The Long Arm of Administrative Law: Applying Administrative Law Principles to Research Ethics Boards

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I. Introduction

Commentators have described the primary responsibility of research ethics boards (REBs) as that of ensuring that research projects involving human participants commence, or continue, only if the participants "are adequately informed, freely consent to participate, and ... are not exposed to unreasonable risks of physical, social, psychological and economic harms that might occur as a result of participation."[1] Whether REBs have the authority needed to perform this responsibility is a question that has animated much of the recent discussion over governance of the Canadian ethics review system. That discussion has been largely premised on a belief that the current system operates in an *ad hoc* fashion, without legislated mandates or enforcement mechanisms.[2] While this may accurately describe the system's evolution, it no longer represents the reality. REBs increasingly operate under mandates derived directly or indirectly from statute law. To the extent REBs derive their mandate from statute law, certain legal duties are likely owed to persons affected by their decision-making activities that deserve more attention than they have received to this point. These duties arise from administrative law, the domain of legal principle that governs the exercise of powers derived from delegated state authority. That administrative law should have an increasing influence on the development of research ethics review in Canada seems appropriate, given the important public interest role assigned to REBs, and the potential impact of their activities on members of the research community and participants in biomedical research alike.

The paper is not an exhaustive treatment of the implications of administrative law for research ethics review in Canada. Rather, the goal is the more modest one of suggesting that this is an important area of legal concern that holds both promise and pitfalls, and should not continue to be neglected. The purpose of this overview, then, is two-fold: (1) to demonstrate the applicability of administrative law to much of what is currently occurring in research ethics review in Canada, particularly in university and hospital-based REBs; and (2) to show that administrative law can have a significant impact on the review of biomedical research and, consequently, on the interests of relevant stakeholders (researchers, research institutions, sponsors, research participants, the public, and REBs themselves).

Biomedical research involving human subjects that takes place within Canada's public universities and hospitals is presently subject to two ethics regimes: the *Tri-Council Pol-*

icy Statement: Ethical Conduct for Research Involving Humans[3] ("TCPS") and the *Guideline for Good Clinical Practice E6 (International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use)* ("GCP").[4] While neither the TCPS nor the GCP have the status of self-applying legislation, there is considerable reason to believe courts would look to these instruments as establishing minimum standards for REB performance.[5] The key question is whether the REB in question is itself subject to administrative law obligations. University and hospital-based REBs operate in an area of some ambiguity in this regard. In our view, most would likely be subject to administrative law on one or more of the following bases: they derive their authority from parent statutes which permit university and hospital boards to create internal bodies with mandatory powers; they operate at least indirectly under government control, through research funding agreements; and they serve important public purposes within a statutory context. Part II of this paper explores these arguments.

In addition to the TCPS and GCP (but often incorporating them), Canadian law-makers have enacted several statutory mandates regulating different facets of health research involving human subjects. The following legislative mandates authorize REB activities that should be subject to administrative law duties:

> the *Clinical Trial Regulations,* applying to tests of new pharmaceuticals;[6] personal health information legislation in Alberta and Ontario;[7] the regulation of medical professionals engaged in human participant research in Alberta and Quebec;[8] and the Quebec *Civil Code* provisions requiring ethics review for research involving minors or persons incapable of giving a competent consent.[9]

University and hospital researchers may find themselves subject to one or more of these legislative regimes in addition to the TCPS and GCP. In Part III, we describe the first three of these regimes.

Having concluded that many, if not most, Canadian REBs come within the scope of administrative law principles, Part IV discusses several principles that have particular relevance to the activities of REBs.[10] Part V addresses the nature of judicial review, and how and when courts may exercise their supervisory jurisdiction over REB activities. Brief concluding remarks are provided in Part VI.

