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# *HREC Members' Personal Values Influence Decision Making in Contentious Cases*

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**ABSTRACT.** This article identifies 14 contentious issues faced by Human Research Ethics Committees (HRECs). The authors argue that HREC members will respond variably to these issues based on their own fundamental values and worldview. In particular, we propose that personal interpretations of current ethics regulations and HREC members' attitudes to consequentialism, Kantianism, and utilitarianism in some cases affect their responses to contentious research issues. We seek to promote understanding of how personal and professional backgrounds of HREC reviewers influence their approaches to value-laden issues embedded in ethics applications. Taking the form of a literature review, our contribution highlights the need for further exploration of how HREC members make decisions, and what factors influence the outcomes of ethics applications.

**KEYWORDS.** Ethics, review, HREC, research, values

## I. INTRODUCTION: BELIEFS AND ATTITUDES

In the course of assessing an application for ethical approval, Human Research Ethics Committee (HREC) members intuitively use a range of decision-making processes that inform their decision as to whether the research should proceed. This literature review suggests that, when considering research projects embedded with moral concerns or issues that raise ethical conflict, HREC members are likely to defer to their own beliefs and attitudes. Ultimately, this is a type of bias inherent to the process of research assessment by HRECs.

Much of the literature that informs this study conceptualizes beliefs and attitudes not as discrete identities, but as an integrated whole known as 'worldview' (Gillam, Guillemin, Bolitho and Rosenthal 2009; Handal

*et al.* 2015). In this context, worldview denotes an integration of assumptions, beliefs, values, and attitudes held by an individual or community about themselves and the world in which they operate (Funk 2001; Lankshear and Knobel 2004; Creswell 2013). English (1984) suggests that a worldview is our psychological orientation, and that our worldview determines how we think, behave, and make decisions, and that an understanding of worldview promotes deeper understanding of decision making (Ibrahim and Schroeder 1990; Creswell 2013).

In their study “Investigative Human Research Ethics in Practice,” Guillemin, Gillam, Rosenthal and Bolitho (2008) investigated HREC reviewers’ ethical frameworks, and observed that

[...] in relation to their personal values, many HREC members spoke about being guided by ‘intuition’ or ‘intuitive feelings’. Some pointed out that values they drew on in this process were the ones they had developed during their life, rather than those set out in the National Statement, or any other formal code or set of guidelines (2008, 19).

Previous qualitative studies raise a number of differential variables as having a possible effect on HREC members’ decision-making (Hey and Chalmers 2010; Sarson-Lawrence *et al.* 2004). These factors include perceptions of self-competence (Guillemin, Gillam, Rosenthal and Bolitho 2008), and personal/professional background (Greenwood, Holmes and Bidewell 2001; Wolff-Michael 2005; Williamson, Riggs, Bandyopadhyay and Daly 2008). Other variables not considered here are also likely to be factors, including gender, age, culture, sexuality, and so on. These have been identified in previous studies as having possible effects on HREC members’ decision making (Greenwood, Holmes and Bidewell 2001; Sarson-Lawrence *et al.* 2004; Wolff-Michael 2005; Guillemin, Gillam, Rosenthal and Bolitho 2008; Williamson, Riggs, Bandyopadhyay and Daly 2008; Hey and Chalmers 2010).

The purpose of this literature review is to inform a future study to further clarify how HREC members’ beliefs affect their decision-making.

The findings made by this review and the subsequent study aim to inform HREC professional development and policy in Australia. Over 300 Australian HRECs are being surveyed in order to explore members' perceptions of various issues associated with the ethics review process. Our intention is to determine the interrelationship of the various factors and their relative strengths in swaying HREC members' decisions

### *Literature Review*

This literature review will explore how fourteen contested items raise the possibility of moral bias as inherent to the HREC approval process. Handal *et al.* (2015) suggest a number of contested items about which there is considerable debate and ethical conflict. These suggested items were explored in an earlier review and were, for the purposes of this study, further semantically reduced to fourteen categories using thematic analysis. The present review presents evidence that some HREC members believe that:

- i. Qualitative and quantitative methods in a research project are inherently incompatible.
- ii. The validity of quantitative research is easier to establish than the validity of qualitative research.
- iii. Projects that do not involve data generation cannot be considered research.
- iv. HRECs can judge the appropriateness of research designs and methodologies.
- v. Incentives for participation in surveys and interviews generally compromise research integrity.
- vi. Research that limits disclosure, intends deception, or actively conceals is morally unjustifiable.
- vii. Consent waivers for participants with intellectual disability can be justifiable.
- viii. Participants, rather than researchers, are entirely responsible for determining the extent of risk involved in participation.
- ix. Risk to researchers is as important as risk to the participants in a research project.

- x. The social benefit of a research project should be weighed against the potential risk to participants.
- xi. The use of placebos in research is unacceptable.
- xii. Research that aims to expose illegal activities is unjustifiable.
- xiii. The benefits of research generally outweigh participants' privacy and confidentiality rights.
- xiv. Allegations of research misconduct should be processed independently of the organization in which the allegation arose.

