

The Low Risk Research Ethics Application Process at CQUniversity Australia

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Abstract The CQUniversity Australia Human Research Ethics Committee (HREC) is a human ethics research committee registered under the auspices of the National Health and Medical Research Council. In 2009 an external review of CQUniversity Australia's HREC policies and procedures recommended that a *low risk research* process be available to the institution's researchers. Subsequently, in 2010 the Human Research Ethics Committee Low Risk Application Procedure came into operation. This paper examines the applications made under the Human Research Ethics Committee Low Risk Application Procedure during the course of 2010 and 2011. The paper contributes to the literature analyzing the decision-making processes of research review committees through an analysis of the quantitative data relating to the *low risk research* applications made and through discourse analysis of the qualitative data represented by the assessment comments of the members of the Committee.

Keywords Institutional ethics review · Institutional research committee · Research ethics review processes · Low risk research

Introduction

Whilst the Helsinki Declaration on Ethical Principles for Medical Research Involving Human Subjects was made in 1972 in Australia the ethical review of research involving humans has occurred since the 1960's. This review process is not only concerned with medical research but any social or behavioral research that involves participation, whether indirect or direct, by humans (NHMRC 2012). To ensure compliance with the requirement to

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conduct an ethical review of any research proposed to be conducted, the National Health and Medical Research (NHMRC) (2012) notes, 'in 1985, the [National Health and Medical Research] Council adopted a recommendation that any institution that conducts research on humans must conform [by having an ethics review committee] in order to be eligible to receive funds for research from the Council.' The NHMRC identifies the connection between research funding and requirement to have an IEC (institutional ethics committee) as being an *effective inducement*. (emphasis added). In March 2007, The National Statement on Ethical Conduct in Human Research (National Statement) was endorsed. The National Statement (2007) provides the guidelines by which ethical research should be conducted and the framework against which applications to conduct research are assessed. Relevantly, the National Statement (2007, 8) provides that:

Institutions are responsible for establishing procedures for the ethical review of human research. That review can be undertaken at various levels, according to the degree of risk involved in the research. ... Research with more than a low level of risk ... must be reviewed by an HREC. Research involving no more than low risk may be reviewed under other processes ...

The CQUniversity Australia Human Research Ethics Committee (HREC) is a long standing HREC but one that did not have a *low risk research* application process as contemplated by the National Statement (2007). In other words, all applications for research were assessed by full complement of members in Committee. In 2009 the CQUniversity Australia HREC underwent external review. One of the recommendations arising from the external review was that CQUniversity Australia consider the implementation of a *low risk research* application process. In 2010 the Human Research Ethics Committee Low Risk Application Procedures came into operation. This paper examines the applications made under the Human Research Ethics Committee Low Risk Application Procedure during the course of 2010 and 2011. Approval to conduct this research was sought through the HREC using the low risk application procedure and the data (i.e. the responses from members) was de-identified before being used for the purposes of the project.

This paper is presented in three parts. The first part presents the relevant definitions from the National Statement (2007) and how they have been incorporated into the Human Research Ethics Committee Low Risk Application Procedures. The second presents the quantitative data relating to the applications made under the Procedure during 2010 and 2011. The qualitative data reveals not all of the applications made under this process were regarded as *low risk* by Committee Members despite the *low risk* assessment by the researcher. Of interest to us was this difference in assessment. The third part therefore examines the reasons given by Committee Members for their assessment of the application as more than *low risk* thereby requiring referral through to the full HREC for review. Using discourse analysis it was evident that subject positioning in favor of potential participants was taken by the reviewing Committee Members. This subject position highlights that the principles espoused by the National Statement (2007) are at the core of the Committee's decision-making process. This paper therefore contributes to the literature examining the efficacy and decision-making processes undertaken by HRECs. Although the data presented is from a single HREC the analysis is important given the national regulatory coverage of the National Statement (2007) and the significant number of HRECs operating across Australia. To that extent the NHMRC (2012) estimates that in 2005 there were more than 220 committees operating across Australia.

CQUniversity Australia's Human Research Ethics Committee Low Risk Application Procedure

In terms of considering the content of the *low risk application* process to be adopted the definition of *low risk research* needs to be considered together with the requirements of the National Statement (2007) regarding review. As noted above, the National Statement (2007, 12) permits the Institution to implement a different process to full HREC review of an application where the research is low risk. The National Statement defines (2007, 12) *low risk research* as descriptive of:

research in which the only foreseeable risk is one of discomfort. Research in which the risk for participants is more serious than discomfort is not low risk.

Discomfort is subsequently defined (2007, 100) as a, 'negative accompaniment or effect of research, less serious than harm' and harm is defined (2007, 100) as, 'that which adversely affects the interests or welfare of an individual or a group. Harm includes (2007, 100) physical harm, anxiety, pain, psychological disturbance, devaluation of personal worth and social disadvantage.'

The identification of whether research meets these definitional prerequisites lies with the nominated reviewers. From this closed question of "is this low risk research" the problematization of "the subjectivity of risk" may be heightened (Beck 2009). According to Lindqvist and Nordänger (2007) the management of risk serves social, cultural and political functions. In substantiating this position they have called on three perspectives provided by firstly Beck (1992) who states that we live in a risk society where fear and safety are in constant negotiation. A second perspective comes from the work of Giddens (1990) where this risk is seen as operating at the individual level where we do something at our own risk. Finally they draw on Douglas (1992) to highlight the way that risk has been socially constructed to control and maintain cultural differences, behavior, norms and beliefs (Lindqvist & Nordänger 2007).

