



### Abstract

Going through Research Ethics Boards (REB) and being held accountable to the highest ethical standards to conduct research with human subjects is commonplace. The goal of such a process helps ensure the selection and achievements not only of morally acceptable ends, but also of acceptable means to those ends when conducting research. Ultimately, REBs must pass judgment about the acceptability of harms and benefits to participants as they relate to research processes and outcomes. In this paper, we explore the implication of integrating “institutional reputation” as a category of analysis in the ethical review process. Informed by a recent Research Ethics Board (REB) review, we seek to engage with the readership in a constructive reflection on the concept of institutional reputation as a source of conflicting interests in research ethics review process.

**Key words** dual loyalties, ethics, nursing, reputational risk, qualitative research

## Conflicting interests: Critiquing the place of “institutional reputation” in research ethics reviews

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### Introduction

Going through Research Ethics Boards (REB) and being held accountable to the highest ethical standards to conduct research with human subjects is commonplace. The goal of such a process helps ensure the selection and achievements not only of morally acceptable ends, but also of acceptable means to those ends when conducting research. Ultimately, REBs must pass judgment about the acceptability of harms and benefits to participants as they relate to research processes and outcomes. In this paper, we explore the implication of integrating “institutional reputation” as a category of analysis in the REB review process. Informed by a recent REB review, we seek to engage with the readership in a

critical reflection on the concept of institutional reputation as a source of conflicting interests for REBs. Using a case report format, we provide an initial account and discussion on the subject matter, including implications for future research. To do so, the paper is divided in three sections: in the first and second sections we provide a description of the “case” by presenting a general overview of the project submitted to the REB, followed by a review of the REB process and feedback as it relates to “institutional reputation”. In the third section we engage in a discussion of the “case” using current works on reputational risk,[1] dual loyalties,[2] sensitive research,[3] and current ethical standards for REBs in Canada[4].

### Section 1: Project overview – Use of control measures in psychiatry

Informed by international debates on the use of control measures in psychiatry, we developed a problem statement that questioned current psychiatric practices and problematized the use of coercive interventions such as seclusion and restraints (both physical and chemical), but

also other forms of exceptional intervention such as forced hospitalization and treatment. This problem statement stemmed from well-documented detrimental effects of control measures use on patients, health care providers as well as the health care system in general.[5-7] Two recent intervention reviews from the Cochrane library assert that there is no evidence that seclusion and restraint have any therapeutic effectiveness.[8,9] By contrast, the negative effects of these interventions are well documented. Apart from various physical and psychological consequences, patient experiencing restraints/seclusion are at risk of sudden death,[10-12] increased length of stay[6] and are less likely to improve clinically than patients who experience more patient-staff interaction.[7] And even though control measures are intended to be methods of last resort for preventing self-harm or harm to others and continue to be considered controversial practices, their use remains relatively common in practice, particularly in psychiatric environments, to manage patients with challenging behaviours. For example, in Ontario, Canada, close to one in four patients admitted to mental health beds between April 2006 and March 2010 experienced at least one type of control interventions during their hospitalization.[13]

In parallel, the notion of "least-restraint" has guided contemporary healthcare policy and legislation nationally (across Canadian provinces) and internationally. In Ontario, Canada, for example, there exists a *Patient Restraints Minimization Act* that is intended to "minimize the use of restraints on patients and to encourage hospitals and facilities to use alternative methods, whenever possible, when it is necessary to prevent serious bodily harm by a patient to himself or herself or to others".[14] Although the application of legislation may vary in different organizations to the extent that "least-restraint" policies and procedures may lead to different types of interventions, it nonetheless serves as a unifying principle on which professional practices should be developed and applied. On the international scene, and of particular

