**Australian Institute of Health and Welfare**

**Ethics Committee: *Guidance for applicants on research merit and integrity*** [[1]](#footnote-2)

**Purpose and content of this guidance**

In considering applications for ethical review, Human Research Ethics Committees (HRECs) are governed by the requirements of the *National Statement on Ethical Conduct in Human Research* (National Statement)*.*

One of the traditional ethical values covered in the National Statement relates to Research Merit and Integrity; the others being Justice, Beneficence and Respect.

The purpose of this Guidance document is to assist applicants in completing section 5 of the Ethics Committee EthOS application form relating to Research Merit and Integrity.

**National Statement Requirements on Research Merit and Integrity**

Research Merit and Integrity is dealt with in sections 1.1 – 1.3 of the National Statement (Attachment A).

In summary, the key requirements of this section of the National Statement are that the research is:

* justifiable by its potential benefit
* designed or developed using methods appropriate for achieving the aims of the proposal
* based on a thorough study of the current literature, as well as previous studies
* designed to ensure that respect for the participants is not compromised by the aims of the research, by the way it is carried out, or by the results
* conducted or supervised by persons or teams with experience, qualifications and competence that are appropriate for the research
* conducted using facilities and resources appropriate for the research and
* is carried out by researchers with a commitment to searching for knowledge and understanding; following recognised principles of research conduct; conducting research honestly; and communicating results.

Typical causes of non-compliance such as:

* poorly framed research questions
* poor data (not enough data, unrepresentative data leading to bias, unreliable data) and
* poor data science/statistical techniques (algorithms, code, inferences, insights, failing to verify statistical assumptions of analysis techniques).

**AIHW Ethics Committee consideration of Research Merit and Integrity**

The Committee encourages applicants to consider carefully how their research project meets the requirements of the National Statement regarding Research Merit and Integrity. There are two ways in which applicants can demonstrate compliance:

* peer review report
* internal clearance/quality control processes.

You should provide evidence of an assessment in at least one of these categories, as appropriate to the nature of the research.

***Peer review report:***

The purpose of peer review reports is to provide the AIHW Ethics Committee with 'expert scrutiny of a project’ via an ‘*impartial* and *independent* assessment of research by others working in the same or a related field’. [[2]](#footnote-3)

Detailed guidance on the Committee’s peer review requirements is provided in Attachment B.

**Internal clearance/quality control processes:**

This method of review is often appropriate in relation to low or negligible risk projects involving (often very large) de-identified government data sets for evaluation and/or policy purposes. This might apply, for example, in cases where the research is performed by specialist researchers engaged, often following a competitive selection process, on the basis of their expertise and a detailed project proposal.

One option would be assessment by a technical advisory group or committee. In this case, you should include:

* the terms of reference
* details about its members (including their qualifications and basis for the membership of the Group)
* the process by which it has engaged with and considered the research project
* any written reports which provide an assessment of the research by the group/committee, for example, the relevant extract from Minutes of a meeting or a refereed publication.

Whichever method is adopted, it must provide the AIHW Ethics Committee with sufficient information to enable it to form a view on whether the research complies with the various National Statement requirements on research merit and integrity, as described earlier in this Guide.

Should you wish to discuss which method of review would be appropriate in relation to your project, please contact the AIHW Ethics Committee Secretariat.

**Attachment A**

**National Statement on Ethical Conduct in Human Research**

**Sections 1.1 – 1.3: Research Merit and Integrity**

1.1 Research that has merit is:

1. justifiable by its potential benefit, which may include its contribution to knowledge and understanding, to improved social welfare and individual wellbeing, and to the skill and expertise of researchers.

What constitutes potential benefit and whether it justifies research may sometimes require consultation with the relevant communities;

1. designed or developed using methods appropriate for achieving the aims of the proposal;
2. based on a thorough study of the current literature, as well as previous studies. This does not exclude the possibility of novel research for which there is little or no literature available, or research requiring a quick response to an unforeseen situation;
3. designed to ensure that respect for the participants is not compromised by the aims of the research, by the way it is carried out, or by the results;
4. conducted or supervised by persons or teams with experience, qualifications and competence that are appropriate for the research; and
5. conducted using facilities and resources appropriate for the research.