II. The Applicability of Administrative Law to Research Ethics Review

Administrative law is comprised of a set of common law principles[11] that govern the exercise of public power in Canadian society. Public power can be conceptualized as the making of authoritative decisions affecting the rights or interests of persons in civil society. Rule of law theory holds that statutes enacted by democratic legislatures acting within their constitutional powers are the sole source of legitimate authority to make such decisions. Developed by the superior courts through the mechanism of "judicial review", administrative law imposes two principal duties on decision-makers: (1) to make decisions in a procedurally just or fair manner; (2) to make decisions which in substance respect the jurisdiction conferred on them by legislators. This paper confines its discussion to the first set of duties, because they have the greatest impact on how decision-makers actually function.

A person exercising a power delegated by statute is *prima facie* subject to administrative law. Since legislatures may lawfully delegate statutory power to any person of their choosing, it does not matter whether the empowered entity is public and subject to control of executive government, or private. Professional regulatory bodies, such as provincial law societies and colleges of physicians and surgeons, are private entities to which the legislature has delegated powers to be exercised in the public interest. A "statutory power" refers to something more than merely being incorporated under statute, which is true of all registered corporations and non-profit societies. It refers to a specific power to make authoritative decisions in the public interest. Activities of a private nature, such as contracting, are generally not subject to administrative law, regardless of whether the person engaging in the activity is a body incorporated under statute or an emanation of executive government.

Administrative law obligations apply to decisions that hold the potential to seriously affect individual rights or interests. This threshold of "serious effect" is not high, and essentially means that courts will not intervene to protect minor or trivial harms to persons' interests.[12] With respect to research ethics review, those whose interests may be adversely affected include researchers, research institutions, sponsors of research, and the individual research participants. While the latter might encounter an obstacle with respect to their standing to seek judicial review of REB decisions (see Part

V, below), there is little question that the interests of all the named stakeholders are sufficiently serious to meet this threshold. For researchers and the institutions that employ them, those interests include career paths and reputations.

With these general principles in mind, we turn now to look more closely at the source and nature of the decision-making functions of university and hospital REBs.[13] The general position is well summarized by David Mullan:

> [T]here also exist many examples, particularly in the provincial domain, of bodies that owe their existence to statute and which, while structurally independent of government, nonetheless perform functions that are sufficiently governmental or public in their nature as to attract the attention of public law. Among the most prominent of these agencies of public policy are universities, hospital boards, and professional organizations. Despite their historic status as autonomous, self-governing bodies, they have been transformed over the years, largely through legislative appropriation and, in many instances, government funding, into bodies that possess an array of regulatory powers in matters of great significance to the polity at large.[14]

While this passage implies, correctly we believe, that many decision-making activities undertaken at universities and hospitals are subject to administrative law, the situation is not entirely straightforward. The importance of self-governance to universities, especially in terms of protecting the value of academic freedom, has sometimes led Canadian courts to be reluctant to bring universities fully within the scope of public law.[15] In 1990, the Supreme Court of Canada surprised many by ruling that neither universities nor hospitals fall within the term "government" so as to make them subject to *Canadian Charter of Rights and Freedoms*.[16] The Court later ruled in *Eldridge v. Vancouver General Hospital*[17] that hospitals *are* subject to the *Charter* when providing health services to the public, because in doing so they are carrying out a specific government program. The precise ambit of the "government program" rule for hospitals, and for universities, remains uncertain. The scope of the *Charter* and of administrative law, as two important components of public law, closely track each other, but are not identical. What the *Charter* cases demonstrate is that in any particular set of facts, there is a need to analyse closely the individual statutory powers and services in play in order to determine whether public law duties will be imposed on university or hospital decision-makers.