importance for this study, a publication in 2013 by the Special Rapporteur on Torture for the United Nations, Mr. Juan M. Méndez, condemned the use control measures in psychiatry, calling for a radical shift in current psychiatric practices.[15] This publication led to fierce debates internationally, including a revision of the original statement by Méndez,[16] albeit very little discussion in Canada. In Germany, for example, the report was integrated to ongoing critiques of coercive practices in psychiatry. As Zinkler[17] explains, moving towards a least restrictive psychiatric system in Germany was well underway in 2011, when coercive treatment in certain German states had been declared unlawful by Germany's Constitutional Court. In effect, this legislative change "effectively stopped the use of coercive antipsychotic treatment in these parts of Germany.[4] It was not the view of the Constitutional Court that coercive treatment per se was unconstitutional but rather that the criteria under which it could be given were far too wide".[17 p1] In 2012, these rulings were extended across Germany by its Federal Supreme Court, resulting in an outcry of protests from various groups, including Germany's professional association for psychiatry. This wave of protest eventually led to a softening of federal law, allowing coercive treatment to take place under strict criteria. What is important to understand here, is not so much the final outcome, but rather the debate that took place following publications of "least restrictive" legislative changes and position statements - including the report from the UN Special Rapporteur published in 2013. In light of these debates, psychiatry as an institution was forced to look inwards and engage in a debate which vehemently criticised its therapeutic foundation and the caritative nature of its interventions. The extreme changes in legislation and overall constraints on psychiatric practices as a whole created a space for dialogue and forced various stakeholders to "think outside the box", and envision the possibility of a different kind of psychiatry - as it was originally intended by Méndez[15].

Drawing on these international debates, the project aimed to

Table 1: Interview Guide - United Nations Declaration (Sample)

**"The mandate has previously declared that there can be no therapeutic justification for the use of solitary confinement and prolonged restraint of persons with disabilities in psychiatric institutions; both prolonged seclusion and restraint may constitute torture and ill-treatment (A/63/175, paras. 55-56). The Special Rapporteur has addressed the issue of solitary confinement and stated that its imposition, of any duration, on persons with mental disabilities is cruel, inhuman or degrading treatment (A/66/268, paras. 67-68, 78). Moreover, any restraint on people with mental disabilities for even a short period of time may constitute torture and ill-treatment. It is essential that an absolute ban on all coercive and non-consensual measures, including restraint and solitary confinement of people with psychological or intellectual disabilities, should apply in all places of deprivation of liberty, including in psychiatric and social care institutions. The environment of patient powerlessness and abusive treatment of persons with disabilities in which restraint and seclusion is used can lead to other non-consensual treatment, such as forced medication and electroshock procedure . ." (Méndez, 2013, p.14)**

not only try and explore how the culture of "least restraint" in psychiatry is operationalized and becomes manifest at the point of care, but also open the discussion to try and see if other ways of doing could be imagined in relation to current psychiatric practices. In other words, we not only attempted to understand the ways in which nurses operationalise and make sense of control measure in their practice, but also attempted to create a space for dialogue with respect to the ways we engage with concepts of risk, danger and violence management in psychiatry more generally. In order to do so, excerpts from the 2013 report from the United Nations' Special Rapporteur on Torture were introduced to our interview guide so it could be read by the research participants (nurses) – see Table 1.

We opted to work with the initial version of the report, as opposed to the 2014 [16] revision of the position, as it represents a radical shift in the way we think of psychiatry (i.e. move towards community resources and an absolute prohibition of restraint and seclusion) and was the initial position that fostered international debate on the question, including a joint position by the World Psychiatric Association and American Psychiatric Association [16].

After reading the excerpts from the 2013 report from the United Nations' Special Rapporteur on Torture, participants were asked questions to foster a professional discussion/reflection – see Table 2.

As part of a reflective exercise, this section of the interview sought to create a hypothetical space from which participants, in this case nurses, would be forced to think of their practice outside the current legislative structure – try and envision a practice without control measure and see if it was even possible or feasible for them.

## Section 2: REB review process and feedback

On March 22nd, 2016, our project was funded by a research institute. We subsequently submitted our protocol to the Research Ethics Board of the Hospital where the study would take place. From an ethics standpoint, the project was

considered to be minimal risk given that it included interviews with health care professionals (nurses) and a separate chart review (not linked to participants taking part in the study). In short, the REB review process took 9 months, 3 resubmissions and 2 formal in-person meetings with the full REB before we obtained REB approval for the project. The following are excerpts of feedback provided by the REB on which we draw to unpack the dimensions of institutional reputation as it unfolded in the review process. All excerpts have been translated into English for the purpose of this paper.