## II. OPEN QUESTIONS AROUND HREC BELIEFS

A careful analysis of the National Health and Medical Research Council's National Statement on Ethical Conduct in Human Research (NHMRC 2007), which regulates the function of HRECs in Australia, combined with some elementary fieldwork conducted with HREC members, has pinpointed a number of key ethical conflicts that stem from differences in committee members' values. Evidence has been taken from a number of fields involved in human research, which the National Statement describes as including medical fields, observational research, qualitative research involving questionnaires, surveys, and focus groups, and any research involving the publication of participant data (NHMRC 2007, 7).

### *Are Qualitative and Quantitative Methods Inherently Incompatible?*

To date, there has been limited research on HREC members' views of the use of both qualitative and quantitative methods (Mooney-Somers and Olsen 2016). However, there is some indication that some committee members are of the opinion that qualitative and quantitative research methods are inherently incompatible. This may negatively bias HREC members against research proposals that use a mixed-methods approach. In the late twentieth century, the research sector was riven by conflict between qualitative and quantitative research (Wiggins 2011). This was once labelled the 'paradigm wars', but this sector review appears to indicate

that the perception that quantitative and qualitative methods are in binary opposition would now appear to be outmoded, or at least evolved to include pragmatism as an additional complicating factor. Pragmatism, a research paradigm driven by the research question, appears to have become increasingly popular in the research sector (Hall 2013; Johnson *et al.* 2016). Despite this important shift, there is still the possibility that HREC members remain trapped in the mentality of the earlier 'paradigm wars', and this itself warrants further research to identify areas of continuity and change. The *Journal of Mixed Methods Research*, which commenced in 2007, is yet to publish research focusing on the possible biases inherent in HREC members' views about the respective validities of qualitative, quantitative, and pragmatism (Hesse-Biber and Johnson 2013). Mooney-Somers and Olsen (2016) provide guidance as to how to improve HRECs' consideration of non-quantitative research proposals, but even the need to provide such guidance may suggest that the sub-textual tension between different research paradigms is ongoing.

*Is the Validity of Quantitative Research Easier to Establish Than That of Qualitative Research?*

Debate between HREC members regarding optimal research-methodology often centres on whether a quantitative or qualitative method is more desirable. Interestingly, the vast majority of research on this focuses on the need to step away from these comparisons, and appreciate qualitative research as a paradigm. The National Statement (NHMRC 2007) reflects this by devoting a chapter to the benefits of methods of data collection and analysis consistent with qualitative research. This contradicts arguments that suggest that qualitative research is ambiguous in its inability to provide numerical data, as it describes in detail how interviewing and observing focus groups can provide valuable data to support findings (Davies and Dodd 2002, 4). The National Statement also refers to the need for rigour in qualitative research, and the ability to replicate a study

with a different research sample or wider population (Thomas and Magilvy 2011). The National Statement discounts the need to apply the quantitative concepts of validity and reliability to qualitative research, but to instead demonstrate rigor by assessing the “[...] criteria of quality and credibility of data collection and analysis” (?????). A variety of academics have also described the need to justify the trustworthiness of qualitative research (Davies and Dodd 2002). Despite this, there remain discrepancies in HRECs suggesting there remains ongoing conflict between members as to the trustworthiness of qualitative research. The subtext here is that qualitative research is still something that needs defending, and that the paradigm wars are therefore not yet fully over.

Much research has sought to determine HREC members’ opinions about the trustworthiness of qualitative research. Daly, Bandyopadhyay, Riggs and Williamson (2008) found that HREC members who have little experience with qualitative research find it more difficult to assess. Given that HREC members come from a broad range of discipline backgrounds, often outside of research-based practice, it would be fair to assume, as do Williamson, Riggs, Bandyopadhyay and Daly that these members may have “[...] difficulty in seeing that a well-designed but complex study does indeed meet the demands of both good ethics and good research design” (2008, 45). Similar views are expressed by Richardson and McMullan (2007). In his own experience, Wolff-Michael (2005) also found that many HREC members had themselves never conducted qualitative research, nor research involving humans. Greenwood, Holmes and Bidewell (2001) expressed a similar view with the observation that Institutional Ethics Committees usually include members with medical expertise, who are more adept at quantitative research, and that the opinion of these members is often rated more highly than those expressed by, for example, academics with religious research orientations, or those with backgrounds in the humanities. To avoid this bias, Daly *et al.* (2008) suggest that committee members with limited knowledge aim to assess such proposals on the basis of research merit, and with an



understanding of the specific features of qualitative research. With many HREC members possessing beliefs and attitudes attuned to their areas of expertise, it is likely that the predominance of expertise and experience of members in quantitative research may negatively predispose them towards qualitative research proposals.

*Can Projects That Do Not Involve Data Generation be Considered Research?*

The National Statement (2007) highlights the importance of principled collection and manipulation of data using a wide range of research methods. The scholarly literature on research methodology frequently emphasises the importance of data, but there appears to be limited exploration of research that does not result in the creation of new data. Research outputs that do not include the creation of data can include non-empirical research such as a visual arts exhibition item, a musical competition, a written treatise, or a creative literary work. However, in areas such as educational research, there appears to be a general disinterest in data and, as Vanlommel, Vanhoof and van Petegem (2016) suggest, teachers frequently disregard educational research, as research findings cannot be easily translated into practice. If these views were more widely known to HREC members, they may assess the ethical validity of educational research in a different way to that of other research. Moreover, it is anticipated that the professional backgrounds of HREC members could have an important impact on their reception of non-data-driven applications, a view confirmed by de Smit *et al.* (2016).