An alternate viewpoint can be gained from Foucault where self-surveillance is a form of risk management. Risk takers are those who step outside of the norms with risk avoidance seen as sticking to the rules, whether these are societal norms, rules of the group or expectations. The authors argue that ethics committees do a type of institutional surveillance, as well as negotiate risk and safety. This becomes interesting when Committee members could be seen as operating from different epistemological frameworks vis-à-vis each other and researchers. As an institutional Committee, the Committee as a whole not only has a role in maintaining the norms for the research community, negotiating institutional norms and name, but also an obligation to implement the National Statement. In contrast it could be argued that the research community is more focused on the perceived outcomes of their research.

In terms of review of such low risk research process, the National Statement (2007) requires that:

5.1.19 Where institutions establish non-HREC levels of ethical review for low risk research, that review must:

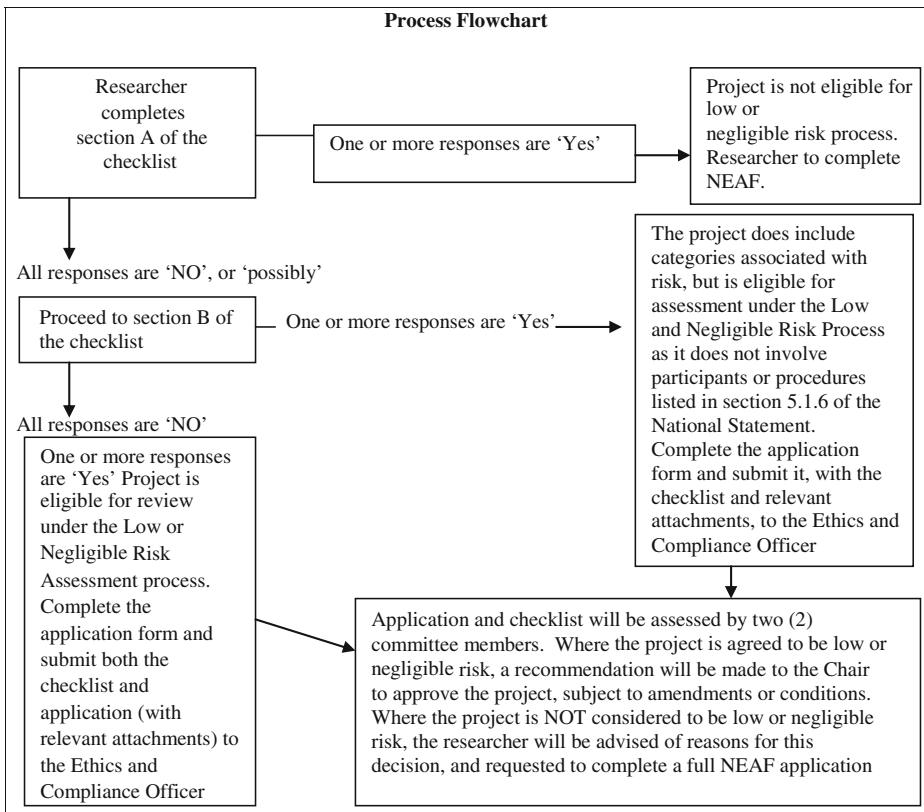
- a. be carried out by people who are familiar with this National Statement and have an understanding of the ethical issues that can arise in the research under review;
- b. be informed by Section "Introduction": Values and Principles of Ethical Conduct, Section "Low Risk Research Applications Lodged 2010–2011": Ethical Considerations Specific to Research Methods or Fields and Section "Analytical Framing": Ethical Considerations Specific to Participants;

- c. take account of researchers’ judgments as to whether their research is suitable for review by a non-HREC process;
- d. have due regard to relevant privacy regulation.

“Discussion”.1.20 of the National Statement (2007, 79) then provides that the levels of ethical review may include, but need not be limited to (a) review or assessment at departmental level by the head of department, (b) review or assessment by a departmental committee of peers (with without external or independent members), (c) delegated review with reporting to an HREC; or (d) review by a subcommittee of an HREC but that, those reviewing research at a non-HREC level must refer to an HREC any research they identify as involving more than low risk. CQUniversity Australia’s Human Research Ethics Committee Low Risk Application Procedure reflects both of these requirements as evidenced by the Process Flowchart for the Procedure in Table 1 below.

It is acknowledged that CQUniversity Australia is not unique in its adoption of a low risk ethics review process. Indeed, a number of other Australian tertiary institutions (including but not limited to Monash University, University of Sydney, Deakin University and Griffith University) have institutional low risk research approval processes. This paper will not examine the practices of other institutions. This

Table 1 CQUniversity australia’s human research ethics committee low risk application procedure



is on the basis that at the time of proposing this research the implementation of the low risk ethics review process was only 2 years old at CQUniversity and the researchers did not want to obscure the objective of the research that is to examine CQUniversity's situation, by also including an examination of practices from other institutions.

Examining the CQUniversity Low Procedure researchers are requested to complete an initial checklist that requires researchers to consider the type of research being conducted and the target participants. In other words, researchers are asked to evaluate their research against the question "is the research low risk research"?

The checklist as was in effect in December 2011 when research was conducted required the researcher to indicate whether the research involved:

- Participants that are identifiable or re-identifiable
- Some form of deception is involved
- The procedure involves experimental manipulation or includes the presentation of any stimulus other than question-asking
- The project involves interventions and/or therapies, including clinical and non-clinical trials and innovations, human genetics or human stem cells

If the researcher indicated that the research involved these procedures then the Procedure determined that the research project could *not* be considered under the Low or Negligible Risk Assessment Process and a NEAF application was required to be lodged for review by the full HREC.

After that initial assessment the research was asked to consider the targeted participants. If the researcher indicated that the target participants comprised:

- Participants aged less than 18 years
- Participants who are cognitively or emotionally impaired, or are highly dependent on medical care
- Aboriginal or Torres Strait Islander People
- Female participants who are pregnant and/or the human fetus
- Participants who may be involved in illegal activities, where the research is intended to study or expose illegal activity

then the project could not be considered under the Low or Negligible Risk Assessment Process and a NEAF application lodged for review by the Human Research Ethics Committee. Where researchers indicated that the research did not seek to specifically target the above groups as participants not include such targeted participants the final assessment process concerned the project topic itself.

