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## Why should ethics approval be required prior to publication of health promotion research?

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### Abstract

*Issue Addressed:* Most academic journals that publish studies involving human participants require evidence that the research has been approved by a human research ethics committee (HREC). Yet journals continue to receive submissions from authors who have failed to obtain such approval. In this paper, we provide an ethical justification of why journals should not, in general, publish articles with no ethics approval, with particular attention to the health promotion context.

*Methods:* Using theoretical bioethical reasoning and drawing on a case study; we first rebut some potential criticisms of the need for research ethics approval. We then outline four positive claims to justify a presumption that research should, in most instances, be published only if it has been undertaken with HREC approval.

*Results:* We present four justifications for requiring ethics approval prior to publication: (i) that HREC approval adds legitimacy to the research; (ii) that the process of obtaining HREC approval can improve the quality of an intervention being investigated; (iii) that obtaining HREC approval can help mitigate harm; and (iv) that obtaining HREC approval demonstrates respect for persons.

*Conclusion:* This paper provides a systematic and comprehensive assessment of why research ethics approval should generally be obtained prior to publishing in the health promotion context.

*So what?* Journals such as the *HPJA* have recently begun to require research ethics approval for publishing research. Health promotion researchers will be interested in learning the ethical justification for this change.

### Keywords

Publication ethics, research, health promotion, ethics approval

### Running title:

Ethics approval and research publication

## Introduction

There is wide agreement among researchers that research ethics approval processes can be bureaucratic, time-consuming and frustrating.<sup>1,2</sup> Indeed, in recent years there has been somewhat of a “backlash” against the “apparent overregulation of research”, including health-related research, which is seen to be “anomalous when compared to the way we regulate other types of risk” such as dangerous sporting activities and far-reaching government interventions.<sup>3 p45</sup> This is particularly the case when the research being reviewed is considered to be of ‘low risk’ and the time spent obtaining ethics approval seems to be out of proportion to the potential harm to research participants. Nevertheless, obtaining research ethics approval prior to undertaking research serves an important purpose, even in the context of low-risk research. In this paper, we will unpack the requirement for ethics approval as a precursor to publication of research. We illustrate its grounding in good research practice and argue for the presumption that research should, in general, not be published if approval from a human research ethics committee (HREC) has not been obtained.

Most academic journals now require that any reports of research involving human participants include confirmation that ethics approval has been obtained prior to conducting the research. For example, this journal requires that: “Manuscripts which report on research involving human participants require confirmation of approval by an appropriate human research ethics committee. Confirmation of HREC approval is required in the manuscript body.”<sup>4</sup> This is supported by publishers<sup>5</sup> and is enshrined in the Code of Practice of the Committee on Publication Ethics (COPE) which states that: “Editors should seek assurances that all research has been approved by an appropriate body (e.g. research ethics committee, institutional review board) where one exists.”<sup>6</sup>

Establishing this fact is usually straightforward. However there are occasions on which journals receive submissions reporting on research that has not been granted HREC approval. This creates a dilemma for editors: should the manuscript be rejected outright, or should potentially important ideas be disseminated even if ethical approval has not been obtained?

## Case study

To illustrate how this kind of issue can arise, consider the following ‘editorial conundrum’, which is based on a real case:

A paper is submitted to a reputable journal that details a new health promotion intervention in a community that has experienced disadvantage. The work looks to be important. It has used innovative methods and has produced promising results. The community was collectively engaged with the project from the beginning. Individuals from the community who participated in the intervention did so only after giving consent. No individual looks to have been harmed; in fact quite the opposite. In the submitted manuscript, the authors of the paper did not include details of research ethics approval. A member of the journal’s editorial team contacted them to request these details. The corresponding author replied, stating that their project didn’t have research ethics approval. They didn’t think it was “the type of thing that needed it”. “Does this mean you won’t publish it now?” they ask...

Cases such as this one are not uncommon. Indeed, the Committee on Publication Ethics (COPE) has managed several similar cases, and continues to provide advice to journal editors on this kind of problem.<sup>7</sup>

Two main issues arise in this scenario, and we will consider each of these in turn. First, is what has been done here ‘research’? If an intervention is not considered as ‘research’ then obtaining research ethics approval may not have been necessary. Second, if the study is ‘research’ but ethics approval has not been obtained, what should the journal editor do?