*Can HRECs Judge the Appropriateness of Research Designs and Methodologies?*

Questioning of the HREC's faculty to qualify on research designs and methodologies seems to stem from various sources. Research by itself is a specialised human activity confronting extant knowledge in order to break new ground. Such a subversive nature when challenging current

understanding can be threatening because puts in doubt not only the object of the research but the protocols supporting it (Bledsoe *et al.* 2007). Research opens new frontiers of knowledge requiring broad and sometimes unconventional methodologies that can originate tensions between the experts and those called to assess their proposals. The unpredictability of working on pioneer territories makes it difficult to anticipate the product of the research, significantly restricting creativity and the versatility that should necessarily accompany the deployment of the proposed methodology. Such conflicts are certainly exacerbated by the strong ‘criticism culture’ embedded in academic peer-review processes that is mostly manifested between the assessors and the one who is being assessed. While the former invoke compliance the latter claims flexibility. Caught between such caveats, the question emerges: to what extent can HRECs judge the appropriateness of research design and methodologies without affecting the core of a proposal and at the same time safekeeping norms and regulations?

In terms of research competence, the Australian National Statement asserts that research should be “[...] conducted or supervised by persons or teams with experience, qualifications and competence that are appropriate for the research” (NHMRC 2007, 11). Likewise, the National Statement entitles HRECs to examine whether the research proposal is “[...] designed or developed using methods appropriate for achieving the aims of the proposal” (2007, 11), an objective that can be translated in a review question as “Why are the methods appropriate to achieve the aims of the proposal?” (UNSW Human Research Ethics 2014, 5). Posing such an ambiguity certainly opens the door to open interpretation and controversy given the academic complexity between research objectives and methodologies. Mooney-Somers and Olsen, for instance, argue that “[...] researchers do not need to use an extant methodology but simply present an underlying logic for their actions, a coherent justification that ties the research aims/questions to the methodology and the methods” (2016, 7).

The National Statement (2007) also states that a HREC's role is to assess each research design from the point of view of minimising harm, and that, after the approval of the given research, researchers are required "[...] in their research design [...] to deal adequately with any harms that occur" (2007, 8). However, harm and danger are subjective notions that are culturally and individually dependent. Anthropologist Martha Macintyre, for example, records her own experience: "When I pointed out that my own research entailed living in a village, in an unlockable house, where people had constant access to my personal belongings and me, the response from one member of the committee was that I had 'placed myself in danger'" (2014, 382). Macintyre also argues that negative HREC responses, which are "frequently bizarre," relate to the individual vocational incentive of 'saving face': "If they haven't asked for some change or for further clarification, they have not 'done their job'" (2014, 382). In such instances where there is insufficient HREC expertise within a given subject matter, there may be an immoral imbalance of power: HREC members with expertise in one subject specialty assert their concerns over a research design that is typical for another particular subject specialty. Haggerty (2004) labelled this increasing tendency 'ethics creep'. Bledsoe *et al.* (2007) suggested that humanities researchers in particular have been damaged in their research capability as a result of increased codification of risk management strategies under the guise of 'ethics'. In return, Bledsoe *et al.* argue, humanities researchers have received no benefit.

Guillemin, Gillam, Rosenthal and Bolitho (2012) interviewed 34 Australian HREC members about their perceptions of the role of a HREC. The researchers specifically asked whether HRECs should assess research design as part of their ethical review. Some respondents argued that "[...] ethics committees exceeded their remit in being overly prescriptive about the type of methodology researchers should use" (2012, 42). Guillemin, Gillam, Rosenthal and Bolitho record an instance in which this led HRECs to request revisions to an applicant's research

methodology, which led the applicant to comment that their respect for the HREC declined as “[...] it was not an ethical issue” (2012, 42). In addition, Martha Macintyre (2014) claims dissonances on the formal review process in regards to the HREC authority to judge the soundness of a research proposal. Citing the National Statement clause 1.2, that where “[...] prior 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” (NHMRC 2007, 10), she claims that this advice is “[...] routinely, ignored at most universities” (Macintyre 2014, 382), and argues that such prior review has already taken place during the confirmation of candidature carried by an academic board of experts in the field and therefore there is no need for HREC qualification.

*Do Incentives for Participation in Surveys and Interviews Compromise Research Integrity?*

The National Statement’s view on the use of incentives in research raises debate about the extent to which such incentives can compromise research integrity. As reciprocation for participation in a research project, the National Statement advocates the use of money or other non-financial incentives, as long as the incentive “[...] does not result in pressure on individuals to consent or participate” (NHMRC 2007, 33). In relation to reimbursement, costs should be relative to participants’ expenditure or time consumption. Payments, however, should not “encourage participants to take risk” (NHMRC 2007, 17). These decisions should also “[...] take into account the customs and practices of the community in which the research is to be conducted” (NHMRC 2007, 17), but it remains unclear whether research in overseas countries should utilise practices such as bribery, which is acceptable in some jurisdictions, but is not generally considered acceptable within Western values systems (Adeyeye 2017). McNeill (1997) is of the opinion that an inducement to participate in research may cloud the subjects’ appreciation of the risks involved in