The Procedure determined that projects examining particular areas (see Table 2 below) may not be regarded as *low risk research*. After completing the checklist if the research project *did not* fall into one of the particular topics the application was eligible to be considered under the low risk process. Where the research was concerned with an identified topic the application was not automatically excluded from the process but could still be considered as *low risk research*. The caveat to that assessment being that the onus was placed on the researcher to establish that the risk to the participants could be mitigated and managed sufficiently so that the benefits deriving from the research outweighed the identified risks. The next part examines the applications lodged under the low risk process over the course of 2010–2011.

Table 2 Table of identified project areas

Research about parenting issues	Research investigating sensitive personal or cultural issues	Explorations of grief, death or serious/traumatic loss
Mental disorders e.g. depression, mood states, anxiety	Gambling	Eating Disorders
Illicit drug use / Substance abuse (prescription or over the counter)	Self report of criminal behavior	Any psychological disorder
Suicide risks /anger management	Gender identity / Sexuality	Race or ethnic identity
Any disease or health problem	Fertility / Termination of pregnancy	Use of personal data obtained from Commonwealth or State Government Department/Agency with participant consent
Deception of participants or concealing the purposes of the research	Covert observation (or minimal disclosure)	Audio or visual recording without consent
Recruitment of a third party or agency (asking participants to provide information about another person)	Withholding from one group specific treatments or methods of learning from which they may benefit (e.g. in medicine or teaching)	Psychological interventions or treatments
Application of physical stimulus /Invasive physical procedures /Infliction of pain	Administration of drugs	Exposure to ionizing radiation
Tissue sampling or blood for pathological or genetic testing	Collecting body fluid (e.g. saliva)	Use of medical records where participants can be identified or linked
Participants suffering from a psychiatric or psychological disorder	Participants suffering from a physical disability or medical condition	Children and/or young people without parental or guardian consent
Residents of a custodial institution	Participants unable to give freely an informed consent because of difficulties in understanding information provided (e.g. language difficulties, NESB)	Members of a socially identifiable group with special cultural or religious beliefs or political vulnerabilities
Participants are identifiable in final report when specific consent for release has not been given	Those in a dependent relationship with the researchers (e.g. lecturer/student, doctor/patient, teacher/pupil and professional/client)	Administration of other substances or devices

Low Risk Research Applications Lodged 2010—2011

During the 2010 calendar year a total of 44 applications were lodged for consideration under the *low risk research* procedure. During the 2011 calendar year, the number of applications increased to 53. Of the 44 applications considered in 2010, 30 applications or 68% were regarded as meeting the definition of *low risk research*. Table 3 below depicts the number of applications lodged according to discipline, the number assessed as being meeting the definition of *low risk research* and the number of applications not regarded as *low risk* thus requiring referral to the full HREC.

Of the 53 applications considered in 2011, 39 applications or 74% were regarded as meeting the definition of *low risk research*. Table 4 below shows the number of applications lodged according to discipline, the number assessed as being meeting the definition of *low risk research* and the number of applications not regarded as *low risk* research thus requiring referral to the full HREC.

Whilst arguably the data highlights that the majority of researchers and members agreed with the researchers' assessment that the research was *low risk research*, of interest to the researchers was why, particularly given the researcher's opinion and assessment of their research as *low risk research*, that upon review it was not regarded as such. What were the reasons for the difference in assessment?

These reasons can be explored further to examine the point at which opinions diverged as to the research being *low risk research*. From a decision-making process perspective such an analysis is important as it serves as learning opportunity for committee members to review their own assessment practices and understanding of the *low risk* process. From a governance perspective it allows review of the decision-making process to ensure compliance with the National Statement (2007). To analyze the comments of the HREC reviewers we proposed an analytical framing comprising discourse and thematic analysis.

Analytical Framing

The analytical framing used in this research was based on two broad approaches to textual analysis, firstly Discourse Analysis and secondly, thematic content analysis. Discourse Analysis (DA) as defined by Punch (2005, 224) is, 'sensitive to how spoken and written language is used, to how accounts and descriptions are constructed, and to the complex processes for producing social meanings.' Punch (2005) therefore suggests that, 'discourse analysis is an important development in qualitative research, starting as it does from the assumption that discourse at all levels, including people's accounts, are an important resource'. Specifically, in the context of researching the work of human research review committees, O'Reilly et al. (2009b, 249) suggest that:

The many variants of DA pose challenges for providing a fully specified account of its methods, and indeed its lack of universally agreed upon procedures means that it is perhaps better understood as an orientation towards analysis rather than a set of executable techniques.

Therefore this paper is informed by the discourse analysis approach used by O'Reilly et al. (2009a, b) as they examined the work of research ethics committees (RECs) in the United Kingdom. O'Reilly et al. (2009a, 188) suggest that:

Table 3 2010 Applications

Discipline	Number (% of total N=44)	Low Risk (% of total N=30)	Referred to HREC (% of total N=14)
Education (Primary, Secondary, Tertiary)	9 (21%)	8 (27%)	1 (7.14%)
Sociology	6 (14%)	3 (10%)	3 (21.42%)
Psychology	11 (25%)	4 (13.3%)	7 (50%)
Management	2 (5%)	2 (6.66%)	
Mental Health	1 (2.5%)	1 (7.14%)	
Human Factors/Occupational Health and Safety	5 (12%)	4 (13.3%)	1 (7.14%)
Law	1 (2.5%)	1 (3.33%)	
Music	1 (2.5%)	1 (3.33%)	
Horticulture	1 (2.5%)	1 (3.33%)	
Nursing	1 (2.5%)	1 (3.33%)	
Engineering	1 (2.5%)	1 (3.33%)	
Business	1 (2.5%)	1 (3.33%)	
Economics	1 (2.5%)	1 (7.14%)	
Tourism	1 (2.5%)	1 (3.33%)	
Not classified 2010/7 Why Volunteer? An investigation into volunteer motives and functions 2010/35 Object properties influence the selection of a spatial frame of reference	2 (5%)	2 (6.66%)	
Total	44	30	14

