

 [ ]  Add a new site Overseas (go to 4.2)

 [ ]  Remove an existing site (go to 4.6)

**4.2.** Type of Site: this may be a place (e.g. Bankstown Campus) or a type (e.g. Sydney cafes; online)

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**4.3.** Site Location:

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**4.4.** Which of the researchers / investigators involved in this project will conduct the research at this site?

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**4.5 Overseas Sites Only:**

 4.5.1. List the countries/jurisdictions that this research will be undertaken in.

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 4.5.2. On what basis is the research lawful in the jurisdiction(s) where it is to be conducted?

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 4.5.3. Are there any local requirements which are necessary for the conduct of this research?

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 4.5.4. How have the researchers / investigators taken into account the opinions and expectations of participants and their communities about the effect of any limits of resources on: (a) the way the research will be conducted; (b) participants’ post-research welfare; and (c) application of the results of the research?

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 4.5.5. Are there local factors which make it problematic to comply with ethical standards expressed in the National Statement ☐ Yes ☐ No

 4.5.5.1. Describe these factors and what steps will be taken to address these matters in a responsible and appropriate manner.

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 4.5.6. Will this research project involve access to, use, collection or acquisition of culturally sensitive artefacts?

 ☐ Yes ☐ No

 4.5.6.1. Describe the artefacts and how cultural sensitivity will be respected.

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 4.5.7. How will the principal researcher / investigator monitor the conduct of the members of the research team who will be working overseas?

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**4.6 Remove a Site:**

4.6.1. Which site/s should be removed?

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# Section 5: Change to Participant Groups/Numbers

# Copy and complete all the questions in Section 5 for each change.

**5.1.** Would you like to:

 ☐ Add a new group – (go to 5.2)

 ☐ Change an existing group – (go to 5.3)

 ☐ Remove an existing group – (go to 5.4)

**5.2. Adding a new participant group**

Copy a new table for each new participant group.

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| --- | --- |
| 5.2.1. With whom or what will the research be conducted? | ☐ Human beings☐ Human biospecimens☐ Human data (data associated with human beings) |
| 5.2.3. Does the new group include? Check all appropriate options | ☐ Women who are pregnant and the human fetus☐ Children and young people☐ People highly dependent on medical care who may be unable to give consent☐ People with a cognitive impairment, intellectual disability or mental illness☐ People in dependent or unequal relationships☐ People who may be involved in illegal activities☐ People in other countries ☐ Aboriginal and Torres Strait Islander peoples☐ None of the above |
| 5.2.4. Group name for these participants: |  |
| 5.2.5. Expected number of participants in this group:  |  |
| 5.2.6. Age range: |  |
| 5.2.7. Other relevant characteristics of this participant group: |  |
| 5.2.8. Why are these characteristics relevant to the aims of the project? |  |
| 5.2.9. What will these participants be asked to do? |  |
| 5.2.10 Are these the same activities that have already been approved for other participants? | [ ]  Yes [ ]  No – complete Section 6 – Changes to Research Design |
| 5.2.11. Are the strategies for recruitment and obtaining consent for the new participants the same as what has already been approved for other participants? | [ ]  Yes [ ]  No – complete Section 6 – Changes to Research Design |
| 5.2.12. Does the new group include participants whose primary language is other than English (LOTE)? | [ ]  Yes – continue to Q5.2.13 below[ ]  No – this table is now complete |
| 5.2.13. Describe what steps will be taken to ensure each participant's free and voluntary consent and participation in the project, given that the person's language is other than English: |  |
| 5.2.14. In what language(s) will the research be conducted? |  |
| 5.2.15. Will an interpreter to be present during discussions with the participants about the research project? | [ ]  Yes [ ]  No – If not, why not? |
| 5.2.16. Will participants be provided with written information in the language in which the research will be conducted?  | [ ]  Yes - please attach if available[ ]  No  |

**5.3. Change an existing participant group:**

Create a new table for each participant group being changed.

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| 5.3.1. Name of the participant group being changed:(Please cite the name used in the original Project Description or Protocol) |  |
| 5.3.2. Please describe the proposed changes: |  |

**5.4. Remove a participant group:**

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| 5.4.1. Name of the participant group/s being removed:(Please cite the name used in the original Project Description or Protocol) |  |
| 5.4.2: Was any data collected from this participant group? If yes, what has happened to that data? |  |

# Section 6: Changes to the design of the project

**6.1** Which of the following was selected in 1.5?

 [ ]  Change to Research Design

 [ ]  Change to Recruitment/Consent Procedure

 [ ]  Administrative/Other (eg changing the CI of the project, change of project title)

**6.2.** Provide a detailed description of the change(s):

Also attach any additional documents e.g. new recruitment flyers, information sheets etc.

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# Section 7: Changes to Funding

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| **7.1. If a new source of funding has been added, complete the following**Refer to the [Researcher Portal](https://research-report.uws.edu.au/wpubs/portal.requery_asp) |
| Name of Funder |  |
| Amount Confirmed | **$** |
| Project ID (E.g. P00000001) |  |

**7.2.** If funding has been withdrawn or reduced, please explain how any funding shortfall will be managed:

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# Section 8: Changes to Reimbursement (including new reimbursement)

**8.1.** Specify the nature and value of any proposed incentive/payment (e.g. movie tickets, food vouchers) or reimbursement (e.g. travel expenses) to participants.

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**8.2.** Explain why this offer will not impair the voluntary nature of the consent, whether by participants' or persons deciding on their behalf.

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# Section 9: Declaration of Chief Investigator

I/we certify that the information provided in this form is an accurate account of the conduct for the above research project for which I/we am responsible.

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| Name of Chief Investigator/Principal Supervisor: |  |
| Signature: |  |
| Date:  |  |

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| Name of Chief Student: |  |
| Signature: |  |
| Date:  |  |

If the Chief Investigator for this project has changed, the previous CI should sign above, the new CI should sign below

I certify that the information provided in this form is an accurate account of the conduct for the above research project for which I am now responsible.

|  |  |
| --- | --- |
| Name of new Chief Investigator: |  |
| Signature: |  |
| Date:  |  |

**Forward this completed and signed form to the Human Ethics Secretariat –** **humanethics@westernsydney.edu.au**