### Selective Feedback Review 1:

In a section entitled Research Protocol, the reviewers speak to the potential risks associated with the study:

*Excerpt:*

6. Risks and their management should be better explained in order to minimize their probability of occurrence. The REB has identified three risk groups: (1) those that specifically affect participants / patients; (2) those affecting the interview participants; (3) those affecting the protection of the reputation of [the Hospital]. Identification, quantification of the likelihood of these risk materialising as well as the means to reduce them, is one of the fundamental ethical responsibilities of researchers. [...]

An elaboration of these perceived risks were further detailed by the reviewers in the section that specifically addressed the Consent Form:

*Excerpt:*

Research team members must identify the risks to which participants are exposed. In this case the residual risk to the institution must also be assessed, particularly when disseminating research results internally, both to institutional members and to external groups listed on page three (3) of the consent form [...]

*Excerpt:*

Please specify what you will do with the various data collected particularly in the situation where they could have an impact on the employment of professionals in this care setting.

Table 2: Interview Guide – Reflective Questions

**a) What are your impressions of this statement?**

**b) In your opinion, how would it be possible to work in psychiatry without the use of any methods of control (pharmaceutical, physical, confinement, others) or how do you imagine a psychiatric practice without the use of restraints/seclusion?**

**c) If you had unlimited means, financial or institutional, to change the current practice in psychiatric nursing, what changes would you make?**

The feedback provided sought to ensure that the anonymity of both participants and the institution would be protected in dissemination activities. However, a particular attention was drawn to the potential identification of reprehensible actions through the interview process and how these would be managed.

In responding to the reviewers, the research team sought to reassure the REB with respect to the explorative nature of the project, rather than being an evaluation of current institutional/professional practices derived from a normative framework. In other words, the details of our answer addressed both the interview process and the outcomes of the research; that is, how we would deal with a person reflecting on a reprehensible practice, while concurrently explaining how information would be treated in the public sphere (ex. anonymization of participants and the research site in future publications).

### Selective Feedback Review 2:

In the following review, a distinct emphasis was drawn to the importance of ensuring institutional reputation, as it became very clear that the subject of the research was considered sensitive and potentially damaging to the institution, should the result of the research reveal, we can only assume, some kind of unethical/illegal practice.

#### *Excerpt:*

The REB would like the following documents to be modified in accordance with the indicated recommendations and to provide or clarify the explanations requested concerning the various aspects of your research project listed below:

The team responded to a few questions and issues raised by the REB. However, the REB believes that there are still major issues that remain unanswered:

Institutional protection (risk management)

1) The REB is concerned because the documentation submitted does not support the conclusion that the institutional risks generated by the research are being managed. Please answer the following questions:

- The links that will be made between the data sources and the interpretation of institutional practices are not sufficiently discussed to allow the REB to conclude that the institution is protected.
- Please indicate what steps will be taken when publishing and disseminating the results for the institution to be protected.

From a methodological standpoint, there was a direct request to remove reference to Mendez's[15] document in the interview guide:

Excerpt:

2) Please confirm that the extract from the text of the United Nations declaration has been removed from the questionnaire. If so, please submit a revised version of the tool.

The events that transpired during this review clarified the nature of the REB's concern. A third review specifically addressed the issues of introducing the Méndez's[15] document to the research project, questioning its validity and its potential effects on professionals (potential feeling of culpability) who would read it during the interview.

### Selective Feedback Review 3:

Excerpt:

We did not find an analysis plan that indicates how information about the response to the UN quote will be handled. It is not known if and how the identity of the institution will be protected. For example, if the publication were to lead to the conclusion that torture is being practised in [the Hospital], it would not only be the institution's reputation that would be at risk, but its ability to provide care, as potential patients might fear going there to obtain the required care, which would increase the risk for them.

Excerpt:

The statement in section 10 indicates that the UN condemns the use of constraints while the referenced document is a report submitted by a working committee. The REB did not find the reference that supports this interpretation.