DA is an approach ideally suited to show how institutional research can benefit from a linguistic perspective, and in particular how RECs position themselves through the texts of their letters. With the turn to language-based approaches, DA is an especially valued approach to analysing textual data. DA appeals to researchers as an analytic tool for its ability to reveal how institutions and individuals are formed, constructed

Table 4 2011 Applications

Discipline	Number (% of total N=53)	Low Risk (% of total N=39)	Referred to HREC (% of total N=14)
Business	3 (5%)	3 (7.69%)	
Education	16 (30%)	13 (33.33%)	3 (21.4%)
Economics	4 (7.55%)	3 (7.69%)	1 (7.14%)
Law	1 (2%)	1 (2.5%)	
Management	3 (6%)	2 (5.12%)	1 (7.14%)
Occupational Health and Safety	5 (9.5%)	4 (10.25%)	1 (7.14%)
Sociology	7 (13.2%)	5 (12.8%)	2 (14.2%)
Tourism	2 (3.8%)	2 (5.12%)	
Psychology	8 (15.1%)	2 (5.12%)	6 (43%)
Environment	2 (4%)	2 (5.12%)	
Technology Use	2 (4%)	2 (5.12%)	
Totals	53	39	14

and given meaning. DA is a difficult form of analysis to define in precise terms, and different approaches lay claim to the term, but there is agreement that it represents a commitment to the study of talk and text in social practice with a focus on language and how it is rhetorically organized.

O'Reilly et al. (2009a, 187) used discourse analysis to examine 260 letters issued to researchers following review of the researcher's application and used discourse analysis to, 'focus specifically on the subject positions that RECs both take and impose on others.' They suggested (2009, 187) that RECs engage in positioning as, 'positions provide authors with a way of accounting for and making sense of themselves in terms of their motives, experiences and reactions and managing their identity and classified the different positions that RECs took in their letters as:

1. RECs being disinterested and responsible
2. RECs as representing the interests of potential participants
3. RECs as facilitating ethically sound, high-quality research
4. RECs as engaged in dialogue.

Using discourse analysis O'Reilly et al. (2009a, 192) found that, 'the identity of the REC is fluid and flexible and that a variety of subject positions can be taken up as an interactional resource.' While the researchers' analysis of the reviewer comments in examining the CQUniversity Australia low risk applications was informed by this particular discursive approach the researchers' analytical framework also looked at content and themes arising from:

1. Variation between responses and across reviewers' responses
2. Content detail of the responses, keeping in mind that these texts could have been carefully crafted or written in haste.
3. Rhetorical organization or the way that texts had been organized to make a specific case or justification of answering "no" to the threshold question.
4. Lastly the researchers looked at how the responses demonstrated *accountability*. Meaning, in this context, how making one's claims and actions can be viewed as constructing the responses so they seem fair or objective.

The authors' recognize that the methodology adopted has limitations in that we used discourse analysis rather loosely as we wanted to follow a process similar to that used by O'Reilly et al. (2009a) to identify specific kinds of positioning. Additionally, the analysis included conventional content and thematic analysis of HREC comments in order to look more closely at the text used. It could be argued that the comments were constructed for a particular purpose, that is, knowing that the comments would be sent to the respective applicants/researchers therefore the text is purposefully composed.

The authors used a combination of discourse analysis categories (O'Reilly et al. 2009a) plus looked at conventional content and textual analysis (Lankshear & Knobel 2006). Therefore the analytical framework looked for evidence that could be allocated as one of four positions previously identified by O'Reilly et al. (2009a) including the other 4 listed points. In order to code the authors looked at the word level and paragraph level of text.

At one level the authors looked for words that corresponded to voluntary participation, informed consent, beneficence. At the second level we scanned for evidence that could

highlight how the reviewer had positioned themselves in relation to the four categories defined by O'Reilly et al. (2009a).

In applying these categories to the CQUniversity Australia *low risk research* applications it was apparent that the subject position taken by reviewers of the applications that were not approved under the low risk process was most commonly in line with the HREC as representing the interests of potential participants. It is suggested that this position was due to the fact that the fundamental, or threshold, question to be considered by the reviewers under the Procedure was, "was the research low risk"? This necessarily required the reviewers to be satisfied that the research was *low risk*, as noted earlier, compliant with the definition of *low risk research* in the National Statement (2007, 16) as being:

research in which the only foreseeable risk is one of discomfort. Research in which the risk for participants is more serious than discomfort is not low risk.

This is not to suggest that comments made by reviewers of the CQUniversity Australia HREC may have been offered under the other subject positions; however, the most evident subject position related to that of representing the participants as proposed by the research application.

In examining and explaining further the subject position as that with respect to potential participants, O'Reilly et al. (2009a, 189) suggest that by taking this subject position:

an identity is, in consequence, imposed upon research participants, positioning them as requiring the protection and intercession of the REC in order to avoid being exposed to the enthusiasm and motives of researchers. This might include, for example, *a defense of research participants' entitlement to voluntary participation and freedom from coercion ...* (emphasis added)

As a consequence of taking this subject position, O'Reilly et al. (2009a, 189) suggest that:

By positioning themselves as aligned with the interests of the participants, the REC manages both its duty to potential participants and the duty that the applicants have to the participants. Particular emphasis is placed by the RECs on the duty to ensure that potential *participants are given full information* about projects in which might participate. *The use of complex language and technical jargon* by applicants frequently represented as an impediment to the proper discharge of responsibilities to participants. (emphasis added)

An examination of the responses of the reviewers to those applications that were not approved under the low risk process and referred to the full committee of HREC shows that this subject position of the potential participant was evident. More specifically, the subject positions with respect to *voluntary participation and freedom from coercion, full information and lessening of jargon* were specifically identified by reviewing members. Additionally, given the focus of the Procedure on the assessment of *low risk* research the notion of harm to potential participants was also a key position taken.

