**Australian Institute of Health and Welfare**

**Ethics Committee: *Amendment requests***

***Purpose of this form***

This form is used to request approval from the Australian Institute of Health and Welfare Ethics Committee (the Committee) for amendments (changes) to already approved projects. Internal AIHW **data collections** require a different amendment request form which can be obtained [here](http://www.aihw.gov.au/ethics/how-to-use-ethos/) or from [ethicssec@aihw.gov.au](mailto:ethicssec@aihw.gov.au).

***Guidance for completion of the request***

Consistent with the legislative and ethical requirements set out in [*Australian Institute of Health and Welfare Act 1987*](http://www.aihw.gov.au/aihw-annual-report-2011-12/app1/)*,* the [*Australian Institute of Health and Welfare Ethics Committee Regulations 1989*](http://www.aihw.gov.au/aihw-annual-report-2013-14/app1/), the [*Australian Privacy Principles*](http://www.oaic.gov.au/privacy/privacy-act/australian-privacy-principles) (APPs), and the[*National statement on ethical conduct in human research*](https://www.nhmrc.gov.au/guidelines-publications/e72), amendments (changes) to projects require Committee approval. In other words, if any changes are made to any aspects of the project as it was originally approved, then that is an amendment and it needs further Committee approval.

The Principal Investigator is responsible for obtaining Committee approval *before* any changes are implemented (within reasonable limits). Penalties apply for not obtaining prior Committee approval, including withdrawal of access to AIHW supplied data.

**NOTE:** Requests for amendment must be cleared by the data custodian before being submitted.

***Guidance for submission of the request***

Although amendment requests can be made at any time, unless extremely unusual circumstances apply, they will be considered at the next available Committee meeting ([dates available here](https://www.aihw.gov.au/our-services/committees/aihw-ethics-committee)). Please submit the completed form to [ethicssec@aihw.gov.au](mailto:ethicssec@aihw.gov.au). Make sure that any attachments are also submitted, e.g the s.29 form (see Section 2(a) below). There is no need to submit the original application with amendment requests.

**NOTE:** The form will not be accepted if it is incomplete or used for another purpose (e.g to report on progress).

For assistance please contact the Ethics Manager at [ethicssec@aihw.gov.au](mailto:ethicssec@aihw.gov.au%20) or (02) 6249 5004.

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| 1. **CURRENT PROJECT DETAILS: refer to** [**EthOS**](https://ethos.aihw.gov.au/Pages/Welcome.aspx) **or the project approval letter** | |
| 1. EC or EO reference number Project title (as approved by the Committee) |  |
| 1. **Current** Principal Investigator PI):   *If the amendment is to change the PI put existing PI details in here and complete Section 2 (a) below.* | Name and title:  Organisation and Centre/Section:  Position in the organisation:  Email and ph: |
| 1. Contact person **if different to Principal Investigator**   *Correspondence is usually sent to the PI unless otherwise requested* | Name and title:  Organisation and Centre/Section:  Position in the organisation:  Email and ph: |
| 1. Progress to date | Date the project was first approved (see project approval letter)  When did the project commence?  If the project has not yet commenced, please briefly explain the reasons and attach any supporting documentation. |

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| 1. **AMENDMENT REQUESTS FOR STAFF CHANGES mark N/A for any that do not apply** | |
| 1. Change of Principal Investigator (PI)   *Make sure that:*  *-the new PI has signed the* [*s.29 form*](http://www.aihw.gov.au/ethics/how-to-use-ethos/) *and that it is attached to this request*  *-that details of a new location for data storage are provided (if applicable)* | Details of previous PI: if same as above insert *‘as above for 1 (b)’*  Change to new PI:  Name and title:  Organisation and Centre/Section:  Position in the organisation:  Email and ph:  Postal address:  Please briefly outline the reasons for the change and attach any supporting documentation.  Will the data storage location change with the new PI?  YES NO  **If YES**, please provide the address for the new physical location and explain the security measures at that location, attaching any supporting documentation. |
| 1. Change of staff: New staff having access to AIHW supplied data and staff leaving the research team   *Make sure that an* [*s.29 form*](http://www.aihw.gov.au/ethics/how-to-use-ethos/) *has been signed by* ***all*** *new staff and that it is attached to the request*  **Note: Changes to the contact information for the online application in EthOS need to be notified to the Secretariat separately at** [**ethicssec@aihw.gov.au**](mailto:ethicssec@aihw.gov.au) | New staff details (copy and paste for as many as applicable):  Name and title:  Organisation and Centre/Section:  Position in the organisation:  Email and ph:  Staff leaving the project: (copy and paste for as many as applicable)  Name and title:  Organisation and Centre/Section:  Date of leaving the project: |

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| 1. **AMENDMENT REQUEST FOR AN EXTENSION OF TIME: mark N/A if not applicable** | |
| 1. Seeking an extension of time for the project completion date | Current approval date of project completion (see project approval letter)  New completion date requested  Please briefly explain the reasons for the request and attach any supporting documentation |
| 1. Data retention and storage | What is the current approval date for the data retention and storage? (see project approval letter)  What is the new data storage and retention date requested (usually seven years from project completion date) |

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| 1. **AMENDMENT REQUESTS FOR CHANGES TO THE PROJECT ITSELF: mark N/A if not applicable** | |
| **Please confirm that this change been approved by the data custodian/s and provide the name/s of the AIHW officer/s who have provided this clearance.** |  |
| 1. Changes to the data elements of the approved project   *Please be aware that changes may require a new application to be submitted: contact* [*ethicssec@aihw.gov.au*](mailto:ethicssec@aihw.gov.au) *for advice before submitting the request* | Please explain the nature of the requested change, e.g changes to cohort or patient numbers (attach any supporting documentation).  Please briefly explain the reason/s for the requested change and attach any supporting documentation. |
| 1. Changes to the design, scope or methodology of the approved project   *Please be aware that changes may require a new application to be submitted: contact* [*ethicssec@aihw.gov.au*](mailto:ethicssec@aihw.gov.au) *for advice before submitting the request* | Please briefly explain the nature of the requested changes and attach any supporting documentation.  Please briefly explain the reason/s for the requested changes and attach any supporting documentation. |

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| 1. **AMENDMENT REQUESTS FOR CHANGES TO THE APPs: mark N/A if not applicable** | |
| 1. Changes to the privacy and confidentiality measures in the approved project   *Please be aware that changes may require a new application to be submitted: contact* [*ethicssec@aihw.gov.au*](mailto:ethicssec@aihw.gov.au) *for advice before submitting the request* | Please explain the nature of the requested change (e.g changes to consent arrangements) and attach any supporting documentation (refer to [*Australian Privacy Principles*](http://www.oaic.gov.au/privacy/privacy-act/australian-privacy-principles)and [*National statement on ethical conduct in human research*](https://www.nhmrc.gov.au/guidelines-publications/e72) *(*ch 2.2-2.3 and Section 4).  Please briefly explain the reason/s for the requested change and attach any supporting documentation, e.g new consent forms. |

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| 1. **OTHER: mark N/A if not applicable** | |
| 1. ‘Other’ refers to any changes not covered in 2-5 above | Please explain the nature of the requested change and attach any supporting documentation. |

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| 1. **DECLARATION: Principal Investigator to sign** |
| I confirm that the details in this amendment request form accurately reflect the nature and extent of the amendments requested.  Printed name and title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Date: ………./………/……… |

*Thankyou*