### Health Promotion ‘Research’

Given that research ethics approval is designed to ensure that a particular *research* project is likely to meet relevant ethical standards, it is necessary for us to briefly consider how ‘research’ might be defined. In Australia, the *National Statement on Ethical Conduct in Human Research (National Statement)* from the National Health and Medical Research Council (NHMRC) provides a useful starting point for this consideration. It determines that research incorporates “at least investigation undertaken to *gain knowledge and understanding* or to train researchers.”<sup>8 p6; emphasis added</sup> That is, research is something that aims to obtain information that was not previously known. For health promotion, this can simply be taken to be obtaining knowledge or understanding that pertains to improving the health of a population. The *National Statement* also posits that to be ‘human research’ (which the *Statement* pertains to), the activity also has to be conducted “*with or about people, or their data or tissue*”, although this is to be “understood broadly”.<sup>8 p7; emphasis added</sup> This definition therefore includes work that involves only observing people, or studies that implement surveys.

These two factors, namely whether an activity will generate new knowledge or understanding and whether it involves humans, are triggers that an activity might be considered human research and that research ethics review may be required. These two elements of the definition of research also help to distinguish research from other activities, such as audits, which are unlikely to meet the criteria for research as they involve measuring a practice or activity against a known standard. In a health promotion context, an audit might take the form of determining whether a particular set of quality indicators has been met in a particular instance. For example, an organisation tasked with capacity building in health promotion might audit the extent to which it has assessed the strength of a coalition, assessed opportunities to promote learning, assessed if their program is likely to be sustained, and so on.<sup>9</sup> Audit is therefore expected to determine whether a particular standard is being met, not to generate new knowledge to inform a standard.

Another category of activity that generates knowledge and involves humans, but is not usually considered to be research, is the category of ‘quality improvement’ (or ‘quality assurance’) activities. These are activities “where the primary purpose is to monitor or improve the quality of service” to improve local practices rather than producing generalisable knowledge.<sup>10 p2</sup> They are similar to audits but they involve intervention as well as measurement, although we note that the definitions of quality assurance often encompasses audit. For example, an organisation that is finding it difficult to improve chronic disease management in a particular Indigenous population might test the effects of developing a better health information system.<sup>11</sup> While some have questioned the robustness of the distinction between research and quality assurance,<sup>12, 13</sup> it is generally argued that if there is nothing unique about the quality improvement intervention (e.g. it uses an established health information system), then the argument could be made that this does not constitute ‘research’ and that human ethics approval is not required, even though human participants are involved.

Both audits and quality assurance activities do, however, sometimes generate new knowledge that is generalisable and may be of interest to people outside the organisation in which such activities are conducted. They can also give rise to ethical considerations.<sup>10</sup> One method for such dissemination is via publication in an academic journal. If ethics approval has not been obtained in these instances, journal editors may face a publication ethics dilemma, and it is an open question as to whether journals should agree to publish reports of audits and quality improvement activities that have not been approved by ethics committees.<sup>14</sup> On the one hand, it can be argued that the intention to publish is one criterion that distinguishes research from quality improvement and that, therefore, ethics approval should be obtained by those conducting the quality improvement activity. But this question may not always occur to those who undertake quality improvement. On the other hand, as

we note above, quality assurance activities can unexpectedly generate generalisable findings, and this information should not necessarily be withheld from publication simply because the utility of the results has not been foreseen.

Further, if an ethics committee has declined to review an intervention that did not appear to be research, it seems unreasonable to penalise authors for not obtaining an approval that they were unable to secure – even if it does raise new knowledge. Difficulties can however arise if a study team merely *assumes* that a quality improvement activity does not need ethics approval, rather than seeking to confirm this assumption with a HREC or other external body. If an editor then disagrees over whether ethics approval should have been sought, a publication ethics issue can arise.

Another perspective is that the need for research ethics review should not rely on categorisation of an activity, such as ‘research’ or ‘audit’, but rather be determined on a case-by-case basis according to whether a particular activity is likely to give rise to ethical issues.<sup>15</sup> It is our view that editors should apply a similar “case-by-case” method in deciding whether to publish quality improvement activities that have not been approved by an ethics committee. Publication should *prima facie* only be considered if authors can explain aspects such as why there was no HREC approval and why publication was not intended or expected at the time the quality improvement activity was designed. They should also be able to demonstrate that they paid appropriate attention to ethical considerations during the design of the activity and as they arose while carrying it out.