Across the entire data set, the comments of reviewers indicate that they were concerned with the impact of the research on potential participants. For example, from the reviewer comments it could be asked, "is there a potential power relationship that was not acknowledged, could the research have flow-on detrimental effects for employment, has the participant been given all of the relevant information concerning their participation?" This is where many differences lay between the researcher's assessment of low risk and the reviewer's assessment of their application. The researchers would argue that the comments

related back to the questions posed in Section B of the flow chart and the definitions of low risk, harm and discomfort. One of the increasingly common foci of *low risk research* at CQUniversity Australia concerns the scholarship of teaching and learning where lecturers are researching their own practice. This presents a specific set of ethical issues in the relationship between lecturer and student. It can be argued that the lines between teaching and research become blurred and this is where voluntary participation and the perception of coercion is not always recognized.

Reviewer responses aligning with the need to protect the *participants' entitlement to voluntary participation and freedom from coercion* included concerns revolving around the relationship between the researcher and their participants and between the participants as a group and the identity of the participants being able to be revealed indirectly. For example concerns expressed with respect to the researcher/participant relationship included:

2010/12 *I presume< researcher> nor the other researchers are not responsible for courses that the research is about. If they are then there are issues of power differential that would need to be completed ... I do not see how this data is unidentifiable. Yes there are 670 students to be covered but they want geographical location, age, gender and course—as it is external courses so for many that would provide much information to narrow down the data.*

In the above quote it can be seen that the reviewer is concerned that the identity of the participant could be revealed through the demographic information being sought. This is possible due to students enrolling across a multi-campus university. While there may be 670 students it becomes easy to group students by campus location (10 sites), then by gender and specific course codes. Of particular concern to this reviewer is the possibility that the principal researcher or the other researchers are directly involved with the content, delivery and assessment of the courses. The perception of coercion is that students may feel obliged to participate because their grades may be affected through non-participation. By taking the subject positioning of the potential participant in this case the reviewer is able to show the researcher that kind of impact that this research may have on recruitment of participants and ultimately the trustworthiness of the collected data.

2011/11 *The context for conducting the surveys is arguably problematic: supervisors and their subordinates rating the quality of leadership in their organization and doing the survey on the job. Assurances are given that doing the survey “will not affect my employment”. What exactly does that assurance mean? And could there be an implication that NOT doing to the survey could “affect” employment? Is there some subtle compulsion here? Non-participation is likely to be obvious to colleagues?*

In this case it can be seen that the reviewer felt that non-participation would become obvious to other people within the organization or workplace. The other interesting point being raised in this review concerns the making of grand claims such as *will not affect my employment* when one is not sure exactly what that means.

The researcher does not indicate that they have spoken to supervisors within the proposed research site about possible implications of negatively rating the quality of leadership in the organization. There is also a play on the linguistic content here through the specific wording that could suggest, as the reviewer highlights, a more subtle message being conveyed that

non-participation could affect employment and that it could be known who did and did not participate in the survey.

2010/29 *I am wondering if there could be a dependent relationship. Should someone decline to be part of the research how can be assured that the data will not be included anyway or that nothing detrimental will be passed on [to] the potential employer that could come against the individual.
It strikes me that this could constitute a dependent relationship—captive audience. This leads on to point 6.1 where consent is expected but is this to be construed as informed or coercive.
There would appear to be a dual role here for the researcher—i.e. Running this type of assessment appears to be what the researcher is employed to + these assessments are being done as part of a contracted activity by the researchers employer + being used for research purposes + feeding back to <employer>.*

One of the major concerns that HREC members at CQUniversity Australia grapple with is the notion of dual roles—that of being the researcher in the workplace and that of the workplace role. Here the boundaries again become blurred for the person wanting to do the research. There is an assumption here that the findings or research outcome will be positive and will *prove what the researcher wanted to prove* through documenting agreement of those being surveyed. An underlying message here concerns possible deception in that by doing the survey the researcher is able to find those dissenting voices within a workplace. In the above review comment the notion of conflict of interest appears not to have been adequately addressed by the researcher where there is a crossover of roles. This shows the importance of the positioning of the HREC reviewer as that of the potential participant.

2011/19 *As the research involves student/lecturer relationship, this is not low risk ... Under research methodology it is stated that because she is 'naturally' assigned permission due to being [course coordinator] then no extra permission is sought. This indicates to me that the applicant does not understand the separation of [teaching and learning] in that the Moodle site is there for [teaching and learning] as the primary interest and doing research around the [teaching and learning] is different. How will the researcher deal with one person of the group not wanting to have their part used in the research? I think the dependent relationship issues means that it needs greater security as a full meeting.*

It can be argued here that a consistent pattern is developing regarding the blurring of boundaries of distinct roles of the academic as researcher and the academic as lecturer. In the *low risk* applications not accepted as such by the reviewers it can be seen that the researchers are positioning themselves in simultaneous and multiple positions, that of the researcher and that of the lecturer or line manager of the potential participants. By looking at the subject positionings of the applicant it becomes clear as to the type of risk and risk management strategies that have been considered by the applicant. Clearly the relationship between researcher / researched in the above reviews has not been fully explored by the applicant. This then brings to the fore the areas for education by the HREC when considering research training. If the applicant is unable to separate the roles then ethical issues regarding recruitment of participants have not been considered.