1.2 Where prior peer review has judged that a project has research merit, the question of its research merit is no longer subject to the judgement of those ethically reviewing the research.

1.3 Research that is conducted with integrity is carried out by researchers with a commitment to:

1. searching for knowledge and understanding;
2. following recognised principles of research conduct;
3. conducting research honestly; and
4. disseminating and communicating results, whether favourable or unfavourable, in ways that permit scrutiny and contribute to public knowledge and understanding.

 **Attachment B**

**PEER REVIEW GUIDANCE**

The AIHW Ethics Committee takes peer review very seriously, so approval of your application will not be granted until satisfactory peer review reports are provided.

This guidance document is designed to assist you, as the applicant, to obtain peer review reports to the required standard. It contains general guidance (see below) as well as specific guidance against each section of the separate *Peer review report for new applications*. It concludes with a Frequently Asked Questions (FAQ) section and a checklist.

Please read this guidance document carefully before approaching a peer reviewer and before submitting the report with your application.

**Purpose of peer review reports**

The purpose of peer review reports is to provide the AIHW Ethics Committee with 'expert scrutiny of a project’ via an ‘*impartial* and *independent* assessment of research by others working in the same or a related field’[[3]](#footnote-4).

The AIHW Ethics Committee requires *at least one impartial and independent* peer review report to be submitted with your application.

Before approaching peer reviewers, we recommend that you familiarise yourself with the National Health and Medical Research Council’s [*Principles of Peer Review*](https://www.nhmrc.gov.au/grants-funding/peer-review/nhmrc-principles-peer-review) (NHMRC principles) and the guide on Peer Review supporting the [*Australian code for the responsible conduct of research*](https://www.nhmrc.gov.au/guidelines-publications/r39)(Code of Conduct).

**This is important**

To avoid any actual or perceived bias or conflict of interest on the part of the reviewer, it is essential that they are seen to be both *impartial* and *independent****.*** What this means in practice is that it needs to be made obvious to the Committee that the peer reviewer is sufficiently removed from the Principal Investigator and other members of the research/project team to avoid any claims of real or perceived bias or conflicts of interest. Section 4 of the peer review form is where the reviewer describes their impartiality and how they have managed any actual or perceived conflicts of interest, including bias.

The last page of the peer review form (the declaration) requires the peer reviewer to confirm that they have understood and applied the NHMRC principles and the requirements of the Code of Conduct (see hyperlinks above) in completing their report. The report will not be accepted if this Section has not been completed.

***Peer review for new applications* report form: guidance against each section**

Page one of the form contains the headings *Guidance for applicants* and *Guidance for peer reviewers.* Please familiarise yourself with both these sections before approaching peer reviewers.

NOTE:

* It is advisable to approach possible peer reviewers early in the application process.
* Applications will not be accepted if a peer review report to the required standard is not available
* If you are submitting an application for a project with existing ‘ongoing’ Committee approval which now requires an updated and current approval (a ‘refreshed’ application), then the requirements for peer review are the same.
* Peer review requirements for internal AIHW applications relating to data collections are different: please contact ethicssec@aihw.gov.au for assistance.

*Section 1: Current project details*

This applies to your new (or ‘refreshed’) application and is intended to record the details of your application as they appear in EthOS. It is your responsibility to complete this section before the form is provided to the peer reviewer. The report will not be accepted if this Section is incomplete.

*Section 2: Peer reviewer contact details*

This section simply records contact details in case the Ethics Secretariat needs to contact the peer reviewer independently. The peer reviewer is asked to complete this section, but you may do so if you wish as a form of assistance to the peer reviewer.