participation, as well as entice people who are socially at risk, such as the poor or drug addicts, to participate in the research project. He concludes that committees such as HRECs are integral in providing an independent review of such research, and to put the health and safety of the subjects ahead of research objectives. In opposition to this view, Viens (2001) and Wilkinson and Moore (1997) suggest that using payments as incentives may hinder the socioeconomic diversity of a sample group by increasing the participation of those from socially-disadvantaged groups, or else help achieve socioeconomic diversity if there are too few participants from lower socioeconomic backgrounds. These two opposing views were directly observed in cross-national research that found a discrepancy in the ethics guidelines between the United States and Australia (Toumbourou *et al.* 2004). By looking at the International Youth Development Study, it was found that the US research centre allowed a payment to participants, whereas in Australia this was not the case. The decision not to provide incentives in Australia was made on the advice of local committee members who suggested that such an incentive would make the research less likely to be accepted by ethics committees. Conversely, Toumbourou *et al.* (2004) suggest that Australian HRECs should be more accepting of incentives. Although this discrepancy exists across ethics committees in different countries, the problem of incentives highlights that fundamental ethical beliefs, such as belief in the importance of social justice for the poor or the degree of necessity of socioeconomic diversity in a survey population, may affect HREC members' decision making.

*Is Research That Limits Disclosure, Plans Deception, or Actively Conceals Morally Unjustifiable?*

The National Statement presents consent in research as an area of concern for HRECs in the ethics review process. The statement outlines guidelines concerning qualifying or waiving conditions for consent in regard to limited disclosure, planned deception, and active concealment.

The National Statement proposes that limited disclosure may be justifiable in regard to the disclosure of the study's aims and/or methods. This is particularly the case in research involving humans, as disclosing a study's purpose may jeopardize the said purpose. Examples of limited disclosure include both overt and covert observation of people in public spaces or other contexts, and role-playing on the part of the researcher to uncover information from the participant. In relation to the use of limited disclosure in research, the National Statement mentions that it may be approved by HRECs as long as it does not involve active concealment or planned deception. The statement appends an extensive list of preconditions and post conditions to the use of limited disclosure that must be recognised and analysed by HREC members when reviewing research that involves limited disclosure.

There has been extensive scholarly debate on the issue of limited disclosure, with arguments for and against its inclusion in research (McGuire and Burke 2008; Athanassoulis and Wilson 2009; McGuire and Lupski 2010; Tai 2012). Tai (2012), in his research on informed consent in research ethics, argues that deception is unjustifiable as it takes advantage of the trust inherent to the researcher-participant relationship. Tai also notes that limiting disclosure may cause participants to act suspiciously if they perceive the existence of a deception, thus potentially jeopardising the results of the study. He comments that receiving informed consent from participants in such a study is impossible, as the research design requires the concealment of the true purpose of the study. Tai's conclusion is that "[...] deception in research is unethical because the spirit of research requires a high moral standard" (2012, 222), and that deception of any kind is not of a high moral standard (a Kantian argument). Within medical research, limited disclosure often occurs in the returning of results to participants. In genome testing, for example, there are arguments both for and against the returning of results. Those in favour of returning results see it as a sign of respect and an ethical obligation to the participants (McGuire and Lupski 2010). However, McGuire

and Burke (2008) and McGuire and Lupski (2010) have expressed that disclosing such results to participants can be detrimental to the participants, as it may create unnecessary worry or anxiety due to participants' limited understanding of the results and their potential consequences. While this refers to deception at the end of a research study, some argue that deception is necessary for methodological reasons, such as when providing particular information to participants is expected to result in altered participant behaviour (Athanasoulis and Wilson 2009). This is particularly the case in placebo studies, which are at direct odds to the aim of informed consent (Wendler 1996; Wendler and Miller 2004).

The use of limited disclosure in research is often justified on consequentialist grounds, that is, on the grounds that limited disclosure should be considered morally right because it produces a positive outcome (Wendler 1996). Limited disclosure can also be justified on utilitarian grounds, that is, on the grounds that deceiving participants may be detrimental to these individuals, but beneficial to society more broadly. Wendler (1996), who has written extensively on participants' rights in research, argues that the utilitarian argument in justification of limited disclosure is a weak one. Indeed, utilitarian arguments have been used to justify the likes of such travesties as the Johns Hopkins Tuskegee syphilis experiment of the mid-twentieth century, in which rural African-American men were deliberately injected with syphilis without the participants' knowledge so that physicians could analyse the disease's progression 'for the greater good' (Gaw 2006). Having said this, such horrific cases, justified by their research designers in the name of utilitarianism, do not necessarily mandate the complete dismissal of all studies founded on utilitarian principles, and this makes it important for HREC members to assess each case using cost-benefit analysis, as Wendler suggests (1996). The range of perspectives on this issue suggests that HREC members may be similarly diversified in their views on the validity of utilitarianism and/or consequentialism, and that these differences in values may surface in HREC members' decision to accept or reject a proposal.