Concerns with respect to participants being able to be identified through the research instrument included:

2010/21 *On the questionnaire the first 7 questions are identifiers and I am not sure of the relevance with the questionnaire.*

With survey questionnaires forming the majority of data collection instruments to be used in many of the *low risk* applications it becomes obvious that many researchers are collecting a range of demographic data for the mere purpose of being able to manipulate quantitative data, so one has to question the relevance of the research and the underlying aim. Is it to test a hypothesis or is it to gain experience in data manipulation techniques associated with computer statistical packages now available? The comments by the above reviewer implies the relevance for collecting data for the sake of data that is also a way of inadvertently identifying participants by the level of demographic data being sought.

2010/41 *How will they protect the identities of participants and their business in resultant examples within the larger report? Or will all participants be identified—if so then this needs to be explicitly reflected in the information and consent forms. The consent form will need to reflect what is required of the participants—that they will be photographed and they can only withdraw up to their point of report publication etc. What happens if they agree to be interviewed but don't want their photo published?*

2011/20 *The request for participants to include their date of birth makes it identifiable.*

2011/29 *My answer is clear—I do not believe this is low risk. The nature of the study lends itself to potentially difficult issues for people around their workplace and indeed potential counseling.*

When the HREC member is sent a low risk application to assess, the initial question being asked, “Do you believe it is “low risk?”” does a specific action. It positions HREC members to just consider whether this application can be assessed as *low risk* to participants but not necessarily whether the application represents ethically sound research. This question directly relates back to Section “Discussion”.1.1.19 sub-section (c) of the National Statement (2007) explained earlier. The use of the wording in this specific question can have the effect of closing down other questions that could be raised concerning the application’s status that could invoke a less objective opinion. The second question asked is whether the risks have been adequately managed. Answering this question gives the reviewer more options to raise issues within the risk / benefit calculation. Finally the HREC member reviewing the *low risk research* application is asked to consider if they believe the research can be approved, and if so, are there any conditions that need to be imposed. With this last question the HREC member has liberty to comment on any issues they believe need to be addressed by the researcher prior to approval. Question one poses a direct yes/no question that initiates the decision-making process. Question two recognizes the premise of the National Statement where there is always risk present. The last question places the onus on the HREC member to decide conditional approval or to grant approval. These questions represent a staged decision-making procedure or a framework within which a shared understanding of how to make that decision occurs. The reasons behind the decision then

come from being positioned a decision-maker who takes up the positioning of the participant with this seen below in the comments regarding full disclosure for the participant.

Further, reviewer responses also aligned with the requirement for *full information*. Some examples being:

- 2010/4 *I think this application is not low risk and to some extent I think it is misleading. It suggests she is just collecting information on people's attitudes but in fact is collecting information on their actions and potentially on their propensity for domestic violence. The fact that she refers them to a GP if there are negative effects confirms the potential risk involved in the research. My concern is that she says smacking is a conversational issue and that is why it is minimal to no risk—however, she also makes the link between smacking and domestic violence and she wants to educate and make parents who smack their children better parents. This is not a benign low risk attitude.*
- 2010/25 *I am mostly concerned that the information sheet isn't exactly up front with participants re what the project's aim is. The application states that it is to investigate the effects of coping skills in interpretation of the athlete's anxiety during sport competitions. The info sheet states that the research is about factors that may help to answer the question of what does it take to consistently perform effectively as a professional athlete.*

By taking a linguistic approach to the wording of the review comments, the research is able to highlight the process of *meaning-making* and *sense-making* when reading text. Discourse analysis is a way of deconstructing the multiple ways in which a text can be interpreted and the multiple subjectivities available to both the applicant and the reviewer. The information sheet plays a dominant role in conveying to the participant the aims of the research and then what their role will be in that research. What is contained within the text positions the participant and also creates the expected action and interaction. Therefore the information sheet acts as the conduit between the researcher and researched or potential participant with the role of the text as one of informing the participant what is expected of the participant. In the above comments it can be seen that what is being expressed by the applicant in the *low risk* application is quite different to how the reviewer has seen the aim of the project and this is enabled by taking the subject position of both reviewer and potential participant. So in this instance the HREC member has taken up more than one subject position. In looking at the responses collected in the dataset it was shown consistently that HREC members took the dominant position of representing the interests of potential participants. More importantly however, is that all HREC members who have responded to low risk applications can be seen as working from the definitions stated in the National Statement (2007). This can be seen in the responses listed below, in particular where the reviewer has commented on the definition of *harm*.

Responses focusing on the harm that may be caused to the participants through the research instrument itself included:

- 2010/5 *I'm not convinced that this is a low-risk application, however, I would be less concerned if the researcher removed the PTSD measure (SPRINT-E) as they have suggested. No. Low risk research is defined in the statement as being research in which the only foreseeable risk is one of discomfort. Discomfort is then defined as negative accompaniment or effect of research, less serious than harm. Harm is defined as that which adversely affects the interests or welfare of an individual or a group. Harm includes physical harm,*

anxiety, pain, psychological disturbance, devaluation of personal worth and social disadvantage. I am not convinced from the application that participants will only be engaged in “discomfort”. I am more concerned that there are aspects of the “harm” definition which are present.