*Section 3: Peer reviewer expertise*

The peer reviewer completes this section of the form. Its purpose is to establish the level and type of expertise of the peer reviewer. The Committee’s expectation is that the peer reviewer will have a comparable level of expertise to that of the Principal Investigator although not necessarily in exactly the same field or (clinical) area. The peer reviewer also needs to have sufficient research experience to comment objectively and authoritatively on the research methodology (see too Section 5 below).

Please advise the peer reviewer that a Résumé or lengthy Curriculum Vitae is not required: we simply need a list of qualifications and a brief outline of relevant experience. If it is applicable to the research a brief outline of the reviewer’s clinical experience is also welcome.

*Section 4: Impartiality and independence*

As explained above, it is very important that the peer reviewer is *impartial* and *independent* so that they can provide an ***objective*** assessment of the research.

This section is very significant because it is here that the peer reviewer establishes their independence and impartiality. They do this by identifying any actual or perceived conflicts of interest in relation to either the Principal Investigator (PI) or other members of the research team. Peer reviewers are also required to explain the nature of any conflicts as well as how it has been actively managed, for example, by describing the nature of the relationship between the peer reviewer and the PI.

The NHMRC [Principles and the Code of Conduct](https://www.nhmrc.gov.au/grants-funding/peer-review/nhmrc-principles-peer-review) provide further guidance on these matters. If, however, either you or the PI have any doubts about the suitability of a peer reviewer to provide an impartial and independent report, please contact the Ethics Secretariat to discuss *before* approaching the peer reviewer (ethicssec@aihw.gov.au or 02 6249 5004).

*Section 5: Peer review report*

In this section the peer reviewer provides their *impartial* and *independent* assessment of the research. That assessment includes the research methodology, the capacity of the PI (and the research team) to complete the project in a timely manner and in accordance with current accepted standards and practice in the discipline.

The peer reviewer is also expected to explain what makes it necessary to obtain the AIHW data requested and how the outcomes of the research will benefit the Australian community, either in the sort or longer term. If the peer reviewer is aware of existing publications arising directly from the research then they may include *one or two* of those publications in the report, for example, publications in a referred journal in the discipline. It is wise to attach those publications with the peer review report (or provide a website if it is a lengthy report such as a report to government).

Please advise peer reviewers that they are not expected to assess the ethical aspects of the research. The Committee makes those judgements, taking into account the peer review report and other documents included with the application, such as the approval from the home institution Human Research Ethics Committee.

If the peer reviewer would like to include comments which the reviewer considers are relevant but are not able to be recorded elsewhere in the form, they can be included in the last part of this section.

*Section 6: Peer reviewer declaration*

In dating and signing the report, the peer reviewer is declaring that they have understood and applied the NHMRC principles of peer review and the requirements of chapter 6 and 7 of Code of Conduct (hyperlinks provided on page one above and in the peer review report form). What this means, in fact, is that the reviewer’s signature attests to their *impartiality*, *independence* and *objectivity* in preparing the report.

Please make sure that this section is completed before submitting the form with your application. The report will not be accepted if Section 6 has not been completed.

**Submitting the peer review report form**

Peer reviews reports are to be attached in EthOS at Section 10.

Please read the checklist below *before* uploading the reports.

**FREQUENTLY ASKED QUESTIONS**

When you interpret the answers to these FAQs, please remember that *the standard* for peer review reports, whatever form they take, is *always impartiality, independence and objectivity*.

1. Do I always have to use the AIHW peer review report form?
	1. Not always but mostly. For exceptions, see numbers 2-5 below.
2. Can I use an NHMRC peer review report?
	1. Yes, you can.
3. My application to NHMRC was not successful. Can I still use the peer review report?
	1. Yes, you can: please include the NHMRC peer review report and decision letter, including the score. Rebuttals to the NHMRC peer review are required where appropriate. The *agreement* of the Principal Investigator should be obtained before providing the NHMRC peer review and score.
4. I have a peer review report from a successful internal funding grant process (i.e. from my own institution). Can I use that report?
	1. Yes you can but because impartiality and independence are very important in peer review reports, it may be necessary to explain how that has been maintained with this internal report. For example, it may be that the peer reviewer at your home institution is from a different Department to that of the Principal Investigator (see too number 6 below)
5. My research is an internally funded project with a technical advisory group (reference group). Can I use their assessment of the research as a peer review report?
	1. Yes you can, but you will need to provide additional information. Specifically:
		1. the Terms of Reference for the group and details about its members;
		2. the named position of members on the Committee and
		3. the home organisation or sector which they represent.