The research team was also presented with Provincial Court documentation supporting the legality of control measures in order to, somehow, counter the elements presented in the research proposal. The discomfort from the REB was most notable when the President of the REB brought the project to the CEO of the hospital, who then contacted the Scientific Director of the funding agency in order to convene a private meeting with the research team (the principal investigators). Despite being a clear transgression of REB functioning standards [4], it is at that meeting that we learned the hospital's reluctance to use a document that alluded to torture in the context of a research project being conducted in their institution and having little control over the way it would be used in the analysis. At this meeting, possible avenues requested by the institution were the censorship of the research – a declaration of non-publication - and/or a removal of any reference to the 2013 UN report [15]; requests to which the research team was firmly opposed. We continued to engage in a dialogue with the REB, by e-mail correspondence and in person, to finally receive approval of the project without censorship, but

with the addition of a preamble in the interview guide and a firm reassurance from the research team as to how the UN report[15] would be used in the analysis – see Table 3.

In hindsight, it is evident that a perceived threat to the institution and to the participants was the potential normative way in which the UN report would be used in the study. Not only did a lawyer on the committee explain that the UN declaration did not have force of law in Canada, it should not be considered as a document on which current practice could be analyzed. In other words, there were concerns about the way the UN document would be used as a normative frame to analyse the data, but more importantly, how it could potentially negatively portray the institution and the practice of its employees, should it be associated with acts of torture. Needless to say, the feedback provided gave way to constructive reflections on issues regarding sensitive research topics and role REBs play in managing reputational risk.

## Discussion

It is relatively well known that before the 1950s, there were very little governmental oversight in regulating research. From the famous Tuskegee syphilis study in the 1932, to inhumane procedures in the name of clinical research during World War II, and the treatment of morning sickness and insomnia in pregnant woman with thalidomide in the 1950s, we witnessed the production of international guidelines in the conduct of research involving human subjects; that is, in response to highly publicized tragic events, often involving the rights of vulnerable people in the name of research, fundamental principles were endorsed in such documents as the *Nuremberg Code*, the *Declaration of Helsinki*, and *The Belmont Report* to ensure the protection of human subjects involved in research – notably the need for voluntary and informed consent, a favorable risk-

to-benefit analysis, protection of confidentiality, etc.[18] These principles, in addition to the National Research Act of 1974 in the United States, paved the way for the regulation of research by REBs.[18] In Canada, the first attempt to produce ethics guidelines was in 1978 by the Medical Research Council (MRC), and then again in 1987, while the Social Sciences and Humanities Research Council (SSHRC) did so in 1981. It was in 1998 that the MRC, Natural Science and Engineering Research Council (NSERC), and SSHRC adopted what is now coined the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*,[4] which has become the official document that governs research involving humans and serves as a reference in the attainment of the highest ethical standards to conduct research.

Today, the policy statement contains clear guidelines with respect to the establishment and conduct of REBs - including the need to operate independently in their decision making; that is, be free of inappropriate influences and conflicts of interest, real or perceived. As an element to consider when reading this paper is the place in which ethics reviews are conducted. In the case reviewed in this paper, the first REB to review the project was within the hospital where the study took place, rather than within the University. Although this is not always the case, moving towards the institutions as a primary site for REB review may arguably create greater potential for conflict and new forms of power relations in the evaluations of research projects. On this particular point are the possible institutional conflicts of interest highlighted in the Tri-Council Policy that may influence the evaluation of risk, including reputational interests that may conflict with institutional obligations to prospective participants. The question of reputational risk is introduced three other times in the Tri-Council Policy, so as to ensure researchers are

Table 3: Interview Guide – Preamble

**Before continuing with the interview:**

**Before you read the position statement of the UN Special Rapporteur, I would like to reiterate that the use of control measures in Ontario is legal. That is, they can be deployed as a last resort intervention and are regulated by law as well as your professional standards of practice. As nurses, we have all used these measures in our practice.**

**The purpose of this reading is to reflect on our practices. Among other things, the text makes parallels between control measures and acts of torture and ill-treatment insofar as they are imposed on a vulnerable population against their will.**

**The position taken by Mendez (2013) led to a heated international debate among many health professionals, psychiatrists in particular, who criticized this statement.**

**In the next section, we ask you to read excerpts from the statement and then give us your impressions.**

**It is important to note that even if the Special Rapporteur describes these acts as reprehensible, we do not in any way suggest that you took part in a non-ethical or illegal practice.**

equally aware of the potential detrimental effects of their research on participants, groups and/or other entities (such as institutions). These provisions, for example, speak to the need to ensure confidentiality in cases where the research topic is considered sensitive (e.g. illegal activities) to ensure trust with participants.