*Can Consent Waivers for Participants with Intellectual Disability be Justifiable?*

The National Statement provides guidelines for working with people with intellectual disabilities, and the waiving of consent in research. These two independent sets of guidelines within the National Statement are not interlinked. First, the National Statement states that “[...] people with a cognitive impairment, an intellectual disability or a mental illness are entitled to participate in research” and that consent for these people to participate in research “[...] must be sought either from that person if he or she has the capacity to consent, or from the person’s guardian or any person or organisation authorised by law” (NHMRC 2007, 34). Nowhere is it suggested that consent be waived for these participants. However, the section of the National Statement on waiving conditions for consent (NHMRC 2007, 11-13) does provide guidelines to follow when considering waiving consent for individuals. There is therefore some conflict between which guideline takes precedence, and there is debate regarding consent waivers for participants with intellectual disabilities (Lai, Elliott and Ouellette-Kuntz 2006; Aman and Handen 2006; Smith 2008).

HRECs play a substantive role in assessing research that involves participants with intellectual disabilities. Iacono (2006) highlighted this ethical dilemma by describing instances in which it arose. In one example, a HREC member questioned the action of a senior staff member of a non-government disability service in their provision of consent on behalf of a participant. As a reaction to this observation, and to avoid its reoccurrence, the HREC member requested that consent should be sought from the next-of-kin of all participants in the study (Iacono 2006). Rather than seeking to assess the participant’s ability to provide consent, as outlined in the National Statement, this member discounted the individual’s right to participate by immediately deferring responsibility to another person. The researchers in this study posited that this decision was unethical, as the capability of the individual must first be assessed to determine their capacity for informed consent (Iacono 2006). Iacono suggests that such decisions by



HRECs and their rejection of research involving participants with intellectual disabilities are largely a result of the conservative worldviews of members. However, it is also a problem that the National Statement does not specify whose role it is, and under what criteria, to assess whether a potential participant with an intellectual disability is able or unable to provide informed consent. Moreover, such decisions have unclear legal implications, which vary according to jurisdiction, adding further complexity. Aman and Handen (2006), in their response to Iacono's paper, agree that HREC members' conservatism may reduce the acceptance rate of research involving participants with intellectual disabilities. They propose that HRECs include members who are active researchers, to prevent bias by non-researchers who may be unaware of research within the field of intellectual disability. Lai, Elliott, and Ouellette-Kuntz (2006) added further to this by noting that there have been inconsistencies in ethics committees' decisions in highly contentious cases. They note that further research needs to be conducted on members' attitudes to research involving participants with intellectual disabilities. However, they do point to earlier research conducted by Siperstein, Wolraich and Reed on physicians' attitudes towards individuals with intellectual disabilities, with the premise that many HREC members are also active physicians. This earlier research found that physicians have a more pessimistic attitude towards children with intellectual disabilities than psychologists or social workers (Siperstein, Wolraich and Reed 1994). Lai, Elliott and Ouellette-Kuntz (2006) conclude that it seems likely that ethics committee members' attitudes shape decision making in research that involves participants with intellectual disabilities, but that more direct research needs to be conducted.

This survey of the scholarship on the inclusion of participants with intellectual disabilities in research clearly identifies ethical complexities surrounding informed consent and other factors of research design. Decisions made by HRECs in relation to these dilemmas are crucial to the continuation of research with these participants, and it remains a possibility that the personal beliefs and attitudes of HREC members may hinder

the approval of research that involves participants with intellectual disabilities. This may limit the dynamism of research into intellectual disability itself.

*Are Participants, Rather Than Researchers, Entirely Responsible for Determining the Extent of Risk Involved in Participation?*

The National Statement defines risk as “[...] a potential for harm, discomfort or inconvenience” (NHMRC 2007, 7). The National Statement asserts that identifying and assessing risk is an obligation for both researchers and participants. Researchers are responsible for “[...] designing the research to minimise risks of harm or discomfort to participants” and “clarifying for participants the potential benefits and risks of research” (NHMRC 2007, 6). However, the statement indicates that the assessment of risk is primarily a responsibility of participants, as “[...] participants’ perceptions of risks and benefits [are] to be considered by review bodies in deciding whether the risks are justified by the benefits” (NHMRC 2007, 7). The National Statement outlines the difficulty that may be had in balancing the tension between researchers’ responsibility to reduce risk to participants, and the obligation to provide participants with the freedom to accept risk. This ethical trade-off stems from respect for a person’s self-determination, as indicated by the completion of an informed consent form, which signifies that a participant understands the risks involved in participation. Individuals’ fundamental beliefs about freedom and choice are therefore expected to influence HREC members’ decision-making.

Wendler and Grady (2008) assert the importance of providing participants with the opportunity to make an autonomous decision to participate, based on whether the research is in line with their own interests or beliefs. Once the participant’s consent form has been signed, Resnik and Ness argue that “[...] competent adult participants are responsible for complying with study requirements and fulfilling other obligations they undertake when they make an informed choice to enrol in a study”

(2012, 746). Resnik and Ness (2012) argue the importance of participant responsibility in light of the ethical argument that clinical research should be considered a partnership between investigators and participants. Some research institutions have gone so far as to develop lists of responsibilities for participants (Rabkin and Small 2001; Stanford University 2011; University of Texas 2011). Chilengi (2009) comments that informed consent stems from the fundamental ethical principle of autonomy and the right to self-determination. The subtext here is that denying participants the opportunity to accept risk may be considered by some as tantamount to authoritarianism. The current literature is therefore unclear about how the outcome of an ethics assessment may be altered by differences in risk perception between HREC members and participants, HREC members and the research designers, or one HREC member and another.