If available, it may also be wise to submit any written reports which provide an assessment of the research by that advisory group, for example, the relevant extract from minutes of a meeting or a referred publication.

1. The peer reviewer is from the same organisation (institution) as the Principal Investigator (PI) and the research team. What do I do?
	1. It is very important to clearly establish impartiality and independence when a peer reviewer and a PI are from the same organisation. It may be necessary therefore to explain the exact nature of their professional relationship so that impartiality and independence are obvious. For example, the peer reviewer is from a different Department, from a different but related discipline, or that the PI and the peer reviewer have not worked together for some time.
	2. If the research is a collaborative one and involves more than one institution, then as far as possible, choose a peer reviewer who is not located at any of the sites where the research is being conducted.
2. My project has been assessed and approved by the Human Research Ethics Committee (HREC) at my institution. Can I use that approval as a peer review report?
	1. No, because an HREC approval is primarily concerned with the ethical aspects of the research although the scientific rigour of the research does form part of an ethical assessment. Accordingly, like other HRECs, the AIHW Ethics Committee seeks assessment of the scientific and data related aspects of the research in the form of a peer review report, not an HREC approval.
3. The peer reviewer wants to submit the form electronically and does not have an electronic signature for Section 6. What do I do?
	1. Please ask the peer reviewer to send an email to you declaring that they have met the requirements for section 6, in other words, the email attests to their impartiality and objectivity in preparing the report. Please make sure that the email is attached to the report and uploaded into EthOS.
4. The peer reviewer is not available until after the due date for the report. What do I do?
	1. In that case, discuss the timeframes with the Ethics Secretariat who *may* be able to grant an extension of time and/or discuss other options.

Please refer to the checklist below before finalising your peer review report and any attachments.

**Checklist for obtaining and submitting peer review reports**

This checklist is for your use only. It does not have to be submitted with the peer review report.

In obtaining the peer review report I have:

□ Read this guidance document and the peer review report form

□ Read the NHMRC principles of peer review and chapters 6 and 7 of the Code of Conduct (see hyperlinks on page one of this guidance document and on the peer review form itself)

□ Confirmed (with the Principal Investigator if necessary) that the peer reviewer is sufficiently impartial and objective

□ Confirmed that the peer reviewer can provide the report by the due date

□ Sent the form to the reviewer electronically with Section 1 completed

□ Provided the reviewer with the relevant research details

□ Provided the reviewer with citation details of publications if requested

□ Checked that all sections of the report have been completed

□ Confirmed that the reviewer has signed the declaration (Section 6)

□ Attached the reports (and attachments) in EthOS by the due date: saved as ‘peer review report’.

If at any stage in the process of obtaining the peer review report form, you or the peer reviewer, have any questions or points of clarification, do not hesitate to contact the Ethics Secretariat on (02) 6249 5004 or ethicssec@aihw.gov.au ***before*** completing and lodging your application in EthOS.

1. This guide draws upon the Department of Prime Minister and Cabinet document *Ethics and Integrated Data – A Practical Guide (2020)* [↑](#footnote-ref-2)
2. National Health and Medical Research Council, Australian Code for the Responsible Conduct of Research (2007), Section 6 (6.1). <http://www.nhmrc.gov.au/guidelines-publications/r39> [↑](#footnote-ref-3)
3. National Health and Medical Research Council, Australian Code for the Responsible Conduct of Research (2007), Section 6 (6.1). <http://www.nhmrc.gov.au/guidelines-publications/r39> [↑](#footnote-ref-4)