A more difficult situation for editors arises when they are presented with a report of an activity that is clearly ‘research’ (and always has been defined as such) but has not been approved by an ethics committee. In most cases, this will be because the research fits into the categories of research defined in the *National Statement* as ‘low risk’ or ‘negligible risk’.<sup>8; 2.1.6</sup> These kinds of research may not necessarily have to receive HREC approval; although projects with low or negligible risk will still need to meet the standards set out in the *National Statement*, and low risk research may also still require a form of ethics review.<sup>8; 5.1.18 to 5.1.21</sup> To this end, as a minimum requirement, researchers are expected to consider, and seek advice as to whether ethical approval is required. This could involve, for example, contacting a research ethics committee or seeking advice from a research governance office. A researcher or investigator should not merely assume that their project will end up as quality assurance, audit or research.

Reaching an absolute position on the need for research ethics approval can never be absolutely ensured, particularly with hindsight, but taking steps like this should help ensure that journal editors receive submitted papers that have actively considered the question of research ethics approval. This is a particularly important consideration in the health promotion context because much health promotion research —such as advertising campaigns, education programs or capacity building activities—would fit into the category of low or negligible risk research.

We therefore contend that, notwithstanding the fact that much health promotion research is low risk, as a general presumption, journal editors should not publish research of any kind unless there is either evidence of ethics approval or (for certain kinds of low risk activity) evidence that the investigators have taken steps to identify and mitigate any ethical issues in their investigation as per NHMRC requirements. To further justify this view, we will now outline and critique some claims that might be made by those who think that ethics approval should *not* be a condition of publication of low- or negligible risk research. We will then provide four arguments to support our view that journal editors should generally decline to publish research of any kind that has not received ethics approval.

### **Claims that ethics approval should not be a precondition of publication**

While ethics approval has been seen as necessary for public health—including health promotion research—at least since the Declaration of Helsinki in 1964, ethics review procedures have only become rigorous in recent years as a result of, for example, privacy and human rights legislation internationally. This is particularly true for low risk research, which has only recently become a focus of ethical concern and analysis.<sup>2</sup> Scholars active in health promotion research might, therefore, question why they are now being required to engage in extra bureaucratic processes to do simply what they have been doing all along, without ethics oversight. Our response to this hypothetical question is straightforward: moral standards change over time—the mere fact that something was once considered ethically appropriate does not mean that it is always ethically appropriate. The one-time acceptance of slavery and excluding women from voting are obvious illustrations of this point, but moral standards change in more subtle ways too. For example, while it was once considered acceptable to be quite paternalistic, and even coercive, in health promotion activities, there is now a moral expectation that liberty and empowerment be taken seriously in considering any intervention.<sup>16</sup> Similarly, while doctors were once considered capable of judging the ethics of their own research, the dominant view is now that ethics committees—even with their limitations in expertise and resources—are, as disinterested collectives, both more objective and more capable of making these assessments.<sup>1, 3</sup>

Health promotion investigators may also raise the point that we have already made above; namely that most of what they do is low risk and that obtaining ethical approval will either add unnecessary time or costs to an intervention without being justified by a risk-benefit calculation. In response, we claim that just because research is low risk does not make it ‘no risk. In Australia the *National Statement* stipulates certain procedures that need to be followed, including the need to establish whether the research is in fact low or negligible risk. Additionally, the risk classification of a particular intervention does not necessarily indicate whether it will raise ethical issues. Health promotion activities are not always benign endeavours, and ethical issues can arise.<sup>17</sup> Further, even small risks can be significant when large populations are involved; when those taking the risks are not given the opportunity to give consent before participation and to withdraw at will; and when the people who are exposed to risk do not benefit directly (or as much as others) from exposure<sup>3</sup>—all of which are features of much health promotion research. Ultimately, all authors should be able to demonstrate to a journal editor how they have considered and addressed the ethical issues in their activities; including seeking advice as to whether ethical approval was required and managing any ethical issues that may arise in the project—whether or not it has ethical approval.

A third, related, objection to obtaining ethics approval is that health promotion timelines and budgets are tight, and that the added bureaucratic burden will get in the way of important research and dissuade researchers from publishing.<sup>1, 2</sup> There is no doubt that ethics approval processes can be onerous, particularly if HRECs are not attuned to the specifics of low risk health promotion research.<sup>2</sup> However, this is an argument for more streamlined and consistent HREC processes (and, importantly, for greater involvement of health promotion researchers on these committees) rather than an argument against HREC review itself.