*Is Risk to Researchers as Important as Risk to Participants?*

In the National Statement's outline of the risks involved in research, focus is placed on the risks to a study's participants and the researchers' role in minimising these risks. The National Statement does not specifically mention risks to researchers, nor does it qualify the role of ethics committees in mitigating such risks. However, the statement's definition of participants includes "[...] those upon whom the research impacts, whether concurrently or retrospectively" (??????), and this suggests that researchers can be included in this definition. The National Statement's inclusion of researchers in risk assessment therefore lacks clarity, and this has been discussed extensively (Dickson-Swift, James and Kippen 2005; Dickson-Swift, James, Kippen and Liamputtong 2008). Dickson-Swift *et al.* (2005) write that the statement does provide for the protection of researchers, and that HRECs need to more actively assess risks to researchers. If risks to researchers are ignored, this may affect future research, such as the potential for valuable researchers to burn out due to excessive workloads, or the avoidance of sensitive research topics by

researchers in their concern for avoiding serious physical or psychological harm. Dickson-Swift *et al.* (2005) state that many HRECs may already consider risks to researchers, but given that there is no mention of this in the many HREC forms and guidelines, any such assessment is beyond the aegis of the formally-codified guidelines. Arguments against HRECs' role in assessing risks to researchers include that the provision of such guidelines would be paternalistic, and that researchers are competent adults who can assess their own risks (Dickson-Swift *et al.* 2005; Dickson-Swift *et al.* 2008). Gillam (2005) accepts that there are risks to researchers, but that it is not the role of the HREC to deal with this issue. Her two arguments include that while the risk to participants is of concern to HRECs, the risk to the researcher is not, and that there are other bodies that are better equipped to deal with this issue. However, if this is the correct procedure, then it presupposes a judgmental hierarchy of competence in which researchers are capable of properly assessing the risk to themselves, while participants are not.

The variety of views evident in the literature suggests that individual HREC members may be influenced by their own worldviews. Those who are more paternalistic in nature may be inclined to protect both researchers and participants from harm, and so too may those who have prior experience of research that has resulted in harm to the researcher. Other members may be more inclined to accept the argument of Gillam (2005) that it is not the role of HRECs to undertake protection of researchers. Further research is needed to determine the interrelationship between HREC members' values and decision making in this regard.

*Should the Social Benefit of a Research Project be Weighed Against its Potential Risk to Participants?*

Under the section headed 'beneficence' in the National Statement (NHMRC 2007, 25-26), risk-benefit analysis involves justifying any risks of harm or discomfort to participants against the likely benefit to the

participants or the wider community. Such issues are at the heart of the classic thought experiments of moral philosophy, such as the Trolley problem (Foot 1967).

Lakeman and Fitzgerald (2009) expressed HREC members' concerns about the balance between risk and benefits with reference to a study on suicide in Australia. A survey completed by HREC members who assessed research on suicide found that the potential for harm to participants was considered the most dominant concern of committee members. Perceived risks included bringing added attention to suicidal thoughts or feelings, and an inability to provide adequate assistance if this was the case. The benefits of the study were also considered in the survey, and all respondents mentioned at least one or more potential benefits of the study. Benefits included increased understanding of suicide, which HREC members saw as potentially contributing to the prevention of suicide through improved treatment and diagnostics. Lakeman and Fitzgerald (2009) concluded that ethical approval of research on suicide did not differ greatly to approval of research in general, and that risk-benefit analysis was sufficient in such a situation.

Risk-benefit analysis has also been used in biomedical research. Rid (2012), for example, evaluated recent debates about risk-benefit evaluations and noted that there had been limited research on HREC members' use of risk-benefit analysis. International studies that comment on ethics committees show that few HRECs use a systematic approach to risk-benefit analysis. A study from the Netherlands found that 6 out of the 53 reviewers surveyed used a systematic approach to risk-benefit analysis, and that the remainder deferred to their intuition (Van Luijn, Musschenga, Keus, Robinson and Aaronson, 2002). Psychological research shows the danger in making intuitive judgments such as this, as they stem from systematic cognitive bias. An example used by Rid (2012) is that people tend to judge activities that they have experience with to be less risky than those with which they are less familiar. In a study by van Luijn, Aaronson, Keus and Musschenga (2006), there were major discrepancies between HREC

members' perceived risk-benefit ratios pertaining to a breast cancer study. Others have seen similar results in the perceived risk of particular activities or procedures (Green, Lowery, Kowalski and Wyszewianski 2006; Hirshon *et al.* 2002; Lenk, Radenbach, Dahl and Wiesemann 2004; Mansbach, Acholonu, Clark and Camargo 2007; McWilliams *et al.* 2003; Shah *et al.* 2004). These variations suggest that, despite ethics committee members actively assessing risk-benefit ratios, there are discrepancies as to how risk and benefit are determined, and that HREC members defer to their own experience, values, and worldview to make such determinations.