(a) University REBs

Canadian universities have sought to comply with the TCPS by establishing or formalizing internal research ethics review processes. All research involving human participants funded by Canada's three major public funding agencies – the Canadian Institutes of Health Research (CIHR), the National Sciences and Engineering Research Council (NSERC), and the Social Sciences and Humanities Research Council (SSHRC) – is subject to research ethics review pursuant to conditions imposed by the Councils under the TCPS. The TCPS creates minimum standards for substantive review of research proposals,[18] requires a standard composition for REBs, and establishes procedures to be followed by REBs.[19] The enabling statute of each Council empowers it to fund research activities, with an implied power to place conditions on its funding.[20] The Councils are also authorized to establish committees to advise them on funding policy. Of the three Councils, the CIHR is the only one with an explicit statutory mandate with respect to research ethics.[21] Within this framework, the Councils do not themselves operate REBs. Rather, they require funded institutions to do so as a condition of receiving and retaining research funding. Council decision-making largely relates to policy matters regarding funding, individual funding decisions, and monitoring compliance with funding conditions.

In general, the authority of universities to establish REBs derives from their governing provincial statutes.[22] Typically, these statutes empower boards of governors and faculty councils to make decisions affecting academic affairs at the institution, and to sub-delegate certain of those decisions. To the extent this describes the basis for REB activity at a university, it will be seen as acting pursuant to statutory power. It is important to note that review of research involving human participants is not optional for faculty members, and the decisions of REBs to reject a research proposal are not merely consultative. In order to comply with the TCPS, universities are required to make the system a mandatory feature of faculty employment. The fact that university REBs perform this role, at least partly, in order to satisfy Memoranda of Understanding entered into with the funding Councils,[23] which Memoranda may be enforceable as contracts by a Council, does not detract from their otherwise having the status of statutory decision-makers vis-á-vis those whose interests they affect.

Other internal university decision-making processes have been made subject to judicial review. This includes decisions dealing with student discipline and academic standing.[24] While courts have expressed more reservations about extending their supervisory role to faculty tenure and promotion processes, matters largely governed by collective agreements, there is now a well-established jurisprudence holding that faculty employment matters are subject to judicial review.[25] REB decisions can have serious impact on issues going to research records, promotion, and reputation, the same issues that contribute to tenure decisions. They should similarly be subject to administrative law.

One additional point may be worth mention here. Much of the reluctance of courts to intervene in internal university affairs relates to an understandable concern about second-guessing the substantive reasonableness of decisions which go to the evaluation of research quality or scholarship. We can expect judges to continue to extend considerable deference to university-based REBs in these areas. The same degree of reticence should not be expected with respect to issues of procedural fairness on the part of REBs, when exercising authority over individual career prospects, and in the cause of serving the public interest in the integrity and safety of human participant biomedical research.[26]

(b) Hospitals

A similar analysis should apply to research ethics committees established by hospital boards. Matters that concern internal management, such as the purchasing of supplies and labour relations with non-medical staff, are not generally subject to administrative law. However, a series of cases have concluded that internal decisions concerning hospital privileges of physicians, will be reviewed by the courts. This includes *Hutfield v. Board of Fort Saskatchewan General Hospital District No. 98*,[27] where a committee decision denying privileges to a physician was quashed for breach of procedural justice.

As with universities, the reputation and ability of hospitals to obtain research funding is subject to a significant degree of government control through Health Canada's requiring GCP compliance. Ethics review of clinical practice issues at public hospitals continues to be largely a consultative exercise, without binding force on clinicians.[28] As such, it is not likely to be subject to public law duties.[29] This is not the case for research ethics review, which is mandatory and determinative.

III. Recent Proliferation of Statutory REB Mandates

We conclude that university and hospital REBs likely owe administrative law duties when carrying out ethics reviews pursuant to internal bylaws and policy, and in compliance with the TCPS and GCP guidelines. If uncertainty remains in that respect, there is no doubt that Canadian governments have been moving to clothe these and other REBs with express statutory authority over ethics review, for a variety of purposes. This Part provides a brief overview of three such mandates. It is highly likely that when acting under these mandates, REBs indeed fall within the scope of administrative law.

