



Navigating ethics approval processes if you are not at a university

By Tricia Cerone and Philippa Smales
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It is commonly known that academic research often goes through an ethics review process, but did you know that *all* research involving human participants should undergo ethical review, according to National Health and Medical Research Council (NHMRC) guidelines?

Whilst independent practitioners, consultants, and NGO workers (referred to hereafter as non-university affiliated researchers or NARs) are still expected to follow the NHMRC guidelines when conducting research involving human participants, the pathway to obtaining ethics approval, and what level of approval is required, are not well known.

The need for outlining this process for NARs was identified by the Research for Development Impact (RDI) Network when a member shared that some of their staff were uncertain of the policies surrounding ethics review and approvals. They were thinking about publishing their research with an Australian journal, and were confused about when ethics approval is required and how it can be obtained. So the RDI Network has put together some guidance: [*Ethics requirements for publication of research: a guide for Australian researchers, NGOs, and independent practitioners*](#).

Making ethics application processes more accessible for NARs should lead to more quality research and evidence shared in various forums (such as academic journals) to reach a wider audience. Fostering these shared learnings and experiences would benefit not only development practice, but academic learning as well.

As mentioned, the NHMRC states that all human-related research should undergo ethics review prior to the commencement of any research. The [*National statement on ethical conduct in human research 2007*](#) explicitly applies to research, and a separate document - [*Ethical considerations in quality assurance and evaluation activities*](#) - addresses evaluation. Evaluations can be considered as a type of applied research, and according to the NHMRC some evaluations may require ethics review.

For research which is deemed to have negligible or low risks (defined below), organisations can use internal review processes. However, all research which is deemed to have more than low levels of associated risk and/or which involves certain participants, should undergo a full review by an NHMRC-registered and certified Human Research Ethics Committee (HREC). While private HRECs do exist, such committees are most commonly affiliated with universities or medical centres.

The NHMRC states that a researcher can contact any HREC to obtain ethics approval; however, not all HRECs accept external applications. Unfortunately, whether or not they accept external applications is not easily found in many instances. Of the 31 university HRECs mapped as part of this research, only six accepted non-affiliated applications according to their websites.

Specific application processes vary depending on the individual HREC and the level of intended risk. According to the NHMRC guidelines, the three levels of risk are:

- Negligible risk – “no foreseeable risk of harm or discomfort; and any foreseeable risk is no more than inconvenience” ([National statement](#), paragraph 2.1.7).
- Low-risk – “the only foreseeable risk is one of discomfort” ([National statement](#), paragraph 2.1.6).
 - As per paragraph 5.1.6(b), research which involves certain participants (such as Indigenous people or people with a cognitive impairment) is always deemed to be high risk, even if the only foreseeable risk is one of discomfort.
- “Research that involves more than low-risk” – sometimes known as high-risk research ([National statement](#), paragraph 5.1.6).

‘More than low-risk’ applications have a rigorous application process and processing times can vary anywhere between 20 days and several months depending on the research subject matter.

HRECs charge fees to process non-university affiliated applications, and these can range anywhere from A\$1,650 – \$3,300, depending on the level of intended risk involved. Fees for ethics applications processed by non-university, private HRECs can range anywhere from A\$3,000 – \$6,000. While these fees are unlikely to inhibit a well-funded large-scale project, unfunded projects and evaluations are likely to be stopped in their tracks. For small- to medium-sized NGOs, fitting this expense within their budgets could prove to be difficult, if not impossible.

Considering the above, the practicality of these processes needs to be questioned. Given the

amount of time and money required to follow official avenues for obtaining 'more than low-risk' ethics approval, how likely are non-university affiliated researchers to seek ethics approval from an HREC? This affects the opportunity for this work to be disseminated widely through publication in academic journals and publications, and therefore limits knowledge transfer, shared learnings, and opportunities for collaboration.

The RDI Network works in partnership with the Australian Council for International Development. For more information, please visit the RDI Network [website](#). Read [part two](#) of this post, which looks at how ethics approval processes play out in practice and can affect international development research.

About the author/s

Tricia Cerone

Tricia Cerone was an intern for the RDI Network.

Philippa Smales

Dr Philippa Smales is the Network and Partnerships Manager for the Research for Development Impact (RDI) Network.

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