*Is the Use of Placebos in Research Unacceptable?*

The National Statement explicitly discusses the use of placebos in clinical trials. The guidelines state that the use of placebos, or non-treatment control groups, should be considered ethically unacceptable when alternative methods exist that produce better outcomes, or there is inherent risk to the participant in the withdrawal or absence of treatment. The use of placebos in research has been discussed in detail in academia, and a variety of views have been expressed as to its place in research. In reviewing the first part of the National Statement's discussion of placebos in conjunction with the Declaration of Helsinki, a number of researchers are of the opinion that the use of placebos in clinical research means that patients are not being given the best treatment (Hoffman 2001; Devdutt and Vicky 2014; Kottow 2010; Stein and Ray 2010). In their respective discussions of placebos in clinical trials, Avins *et al.* (2012), and Kottow (2010), raise the view that the use of placebos is deceptive in nature. These scholars propose that it is better to compare treatment to a true clinical alternative (the usual praxis of care for a particular condition), rather than an artificial intervention (placebo), in order to maintain trust between the researcher and the participant. This opinion stems from the ethical principle of beneficence, or that researchers should avoid harming human subjects, maximise benefits, and reduce risks. The use of placebos

may also impinge upon participants' autonomy, as they are unable to give informed consent due to the nature of placebo studies, which deny participants the knowledge of who is being administered a placebo and who is not (Justman 2013; Asai and Kadooka 2013; Devdutt and Vicky 2014). Once again, HREC members' attitudes to the importance of individual freedom are likely to affect their decision making in such instances.

The debate on the use of placebos in research is closely linked to moral obligations and the philosophical underpinnings of ethics. Kottow (2010) suggests that participants may be more willing to accept placebo trials due to a perceived moral obligation to contribute to the common good. However, he argues that democracy, or the right to choose, supersedes this obligation. In addition, the public good may not be the chief concern in research, and results are not always beneficial to the wider population. This view is in direct opposition to consequentialism, and hinges on the Kantian imperative that human beings are always to be respected as ends in and of themselves. This Kantian argument is lost when people who offer informed consent to contribute to placebo-based research lack the knowledge to make this informed decision (Kottow 2010). This may indicate that HREC members face internal philosophical debate when it comes to assessing research involving placebos. How they choose to respond to these applications will largely depend on their worldview.

### *Is Research That Aims to Expose Illegal Activities Unjustifiable?*

The National Statement explicitly considers research that aims to expose illegal activities, providing specific guidelines on how to undertake such research. Such research raises ethical concerns, in particular regarding participants' consent. Such research is also likely to present risks to participants, as indicated in two statements: (i) “[...] where research involving limited disclosure aims to expose illegal activity, the adverse effects on those whose illegal activity is exposed must be justified by the value of the exposure” (NHMRC 2007, 12); and (ii) “[...] it should be clearly established that



these risks are justified by the benefits of the research” (NHMRC 2007, 36). These arguments are consequentialist in nature, as they indicate that the end product of the research justifies the risk to participants.

The literature raises a variety of views about the ethical concerns of research that aims to expose illegal activity. Most of these concerns are raised under the premise that the participants of this type of research are exploited as members of “vulnerable populations” (Singer *et al.* 2008). Issues that arise for these participants include their ability to provide informed consent in a situation where they may be cognitively unable to weigh the risks involved in their participation (Brody and Waldron 2000). In addition, given that many crimes have financial gain as a primary aim, this population may be more easily coerced into research when monetary incentives are used, thereby clouding their judgment and reasons for involvement in such studies (Fry and Dwyer 2001; Buchanan *et al.* 2002; Ritter, Fry and Swan 2003; Fry *et al.* 2005; Fry, Hall, Ritter and Jenkinson 2006). Confidentiality and privacy are also concerns, as participants in research aiming to expose illegal activity are likely to be concerned about their exposure from their participation in such research (Fisher 2004; Anderson and DuBois 2007). As well as risk to participants, there is also likely to be an increased risk for researchers undertaking such studies (Feenan 2002; Israel 2004). These types of ethical dilemmas are often resolved on the philosophical grounds of utilitarianism or Kantianism (Buchanan *et al.* 2002). For example, if there is a concern regarding breaching participants’ confidentiality in order to protect their next-of-kin, this may be considered morally unjustifiable in Kantian terms.

*Do the Benefits of Research Generally Outweigh Participant Privacy and Confidentiality Rights?*

The clause in the National Statement relating to beneficence suggests that there may be cases in research where risk of harm or discomfort to participants can be justified if the benefits of the research outweigh the



negative impact on participants. This is a utilitarian argument. Although there is no direct guidance in relation to the waiving of participants' confidentiality and privacy rights, there may be reason in some research designs that this is necessary to gain the benefits of a study. Particular fields of research may be more predisposed to the need for waiving privacy rights. Issues relating to children and teenagers, including suicide, child abuse, and violence, are areas of study that may require adjustment of the traditional ethical and legal frameworks, and in some instances researchers may perceive a legal or ethical duty to disclose confidential information to protect participants or the wider community from harm (Moolchan and Mermelstein 2002; Lothen-Kline *et al.* 2003; Buchanan, Gable and Fisher 2009; Fisher and Goodman 2009; Ma, Phelps, Lerner and Lerner 2009; Benson, Leffert, Scales and Blyth 2012). In such instances, Australian teachers have a legal responsibility to report instances of child sexual abuse, and this directly contradicts the ethical principles of research (Department of Education 2016). Australian teachers who are also active researchers are therefore subject to two internally contradictory sets of guidelines, and the presumption is that the mandate to report instances of abuse supersedes the mandate to protect confidentiality.