A. Clinical Trial Regulations to the Food and Drugs Act

The *Clinical Trial Regulations* require sponsors of clinical trials for new drugs to obtain the "approval of the research ethics board"[30] for each research site. REBs serving this function must be comprised of a membership similar to that set out in the TCPS.[31] However, the *Regulations* do not otherwise designate specific REBs to serve this role. The requisite ethics review can therefore be provided by any entity, whether affiliated with a public institution or operating in the private sector. The only limit is that the REB not be affiliated with the sponsor of the trial. Private companies such as Institutional Review Board Services (IRBS) currently provide ethics review services to satisfy the *Regulations*, as well as American and international standards.[32]

The *Regulations* charge REBs with reviewing the sponsor's research protocol and informed consent form. REB approval is a required element in the sponsor's application for authorization by the Minister of Health, which must include a separate statement that the trial will be conducted in accordance with "good clinical practices." The latter is defined in part as "generally accepted clinical practices that are designed to ensure the protection of the rights, safety and well-being of clinical trial subjects and other persons", which likely effectively incorporates the GCP.[33] The *Regulations* do not otherwise set out substantive criteria to be applied by REBs in their review function.

The legal status of REBs performing reviews under the *Regulations* is ambiguous. This follows from the unusual situation of a delegation of decision-making authority to entities described by their composition, but neither created by the legislative scheme itself, nor required to have legal person-

ality. The clear intention is that existing institutional REBs will fulfill the mandatory role created by the *Regulations*. However, it could also imply that the role is quite limited in nature, perhaps akin to that played by auditors or other professionals when called on to certify a fact as part of a government authorization scheme. Such a function would not generally be viewed as being subject to judicial review. The professional would, however, be duly accredited by (and responsible to) a professional organization. This is not true of REBs. The Regulatory Impact Analysis Statement accompanying the *Regulations* refers to the desirability of an accreditation system, as well as of increased financial resources to support REB activities.[34] However, the *Regulations* are silent on these matters. The idea that the REB role is a limited, non-discretionary one is not consistent with the fact that ministerial authorization of clinical trials is conditional on approval being given by an REB.[35] The *Regulations* delegate to REBs a public power with significant consequences. As such, their decisions should be subject to administrative law obligations.

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B. Personal Health Information Legislation

The provinces of Alberta and Ontario have enacted legislation that requires ethics review of protocols for research that seeks disclosure of health information.[36] Section 49 of the Alberta statute states "a person who intends to conduct research may submit a proposal to an ethics committee for review by that committee." The use of the permissive "may" implies that ethics review is not mandatory. However, the statute prohibits "custodians" of health information (i.e., any individual or institutional holder of personal health information, other than the individual who is the subject of the information) from disclosing information to researchers in the absence of ethics committee approval. The approval must go to several matters extending well beyond issues of appropriate consent, including researcher competence and scientific value of the proposed research.[37] By regulation made pursuant to the statute, the Minister of Health has designated several named research ethics committees operating at Alberta's universities and other agencies as ethics committees to fulfil this function.[38] In short, any health researcher seeking access to health information held by custodian institutions must obtain ethics approval under the statute. The REBs designated under the legislation are clearly statutorily delegated decision-making bodies, subject to administrative law duties.

C. Medical Profession Regulation[39]

Alberta's *Medical Profession Act* authorizes the province's College of Physicians and Surgeons to regulate the medical profession.[40] It further authorizes the governing body of the College, the Council, to appoint committees to assist it in carrying out its regulatory duties. Pursuant to this authority, Council passed bylaw 53, creating and authorizing the activities of a Research Ethics Review Committee ("RESC"). Under the bylaw, every registered medical practitioner is required to obtain the written approval of the Committee before "engaging in a research project involving human subjects", unless the project is otherwise subject to the authority of another named research ethics review agency. The agencies named are those designated by regulation under the *Health Information Act*.[41] The bylaws require the RESC to adopt procedural and substantive standards consistent with the TCPS. The Committee "may approve, refuse to approve or require modification of any research proposal submitted to it."[42] An unsuccessful medical practitioner applicant can appeal the RESC decision to the Council. The Council may refer the matter to a university-based REB for its advice before rendering an appeal decision. The Research Ethics Review Committee, as well as the Council in its appellate role, are exercising delegated statutory powers and are subject to administrative law obligations.