In any case, it can be taken for granted that REBs display a general aversion to risk; that is, their main objective is to protect potential participants from potential harm associated with proposed research projects. Despite its common usage in healthcare,[19] however, the concept of risk, and more importantly, how it comes to be operationalized in practice remains relatively undertheorized. As Furedi[20] explains, while publications on the topic of risk proliferate, we do not have a good understanding of the concepts on which it relies, such as fear (perceived threat). The main point being, that risk has no objective meaning by itself, and must always be understood in the context in which it is being discussed/formalized. According to Ewald, risk finds all of its meaning in cultural scripts, to the extent that 'everything depends on the shared values of the threatened group. They are what gives the risk its effective existence'.[21 p225] As such, identifying whether something or someone is at risk (or not) from an REB standpoint, must be understood as a contextually bound process. For this paper, the question of reputational risk raised by the REB cannot be overlooked and warrants further reflection. It is clear that the REB's interrogations have merit, to the extent that researchers must consider its place in the overall process and outcomes of the research project. What is less evident and somewhat silent, however, is the way reputational risk has come to take a predominant place in the REB review process and, arguably, overshadow any potential benefit to the research, such as exploring least restrictive way to engage in patient care. It further problematizes the capacity of qualitative researchers to conduct research on sensitive topics, as Perron, Jacob and Holmes[22] have previously discussed in the context of conducting critical research projects in forensic psychiatry. In effect, their work speak to an ethical problem, where REBs are becoming gatekeepers for institutions, as they envision potential threats associated with disruption of the status quo.

Here, we draw on the work of Adam Hedgecoe[1] who has come to problematize the place of reputational risk, academic freedom and research ethics reviews. Although Hedgecoe's work primarily problematizes the work of REBs within the University structure, his reflections can be applied to other contexts, as he suggests that these committees are increasingly coopted to serve as mechanisms for institutional reputation management – somewhat of a departure point

from traditional ethics review, which focus on the researcher's role in protecting participants. As Hedgecoe[1] explains, the introduction of reputational risk assessments within research ethics is largely based of the influences of risk management practices from the private sector and high profile corporate scandals – where management of "reputation" has emerged within organizational practices to mitigate risks to external reputation. That is, "reputation" has come to reflect a new space of vulnerability – one that has created new demands to make it manageable from and institutional standpoint. The challenge then is to try and "understand how the logic of reputational risk management is beginning to percolate and pervade internal control and risk management agendas";[23 p4] and in so doing, look at the ways in which the REB, and to some extent the "vulnerability" of participants, are being instrumentalized in the process.

In reflecting on the role that the REB played in the current analysis, we cannot ignore the emergence of a new form of "double loyalties", where there is an emphasis put on reputational risk in relation to the risk posed to research participants. The problem of dual loyalty in this case is the fact that we are asking to weigh the benefits of the research for the participants (or patients in this case) against the objectives and reputation of the institution. For this case report, the issue of torture in mental healthcare was a sensitive topic and seen as potential threat to the institution.[3] As a result, the challenge faced by our research team was very much linked to this perceived threat where participants' interests and potential benefits to the population (i.e. patients who experience control measures) were being outweighed in favour a maintaining the status quo due to envisioned reputational risks – thus creating an issue of double loyalties for researchers, and we would argue, REBs as well. REBs are now positioned to not only take it upon themselves to protect human subjects, but also institutions, a reality that may very well highlight conflicting interests.