The National Statement also describes the importance to policymakers and legislators of research that aims to uncover illegal activity. A variety of scholars have discussed specific cases where such research has had beneficial results for broader society (Fisher *et al.* 1996; Moolchan and Mermelstein 2002). The premise of these arguments lies within a utilitarian philosophy, where harm to a few is justified by the broader societal benefits that may result from the research. HREC members who possess utilitarian philosophical leanings may be more inclined to accept such an ethical trade-off, as opposed to those who have Kantian views, which propose that a human being should never be used as a means to an end (Carpenter 2008). Further research on HREC members' beliefs about breaches of confidentiality and privacy may highlight these discrepancies in members' philosophical beliefs and their impact on decision-making.

*Should Allegations of Research Misconduct be Processed Independently of the Organisation in Which the Allegation Arose?*

The National Statement refers allegations of research misconduct to the guidelines set by the Australian Code for the Responsible Conduct of Research (NHMRC 2007). This code encourages responsible research conduct, as well as outlining the processes involved in processing allegations of research misconduct. The Code stipulates that ‘serious research misconduct’ should be investigated by a body independent to the organisation in which the misconduct took place. The seriousness of the misconduct must be judged against its possible consequences. The Code recommends deferring judgment to an external body in order to “[...] maximise experience, simplify avoiding conflicts of interest, and achieve transparency and accountability” (NHMRC 2007, §9.3).

Research misconduct processes in Australia differ from those in other countries. Breen (2003) and Hall (2006) note the existence of overarching bodies that review research integrity in the United States and Scandinavian countries. These bodies effectively minimise conflicts of interest and mitigate inadequate processes conducted by internal examinations from the organisations in which the allegation arose. A number of cases exemplify the importance of independent reviews of serious research misconduct. Hey and Chalmers (2010) reviewed an allegation of misconduct in the use of continuous negative extrathoracic pressure (CNEP) in respiratory support for premature babies, a landmark case in the UK that spanned twenty years. In this case, a group of parents claimed to be unaware that this procedure was used on their children, and reported this misconduct to the organisation that conducted the research. Initially, the General Medical Council reviewed the allegations and found that they were true. However, subsequent reviews by external bodies, including Hey and Chalmers themselves, found that the research adhered to ethical guidelines and that there was no evidence of misconduct (Hey and Chalmers 2000). The 25-year saga

resulted in substantial monetary loss and stress to both the children's families and the researchers. It exemplified the need for an independent process for review of misconduct due to many members of internal committees' lack of expertise, and the lack of trust or respect for review processes from those who were immediately involved in the incident in question. Hey and Chalmers (2010) also proposed that the aggrieved parents, perhaps justifiably, lacked respect for the internal review process, and that this was a factor in their proceeding to litigation as a mechanism for achieving justice.

This example highlights a number of issues that could arise from mishandling allegations of misconduct. Newcombe and Kerridge (2007) reviewed the issues involved in Australian HRECs' processing conflicts of interest in pharmaceutical studies. They found that the majority of HRECs from within the institution where the conflict arose were reluctant to arbitrate such conflicts due to uncertainty about the role of HRECs in managing such conflicts. This suggests that conflicts of interest may best be assessed by objective external committees, such as those present in the US and Scandinavian countries, a view supported by Hall (2006) and Van der Weyden (2006). Hall states that the creation of such a body in Australia would protect organisations from claims of cover-up, nepotism, 'protecting your own', or other forms of corruption. A number of researchers have suggested that a national body would be the most beneficial for a number of additional reasons, including creating a body of expertise, providing a safe place for whistle-blowers, encouraging education, codifying guidelines, and avoiding conflicts of interest (Smith 2006). If HREC members were educated in the consequences of internal management of research misconduct as mentioned above, and of the benefits of external assessment, they may come to believe that independent analysis of misconduct is beneficial. At present, it is unclear what proportion of HRECs are aware of the potential negative externalities of internal reviews of research misconduct, or of the possible benefits of a codified national approach.

### III. CONCLUSION

The literature relating to the fourteen themes reviewed here suggests that each individual member's ethical worldview will affect their assessment of a research proposal. Ultimately, key beliefs, such as whether it is worthwhile to risk the wellbeing of the individual for the common good, the democratic right of the individual to knowingly accept risk, and the issue of incentives, can all be influenced by intuitive decisions informed by worldview, which incorporates personal judgments derived from context and experience (Van Essen *et al.* 2004; Pieper and Thomson 2011). This is a complex world of personal beliefs, which are not value-neutral, but reflect mixed orientations towards consequentialism, Kantianism, and utilitarianism, depending on the nature and context of each project (Handal *et al.* 2016). The literature suggests that reviewers, based on their professional background and personal experience of the world, generate views about issues that impact their review of ethics applications (Gillam, Guillemain and Rosenthal 2006; Handal *et al.* 2015). A possible long-term consequence of this is that reviewer beliefs, both well-informed and less-informed, may be passed on to novice researchers who become the next generation of reviewers, thereby reducing the dynamism of research itself by possibly entrenching outmoded frames of reference. Another possible outcome is that HREC members' differences in fundamental values may delay the approvals process, further reducing the dynamism and timeliness of the research sector (White *et al.* 2016). This literature review makes it all the more clear that further study needs to be done on HREC members' ethical worldviews.

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