In Quebec, the province's *Code of Ethics of Physicians*,[43] a regulation to the *Medical Act*, similarly requires medical professionals to obtain the approval of a "research ethics committee" before engaging in human participant research. To date, Alberta and Quebec are the only provinces to have legislated such a requirement of their medical practitioners.

IV. Impact of Administrative Law on Research Ethics Boards

Having made the case in Parts II and III that at least some REBs are within the reach of the "long arm of administrative law", this paper considers the implications of this observation. Part IV selectively draws upon several common law principles to demonstrate the substantial impact administrative law can have on REBs and the oversight of human research generally. Specifically, the principle of procedural fairness, the maxim "he/she who hears must decide", and the rules concerning quorum will be briefly explored. The magnitude of the impact these principles can have on the decision-making process currently employed by individual REBs is a function of the degree to which corresponding procedural requirements are already embodied and clearly articulated in the regulatory instruments[44] to which they adhere. Therefore, the discussion will also identify the presence or absence of relevant procedural rules in three of the key regulatory instruments referenced earlier in this paper: the TCPS, *Clinical Trial Regulations*, and the GCP.

1. Procedural Fairness

Procedural fairness (natural justice[45] is regarded as one of the concepts that form the "bedrock of administrative law."[46] Mullan notes that procedural fairness has two distinct arms: one arm requires that "the decision-maker provide adequate opportunities for those affected to present their case and respond to the evidence and arguments being advanced by other participants or in the knowledge or possession of the decision maker"[47]; the second arm requires that "decision makers be independent and unbiased."[48] The application of each arm is not contingent on a rigid characterization of the decision-maker's function; rather, it "applies to all statutory delegates and persons exercising public authority whose decisions are required to meet the standards of procedural fairness."[49]

Some of the process requirements set out in the regulatory instruments that are applicable to research involving human participants reflect, or at least are not inconsistent with, essential elements of procedural fairness. "Respect for justice" is included among the guiding ethical principles of the TCPS.[50] Justice, which the TCPS states "connotes fairness and equity",[51] must be embodied not only within the standards research protocols are measured against, but also the process by which the protocols are reviewed. The TCPS articulates this, in broad terms, as follows: "Procedural justice requires that the ethics review process have fair methods, standards and procedures for reviewing research protocols, and that the process be effectively independent."[52]

While the TCPS sets out some process requirements that are designed to be procedurally just,[53] fewer such requirements are provided for in the GCP and the *Clinical Trial Regulations.*[54] Unlike the TCPS, the guiding principles of the GCP make no mention of the need for process requirements to be just (fair). That said, the section of the GCP which deals with the composition, functions and operations of REBs[55] does establish a number of relevant procedural requirements which will be addressed in this paper.[56]

Consistent with the first arm of the principle of procedural fairness, the TCPS requires that a researcher be given the opportunity to provide the REB with information (in writing and, where "reasonable", orally) respecting his or her proposal and to respond to any concerns of the REB before a final decision is made.[57] The GCP also gives researchers the chance to provide the REB with information on any aspect of the research (impliedly, they can do so orally), although it does not expressly provide researchers with an opportunity to respond to REB concerns before the REB exercises its power to "reject" a research proposal.[58] Nonetheless, these instruments, in large measure, furnish procedural mechanisms that have been crafted to ensure researchers are given the opportunity to be heard and thus to influence the decision-makers. It should be noted, however, that few procedures, if any, are in place to hear from others (e.g., those who could potentially represent the perspectives of prospective participants, research institutions, and research sponsors). Thus, researchers are the only persons affected by a decision who are expressly granted standing before the REB. This point will be discussed later in the paper.[59]

The second arm of procedural fairness — the obligation that decision-makers be independent and unbiased — can be of particular significance to REB decision-making activities.[60] The GCP provides scant procedural guidance on these matters, other than to advise that only REB members who are "independent" of the researcher and research sponsor should vote or provide an opinion on the proposed research.[61] The *Clinical Trial Regulations* make no reference to the issues of independence and bias.