- 2010/8 *I don't believe it is low risk due to the nature of some of the sample statements. Answering these questions may elicit more than mere discomfort and trigger possible distress for those participants who may be struggling with mental health concerns. The research even used the term “distress” in the information sheet.*
- 2010/11 *I do not think that that application fits within the remit of the “low risk” application procedure, eliciting homophobia (even mildly by asking questions about it) has the potential to cause “harm” (as defined by the national statement—especially questions regarding feelings if ‘your’ child was gay.*
- 2010/13 *Having worked with patients with breast cancer I think that the research is quite worthy however, I do not believe it is low risk. The lay persons’ description “perceived stress and awareness etc” is certain to precipitate some emotional feelings and they could be quite dramatic and when you hit Q11 [in the survey] and talk about recurrence then this is something that is possibly very distressing to the individual.*
- 2010/14 *I think we would need to see the questions. On initial reading I would say that it is not low risk. She wants to survey a number of parents—20 min survey—presumably about stress level involved with having an ASD child. She states that the only risk is filling out [the] survey. I think this is hugely naïve ... ASD parents are often crying out for support and assistance.*
- 2010/20 *Part of the methodology involves exposing participants to a scenario in which they may experience a concept called schaudenfraude—a feeling of joy based on the misfortune of others—and therefore invoking a situation/feeling upon the participant that is considered morally wrong (as evidence by the researcher’s proposal) but the researcher does not acknowledge any potential risks with this, nor does the researcher offer any risk management with regard to this. I believe their application needs to be subjected to the scrutiny of the full ethics committee, and requires a full application to be submitted—in particular addressing the potential risk for participants through exposure to this scenario and the emotion it is supposed to elicit.*
- 2010/25 *Definitely not low-risk—the student is wanting to examine both positive and negative aspects of anxiety. I think it needs to be subject to a full ethics review, and in particular the student needs to consider how she is going to manage anyone who might develop the “emotional response” mentioned ... particularly if she is going to be approaching people she knows.*
- 2011/24 *While I agree with [the other reviewer] ... I do have some concerns about this one being considered a low risk, especially given the nature of the participant population. People suffering from chronic pain are also much*

more likely to be suffering depression and/or a number of psychological disorders and it doesn't seem that the research acknowledges the potentially fragile nature of the participant group they are proposing to work with. ...

2011/28 *Unfortunately I do not believe that risk has been addressed at all. There could be a risk if mother is struggling with postnatal depression and asked to answer regarding feelings etc. Could lead to accentuating feelings of failure. Needs to look more seriously at the fact that postnatal depression can end tragically.*

2011/30 *I am not sure about this project and will defer to the advice of other reviewers. Whether or not it is low risk depends really upon who is picked up in the survey. If somebody had a lot of stressful events, they may react badly. The research acknowledges this and ... indicates that de-briefing will take place immediately after the completion of the questionnaire. However, this does not align with the methodology where completed surveys are placed in a collection envelope. This needs clarification. If the researcher is present when the surveys are completed, [do they] have the skills to provide a debriefing ...*

A recurring theme that could apply to the quoted comments presented in this discussion is one of limited applicant positioning as the participant despite having to describe the participant experience. This indicates an inability on the part of the researcher to successfully take up the subject position of the participant. Here it can be argued that while the HREC member is having the subject position of the potential participant imposed upon them during the review of the *low risk* application, there is limited or no evidence shown that the applicant has taken that particular subject positioning when considering the risk management strategies or the likely *effect* that participating in the research would have for that person. This highlights an area of research training to be addressed and the usefulness of discourse analysis in being able to demonstrate this limitation.

Essentially part of the ethical consideration for the applicant is the communication or linguistic device required to share with the participant the expectations and understanding of the research. A comment relating to the use of jargon and the explanation of complex research included the following response:

2011/6 *This is a complex piece of research—it's certainly not high risk but I think that the non-plain English approach used makes it hard to decipher what's really going on and I also believe that asking a group of teachers about their leadership/support social networks will uncover dependencies and inter-dependencies that could be problematic—this is after all a study of relationships and from that perspective I think it needs more attention to risk and risk management than has been detailed here. The researcher has indicated that school counselors will be available—I'm not sure that entirely appropriate either—I think nonaligned support would be more appropriate ... so I think this should go to a full committee*

What is being highlighted in the text of the above response is that complex research can become high risk if the language and communication used with the potential participants is not clearly understood. If the HREC members are having difficulty with the language, then the level of plain English statements concerning the information sheet has not achieved the desired outcome. This in turn can lead to interpretations and meaning being read into texts that may or may not be present. The effectiveness of the discourse analysis approach to reviewing responses

from HREC members can deconstruct the thinking sitting behind the response and can show the subject position that has been taken up. In the above response the HREC member begins to call on their own experience when working with a group of teachers about how people may respond to the questions being posed by the researcher. In this instance the HREC member is taking up more than one subject position because there is a lack of clarity with the proposed experience of the participants. Here the HREC member is drawing on experience as an educational researcher and as someone who also worked in the school environment. What this then demonstrates is how subject positions can change due to the proposition being set out. In the end the HREC member recommends that the application go to the full committee due to their response, not as someone reviewing low risk application, but rather as someone who knows the sector and the likely reactions to the perceived aim of the research. While the HREC member could still be seen as taking the subject position of the participant, this is being driven more from a researcher subject position. Creeping in also is an element of research methodology shown in the wording “*This is a complex piece of research—it’s certainly not high risk but...*” indicating that if the researcher was to change the way of doing the research, then perhaps the aim of the research would be clarified, leading to being able to address the ethical issues arising from dealing with a group that has a particular relationship to the research site, to the researcher and to other participants.

Discussion

O’Reilly et al. (2009a, 192) concluded from their research that:

Positioning is not necessary intentional, but may nonetheless involve the active claiming of identities. Recognition of the potential implications of the positions adopted may mean that authors are less likely to position themselves in ways that they did not intend, as well as informing strategies in struggles with identity. Our findings have important implications for addressing the criticisms that have been made, in the UK and elsewhere, of the performance of RECs, including obstructing research that would be of benefit to patients, undermining researchers’ professional responsibilities and integrity, and unwarranted paternalism among other problems. Our analysis offers some suggestions that perhaps deserve consideration and evaluation.