The concept of dual loyalty in healthcare is not new. It has taken on many forms, from critics of military physicians in complicity with abuse and torture in Guantanamo, to more common professional tensions of care and custody in the context of forensic psychiatric care.[24-26] Generally speaking, dual loyalty stems from an ethic of undivided loyalty to the welfare of the patient.[2] In practice, however, health professionals often have obligations to other parties besides their patients – such as family members, employers, insurance companies and governments – that may conflict with undivided devotion to the patient. In the context of an REB review, dual loyalties become problematic when the interests of the institution are imposed in a manner that may come to violate this devotion

to participants/potential beneficiaries. herein this context, it is not an overt ethical violation that we are talking about, but rather an insidious one - one that would ensure the status quo in avoiding to engage in a dialogue about current practices in psychiatry; one that would negate the possibility of creating an alternative discourse to the experience of being restrained; one that would perpetuate medical dominance over patients by limiting, through the REB, the production of knowledge that goes against current ways of doing.

### Implications for research

Engaging in research on sensitive topics may pose a risk to host institutions in that their practices may become amenable to the scrutiny of outsiders. As a result, researchers may see the scope of their study limited, modified or even denied by research ethics boards because of the perceived threat the research may pose in challenging, disrupting or making public current ways of doing. Keeping in mind current emphasis on institutional reputation as criteria in REB reviews, it is important to consider its potential implications for research.

Engaging in research on current practices in health care is necessary; that is, there is a need for clinicians and researchers alike to be critical of current practices in order to ensure that they are, in fact, responding to their patient's needs. However, in looking at the role "institutional reputation" plays in the possibility of engaging in certain types of research, we come to question the neutrality of such an endeavour, where some topics may prove to be worth investigating, but too risky for the institution to endorse. Here, we can appreciate the complexity of opposite logics at play, where patients' best interests (the care they are provided) are juxtaposed to the institution's reputation. This may include the risk an institution sees in their employees using research projects as a means to disclose institutional issues and losing control over the messages are shared with the public sphere. In a previous publication on the politics of threat in correctional institutions, Perron, Jacob and Holmes[22] addressed ways of working within current institutional REB processes to make sensitive research possible. A large portion of their discussion had to do with maintaining independence as researchers, so as to ensure the ability to publish uncensored results - a position that may very well block sensitive research from even taking place in certain settings. This condition, however, is the result of recruitment and/or data collection needing to take place within the institution and, as result, grants the institution's review board the possibility to impose parameters on what constitutes a risk to the institution's reputation, and the ways in which researchers must mitigate this risk. However, given

the evolving ways of conducting research, and if flexibility in recruitment is possible - such as engaging in recruitment outside the institution through social media, regulating bodies, public advertisement, etc. - institutional capacity to influence the research process could greatly diminished and allows for increased independence of the researcher. Evidently, this process does not negate researchers' obligations toward participants or the need for ethical review, but it nonetheless offers an opportunity to move away from conflicting interests that may be at play within institutions themselves.

The nature of any sensitive research topic gives rise to particular tensions regarding the potential threats of research to an institution. In this sense, research becomes the site of a political struggle, where ethics and politics are difficult to untangle. By exploring a case example where institutional reputation was used as a category of analysis in the ethical review process, we are able to appreciate the difficult and possible irreconcilable gap that exists between one's ethical commitment to potential beneficiaries of the research (ex. patients) and the institution's need to avoid risks to its reputation if the research was to take place and yield unfavourable results. As such, finding new ways to ensure independence of researchers and their projects may be one way to avoid the creep of institutional reputation as a deciding factor in the conduct of research.

### Final remarks

In this paper, we explored how REBs are being integrated in the management of institutional reputation, creating a certain conflict of interest. That is, the REB is becoming a tool, or gatekeeper of reputation having multiple effects on the ethical process review, including potentially new forms of perceived vulnerability. In our case, the interview, where professionals where to engage with emerging "least-restraint" international discourse in relation to their practice, became a potential threat for the institution, to the extent that professional and organizational practices would potentially be subject to public scrutiny and criticism.[3] In our reflection, we are forced to ask ourselves what are the ramifications of this new form of risk management and to whose' benefit? On a larger scale, this paper adds to the body of literature documenting the difficulties of conducting qualitative research on sensitive topics, where projects are being overly scrutinized by institutions who wish to have control over its outcomes.[22]

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