In contrast, the TCPS devotes greater attention to the issues of independence and bias under Section 4, which bears the title "Conflict of Interest", and in an article[62] that appears in the "Ethics Review" section. On the issue of bias, the TCPS states that REB members must "disclose actual, perceived

or potential conflicts of interest to the REB"[63] and provides the following examples of situations in which a "clear" conflict exists on the part of a REB member: the member's own research project is under review by the REB;[64] the member has been in direct academic conflict or collaboration with the researcher whose proposal is under review;[65] or the member otherwise has a personal interest in the research under review (e.g., "as an entrepreneur").[66] Where a conflict of interest exists, the member is required to absent himself or herself from the room for the duration of the REB's review of the relevant protocol.[67]

The TCPS also addresses the concept of independence under the heading "Institutional conflicts of interest." REBs must act independently from and maintain an arms-length relationship with their "parent organizations" (host institutions); consequently, institutions must ensure that their REBs have "the appropriate financial and administrative independence to fulfill [their] primary duties."[68]

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Legal issues relating to the second arm abound in the procedural fairness jurisprudence. This case law offers a rich resource, particularly in light of the dearth of guidance in the GCP and *Clinical Trial Regulations* on such matters as an appropriate test for determining whether bias exists. As a matter of administrative law, a decision-maker can be disqualified on the basis of bias even where actual bias has not been shown. A reasonable apprehension of bias is all that is required.[69] Such an apprehension exists with respect to a tribunal member "where a reasonable person, knowing the facts concerning the member, would suspect that the member may be influenced, albeit unintentionally, by improper considerations to favour one side in the matter to be decided."[70] Such bias may be found in several general situations, including where the decision-maker has a personal financial interest in the outcome of the proceedings or has a personal relationship with a party.[71]

Although the TCPS is more informative than the GCP and the *Clinical Trial Regulations* on such things as a test for personal bias,[72] it contains gaps and ambiguous provisions which warrant rectification. For instance, does bias exist on the part of a REB member if he or she has a close friendship with the researcher whose research proposal is under review? What if the member is reviewing a superior's proposal? Does bias exist where members of a REB are under direct or indirect pressure to approve a research project due to the financial implications of the study for their institution?[73] These questions are not specifically answered in the TCPS even though it is not uncommon for REB members (particularly those working in small institutions) to confront such situations. Therefore, recourse may be had to administrative law jurisprudence which has grappled with personal relationships between parties and decision-makers. Locating case law dealing with analogous forms of decision-makers is of paramount importance given that findings of bias are context-specific.[74] In terms of determining an appropriate comparator for REBs, Lemmens and Freedman suggest that they "are situated on a continuum somewhere in between administrative tribunals and administrative licensing boards."[75]

Administrative law can also offer a guiding hand on the issue of institutional independence by furnishing the applicable test for ascertaining whether a sufficient degree of independence exists between a REB and its host institution. According to Blake, "[b]ias at an institutional or structural level can be shown only if a fully-informed person would have a reasonable apprehension of bias in a substantial number of cases decided by the tribunal."[76] This test may be relied upon in determining whether there has been a breach of procedural fairness in situations where the person responsible for directing and controlling an institution's research program also participates in the REB decision-making process, by contributing to the discussion either as a voting or *ex-officio* REB member. Again, case law dealing with analogous circumstances might be of assistance in answering that question.