Following from this particular analysis O’Reilly et al. (2009a, 193) suggested that:

We would argue that it is important for RECs themselves and also for researchers that RECs continues to manage their identity as one that explicitly disavows a stake in particular research projects, and that is aligned with the interests of possible participants. This is not to suggest that RECs should not be supportive of research (and the potential benefits to be gained from it) in more general terms, but rather that they should continue to demonstrate that their decisions are not influenced in any way by their own ability to benefit. Indeed, one of the positions that RECs commonly adopt is as the facilitator of ethically sound, high-quality research; yet they manage to achieve this without compromising their primary concern with the interests of potential participants. To do otherwise would, we would suggest, risk the social license for research.

The comments of the reviewers indicate that the subject position taken by members certainly adhered to the goal of determining whether the research presented in the application met the definition of *low risk* research. The process of discourse analysis has highlighted that the subject position taken by the committee members was aligned with the potential

participants. In looking at the responses it was shown consistently that HREC members took the position of representing the interests of potential participants. Again the researchers would reiterate here that all HREC members who have responded to low risk applications can be seen as working from the definitions stated in the National Statement (2007).

The researchers would argue then that the analysis shows *accountability in action* of the HREC. This is demonstrated firstly in adhering to the definitions of *low risk* in the National Statement (2007). Secondly HREC members can be seen as following the National Statement (2007) in their responsibility for protecting potential research participants. This may provide the evidence against the recurring claim that ethics committees are there as *gatekeepers* and exist to stop, or at very least, hinder research. In fact the researchers would consider that this initial research highlights that the CQUniversity Australia HREC is supportive of *good* research at CQUniversity Australia, but due to the subject positioning aligning with the potential participants, this may appear as *gatekeeping*. In reflecting on the points raised by O'Reilly et al. (2009a) concerning the need to maintain specific subject positions in relation to the research and the non-neutral relationship of the HREC as a governance body of the university, it highlights the possible conflicting roles of HREC members as protecting the interests of the institution in advocating the kind of research being done under the banner of the university and being the arbiters of *good* research. The subject positioning that receives less attention here is the one of being an educator of what constitutes ethical research, the ethics of research, plus the mentoring of early career researchers. In lessons for researchers, the main point to which many researchers may need to give further attention, is the potential impact that their research may and will have on participants, as well as developing a shared understanding of the definitions used in the National Statement (2007). This requires on-going education and dialogue among both researchers and members of the HREC. This is the first time that the comments of the CQUniversity Australia HREC have been examined in such a way so important lessons can only come from this analysis. It came of a surprise to the researchers, as members of the committee, that the subject positioning was so evident. This awareness of the position taken by committee members may, or may not be, how the committee wishes to position itself with respect to the assessment of *low risk research*. This analysis, at the very least, will allow that discussion to be had. There are however, not just lessons for the Committee. Notwithstanding, from a compliance and audit point of view this subject positioning highlights the Committee's commitment to the principles of ethical research established in the National Statement (2007). The analysis clearly reinforces the focus of the National Statement (2007) to protect research participants and that the responsibility of the HREC to this focus is obvious. This may provide evidence against the oft-repeated sentiment and claims that the HREC is seeking to prevent and opposed to the promotion research. The usefulness of the Procedure is evident in the number of applications, indeed they were in the majority, that were regarded as meeting the definition of *low risk research*.

Conclusion

This paper draws on changes in the review processes at one university. This is because the authors wanted to look closely at what was happening in our own institution with recently changed processes and because the authors were in the privileged position of being members of the Committee. The new process has been in place for only 2 years. Because this change to process is relatively recent there is

only a small range of data, however the authors believe there is enough to make an informed discussion on how this change has been effected and how the authors see these effects operationalize within the HREC. While it may seem as though the authors have highlighted shortcomings among researchers at this institution, what the authors found enormously illuminating was how the Committee could act as educators to the research community and present various perspectives to peers about the act of research. This is particularly useful in that CQUniversity has postgraduate researchers / students, both domestic and international that could benefit from increased exposure to research training. The authors believe as an HREC that there is a duty to ensure that the research being carried out under the auspices of the institution is both ethical and sound and therefore accept the position of being both active and passive arbiters of good practice.

The authors see that the results of this research will be able to assist in the discussion relating to further refining of the current definition and understanding of the National Statement definition to suit the local context.

In 2010 the Low Risk Research Procedure was implemented by CQUniversity Australia reflecting the options available for the conduct of research under auspices of the National Statement (2007). This project analyzed the written comments of HREC members reviewing applications made under the *low risk* Procedure for the years 2010–2011. Whilst the majority of applications under the Procedure were approved a number of projects were regarded as having not met the definition of *low risk research*. The reviewers' comments were analyzed using discourse analysis to understand, given the researchers' assessment, why the research project was regarded as not meeting the definition of *low risk research*. The analysis highlighted that the subject position taken by HREC members was aligned with potential participants. As this is the first time that the work of the Committee has been reviewed in such way it is anticipated that drawing awareness to the subject position taken will generate discussion by the Committee as to whether this subject position should be maintained by the Committee. The decision-making processes of HRECs are subject within the literature (see Sikes and Piper (eds) 2011) to criticism, whether well-founded or not. Arguably this analysis shows that the CQUniversity Australia HREC is supportive of research and the subject position aligning with the potential participants demonstrates the Committee's commitment to the research ethics framework required by the National Statement (2007). Whilst this paper reports on data from one operating HREC the researchers argue that the significance of the research lies in the fact that the work of HRECs is nationwide and the research assessment framework is governed by the National Statement (2007).

The results from this initial study highlight further avenues of data collection, namely interviewing Committee members to investigate their decision-making. As the Committee comprises a range of people representing a broad community and an enormous range of both expertise and experience it would be very interesting to explore the ways in which they weigh up the different applications; especially as the discipline and institutional backgrounds vary and members do not necessarily review research applications in their own discipline. In the end what this research has highlighted to the authors is the way a process such as undertaken here can act as a way of reviewing own practice and to determine what it is the Committee does to be accountable to the National Statement and guidelines for research.

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