A fourth objection, which we believe is the strongest, is that preventing publication in the absence of HREC approval may be doing little more than “keep(ing) the journals’ hands clean.”<sup>18 p528</sup> After all, preventing publication won’t actually stop the research (which has already been conducted) and could also be doing a disservice to those who have participated in it. However we do not think that this argument holds in the modern research context where nobody (at least in well-resourced settings with robust research oversight systems) can claim not to have known of the need to consider ethics approval, or had the opportunity to do so. Preventing publication will help dissuade such

research from being done in the future. If an author knows she or he is unlikely to have their work published in a reputable journal without appropriate ethical oversight, they are more likely to take appropriate action with regards to ethics approval. Publication without ethics approval might also arguably perpetuate problematic exceptionalist claims about ethics approval in health promotion research being non-essential, as well as ‘sending a message’ that research can still be disseminated even in the absence of ethics approval.

The issue is more complicated if the research has been conducted in a setting in which research oversight is weak or non-existent. It may not always be clear whether ethics approval that has been obtained is appropriate (for example when an ethics committee in one country has given approval for research in another). Editors would need to exercise discretion in this instance, bearing in mind, as van Tellingen and Simkhada argue, that insisting on local ethics approval could help to create an incentive for the “next generation of researchers to go through the extra hoop” of applying for ethics approval in developing countries.<sup>19</sup> pp429-430

### **Claims in favour of obtaining research ethics approval prior to publication**

Having refuted what we believe to be the major arguments against preventing publication on the basis of failure to obtain ethics approval, we now set out four positive claims to support our position that studies should not, in general, be published unless authors can clearly demonstrate that the activity has undergone appropriate ethical oversight prior to it taking place. While several of these points speak to a justification for obtaining research ethics approval as a good in and of itself, they are also arguments for not publishing research unless it has been approved by a HREC.

Our first claim in favour of HREC approval of health promotion research intended for publication is that obtaining research ethics approval can enhance the legitimacy of the process of health promotion investigations. This is not to say that such processes are currently spurious, but that the oversight of an ethics committee, or the undertaking of processes to ensure compliance with the *National Statement* (as required for low risk research) will help ensure that research funders, policymakers and other users of health promotion research give this research the same status that is granted to other kinds of health research. In this regard we agree with Wilson and Hunter that one of the key factors that distinguishes research from other risky activities—and that justifies relatively stringent regulation—is that research relies heavily on public trust, both for its funding and for public participation.<sup>3</sup>

A second, related point is that research ethics approval processes can help to ensure that a research project is well-designed – a foundation for ethical research.<sup>8</sup> p10 para 1.1 Despite the name ‘ethics’ review, the HREC approvals process also involves oversight of the methodological and other scientific aspects of a proposed project. This can occur through either expert peer review as a part of the HREC application process, or in receiving comments from HREC members. While there are ongoing tensions in the research ethics community regarding the balance between scientific and ethical review of research by HRECs,<sup>20</sup> the idea that ‘unscientific’ or unnecessary research is unethical research is compelling.<sup>21</sup> It is our contention that, rather than being an added burden, the opportunity to obtain further peer review on a project can be seen as an additional opportunity to ensure an intervention is needed and optimised prior to it being introduced to a population.

Third, in addition to improving the scientific aspects of research, research ethics approval can assist investigators to identify any aspects of their planned activity that may give rise to risk. As Wilson and Hunter note in their argument in favour of research ethics committees: “researchers will often be in a poor position to assess the ethical implications of their own research, and given the stringent nature of their duties toward research participants, and the likelihood of research ethics committees making

both better and more democratically legitimate decisions than individual researchers, this gives a reason to support this form of regulation of research.”<sup>3 p51</sup> Importantly, a health promotion intervention or research process could be risky in ways that may not be fully realised or appreciated by researchers, and the structure of the ethics approvals process, together with the collective experience of HREC members, could help to draw these out. Health promotion scholars and ethicists have, for example, grappled with the surprisingly complex issue of whether it is ethical to conduct research in which financial incentives are used to promote desired health goals.<sup>22</sup> Others have conducted in-depth explorations of the ethical dilemmas raised by involving community health workers in health promotion research,<sup>23</sup> and of participatory action research for health promotion more generally.<sup>24</sup> Even seemingly straightforward health promotion research techniques such as interviews and focus groups can be harmful, as can be seemingly innocuous health promotion interventions such as advertising campaigns. HRECs are well placed to help detect and mitigate these sorts of problems.