2. He/She Who Hears Must Decide

The ancient legal maxim "he/she who hears must decide" has informed administrative law jurisprudence. The right of

parties involved in a hearing to have the case decided by those to whom it was presented lies at the heart of the maxim. Parties are deprived of this right "if the decision is made or influenced by persons who have not heard the evidence and argument."[77] Therefore, "a member of a tribunal who participates in a decision should not be absent from the hearing or any part of it."[78]

This maxim may be transgressed in the REB decision-making context — for example, where a member of a REB hosted by a health care facility temporarily leaves a full review "hearing"[79] to respond to a page received in relation to his or her busy clinical practice and, on returning to the hearing, takes part in the remaining discussion and casts his or her vote without having participated in the full discussion. The discussion preceding a vote can reasonably be regarded as forming part of a REB's hearing; indeed, it is an critical element of the decision-making process.

"Only researchers hold party status to go before the REB. If they are not aggrieved by the decision because REB approval was secured, who will seek judicial supervision?"

Although the TCPS fails to directly or indirectly address the need to adhere to the maxim, the GCP offers voice to it, albeit in somewhat imprecise terms. Section 3.2.4 of the GCP reads: "Only members who participate in the [REB] review and discussion should vote/provide their opinion and/or advise." While this section would benefit both from the inclusion of the word "entire" (before the word "discussion") and the use of mandatory language ("shall" in the place of "should"), it nonetheless addresses the essence of the maxim. Administrative law can serve an important role by filling in this procedural gap, at least for those reviews in which the GCP is not in play.

3. The Quorum Requirement

A quorum is generally regarded as "the minimum number of members who must be present for a body to exercise its powers validly."[80] In some contexts, a quorum exists only if there are a minimum number of persons present from prescribed membership categories (e.g., public or lay members of professional disciplinary bodies).

Significant legal consequences befall decision-making bodies that conduct proceedings in the absence of quorum. As one court has put it, the lack of quorum results in "no decision at all."[81] Regarding the loss of quorum during the course of a hearing, Blake remarks:

> ... If one member [of the tribunal] dies, becomes too ill to continue, or ceases to be a member of the tribunal, leaving no quorum, the remaining members may not continue the hearing. They cannot continue even if the absent member is replaced, because the replacement has not heard the evidence presented before joining the panel. A new panel must commence the hearing anew.[82]

Article 1.3 of the TCPS establishes mandatory rules respecting REB membership.

The REB must consist of at least five members, including both men and women, of whom at least two must possess broad experience in the methods or in the areas of research that are covered by the REB, one must be knowledgeable in ethics, one must have knowledge of the relevant law (mandatory only for biomedical research), and one must be recruited from the community served by the institution. Commentary under a subsequent article which deals with full review hearings/meetings states that institutions should set quorum rules for REBs.[83] This commentary goes on to state, "decisions requiring full review should be adopted only if the members attending the meeting possess the range of background and expertise stipulated in Article 1.3."

The statement that decisions should not be adopted where the appropriate representation on the REB has not been achieved is intended to inform some of the content of a REB's quorum rules. It also serves to specify the consequence that flows from failing to meet this procedural requirement. Thus, it might be contended that administrative law rules concerning quorum have little to offer in the REB decision-making context. This is not necessarily the case for several reasons. First, the authority or weight that should be accorded statements appearing in commentary is unclear. In contrast, the binding nature of administrative law is clear. Second, some REB members may perceive administrative law principles to be more authoritative than TCPS

provisions and, if so, this may result in greater compliance with quorum requirements. Finally, given that the *Clinical Trial Regulations* and the GCP do not speak to the consequences of proceeding without a quorum, administrative law can fill this void.