Our fourth claim is grounded in the idea that, irrespective of whether people are put at risk, investigators who seek or obtain ethics approval are showing due respect for persons. Investigating and then potentially obtaining ethics approval indicates that potential problems with the activity, potential risks to participants and the desire to disseminate its findings are all being taken seriously. Without ethics approval, or at least a demonstration that questions regarding ethical conduct of the activity have been addressed, health promotion investigators are failing to accord appropriate respect to those in whom an intervention or other health promotion activity is to be undertaken. This is a ‘good’ of ethics approval in and of itself, in that it does not require empirical evidence of harm mitigation in order to be justified.

### **Returning to the journal editor’s conundrum**

In the case study described above, we asked what the editor should do if the activity was clearly ‘research’ and was being sought to be published without HREC review or authorisation. If the claims we have set out in this paper were to be followed strictly, it would likely suggest that publishing the paper is not justified. We would argue that the editors’ default position should be not to publish the article unless a compelling case can be made for publication.

In this case, one consideration might be the relative disadvantage of the population - and therefore the extra emphasis on placing information in the public domain that could assist in changing that in the future. Another aspect might be the apparent ethical soundness of what was undertaken, and the extensive community engagement that the authors report as having occurred. An editor could ask to view documentation of this. Moreover, the study itself did not seem to have any scientific problems. Mindful of this being effectively seen as equivalent to retrospective ethics review (which we go on to reject below) there should be transparency about the process. If the editor decides to publish a paper without HREC approval when such approval might reasonably be considered as necessary, its publication should be accompanied by an editorial or expert commentary highlighting the lack of ethics approval and explaining how the journal reached its decision. Some journals are actively engaging in this practice.<sup>18</sup> This will both help facilitate the information to engender change, and ensure that more members of similar disadvantaged populations are not then recruited into a redundant project.

This approach is consistent with the view that journal editors are themselves moral agents, who are expected to “consider the moral aspects of any study submitted.”<sup>15</sup> This is not to make journal editors solely responsible for these decisions, but to ensure that they are engaging in the ethical aspects of activities in health promotion rather than accepting at face value any previous oversight by a HREC. This is the approach taken by medical journals such as the BMJ - to consider a submission

and follow-up any ethical concerns, whether they deem the paper research or audit, with an author. It is also supported by the International Committee of Medical Journal Editors' *Recommendations*,<sup>25</sup> and the COPE Code, which states that "editors should recognise that such approval does not guarantee that the research is ethical."<sup>6;10.2</sup>

One final consideration is the timing of ethical oversight activities. It could be argued that journal editors should agree to publish research subject to the researchers obtaining retrospective ethics approval. There are cases in the public domain in which researchers have sought, or even obtained, retrospective ethics review<sup>7</sup> and some journals have requested this kind of approval in the past.<sup>26</sup> However while a HREC may be able to say in hindsight that no ethical issues arose, this is contrary to the purpose of ethics review; namely to protect human participants in research. For this reason, groups such as the Committee on Publication Ethics reject the use of retrospective ethics approval to provide a gateway to publication, and we support this position.

### Conclusion

There is relative consensus in the literature that journal editors have their own set of responsibilities pertaining to the investigations they publish, separate to those of research ethics committees.<sup>15</sup> Thus, while editors should take into account a decision of an ethics committee or its Chair, they also have discretion - if not an obligation - to come to their own determination about the ethical issues a particular investigation gives rise to. We have provided four claims in support of the idea that journal editors should publish health promotion research only if ethics approval has been obtained, or a justification has been given for not obtaining approval. Of course, while there are well-established ethical principles to inform these deliberations, each decision regarding publication will also require considering and applying those principles in context. Journal editors will need to continue to use their judgment and, where necessary, seek guidance from bodies such as the Committee on Publication Ethics. Notwithstanding these qualifications, we believe that the onus should be on authors to explain why they have *not* sought and/or obtained ethics approval and the default position should be that such research is not published even if this means losing opportunities to disseminate information.

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