V. Judicial Supervision/Intervention

None of the regulatory instruments relevant to the conduct of research involving human participants establish a right of appeal to the courts. Nonetheless, legal mechanisms exist that can provide the means by which to invoke some level of judicial supervision of and intervention in the decisions of public decision-makers, including REBs. However, these mechanisms usually cannot be successfully pursued until available internal appeal mechanisms have been exhausted.[84] Therefore, a researcher who is dissatisfied with the decision of a REB that operates in accordance with the TCPS likely must first avail himself/herself of internal appeal mechanisms. Such mechanisms include requesting the REB to reconsider its decision[85] and, if dissatisfied with the outcome of the reconsideration process, to appeal the REB's decision to the institution's appeal board.[86] It is noteworthy that the GCP does not expressly provide for an internal appeal process but rather, assumes that the REB has such a process.[87]

After pursuing available internal appeal mechanisms, the courts may provide a potential avenue of recourse to at least some individuals who are negatively impacted by a decision rendered by a public decision-maker. In seeking the invocation of judicial oversight, such individuals are often faced with issues regarding the appropriate court from which to seek relief (e.g., Federal Court or a provincial superior court), differing rules applicable to statutory and non-statutory decision-makers, the potential for legislative instruments to impact on when and how judicial review is to be sought, and the appropriate remedy to request from the court.[88] Relief in the nature of c*ertiorari* is frequently requested as this common law remedy permits the quashing of the decision under attack. As well, a court may be asked to exercise its equitable jurisdiction by issuing a declaration that the decision is a nullity. Other remedies may also be attainable.[89]

It may be helpful to pause to consider a situation that could well lead to judicial intervention in a REB decision. Suppose one of the REB members who took part in a negative review of a proposed research project has a longstanding acrimonious interpersonal relationship with the researcher. The researcher, after unsuccessfully pursuing internal appeal mechanisms, initiates the judicial review process and seeks to have the REB's decision quashed on the basis of serious procedural impropriety; namely, the presence of a reasonable apprehension of bias on the part of the REB. The court, in deciding whether to grant this remedy, would determine whether a reasonable apprehension of bias exists. This would involve assessing the structure and function of the REB process since, as previously noted, allegations of bias require courts to undertake a contextual analysis.[90] Even if the court took into account the reality that, as a practical matter, a significant portion of a REB's membership must frequently be drawn from the staff/personnel of its host institution, it would likely find the existence of a reasonable apprehension of bias. The following remarks by Mullan buttress this view:

> Whatever the uncertainties as to the meaning and application of the test for bias, there are many situations where disqualification is almost inevitably going to occur. Adjudicating in cases involving close friends, personal enemies, business associates, and rivals, not to mention family members, provide clear, though nowadays infrequent examples.[91]

If such a finding were made, the court would almost certainly quash the REB's decision because "where a party has established a reasonable apprehension of bias on the part of an individual decision-maker or with respect to the decision-making institution itself, any decision taken in respect of that person is invalid. Normally it will not matter that the other members of a multi-member panel were impartial or that the decision on the merits was sound in other respects."[92]

Before leaving the matter of judicial supervision/intervention, it bears noting that, due in part to the current participatory structure of the REB process, procedural impropriety on the part of a REB may continue unchecked. For example, as previously observed, concerns have been expressed that some REB members may be reviewing research proposals submitted by close personal friends or by their superiors or may be improperly influenced/pressured when reviewing protocols that, if approved, would reap significant financial benefits for the institution in which they work. Assuming such situations can lead to a reasonable apprehension of bias, the possibility exists that they can nevertheless persist unabated.

Only researchers hold party status before the REB. If they are not aggrieved by the decision because REB approval was secured, who will seek judicial supervision? Applications for judicial review of a board's decision can only be brought by persons or groups with *locus standi* (standing).[93] Although standing can be granted to non-parties, the decision to do so is in the court's discretion and, at least traditionally, this has been difficult to obtain.[94] Moreover, even if standing to challenge procedural impropriety on the part of a REB could conceivably be granted to non-parties, practical considerations make this unlikely to occur. Those persons with the financial wherewithal to absorb the costs of seeking standing and, having done so, to proceed with the merits of the judicial review application, may in many cases be limited to research sponsors and research institutions. Where the research project has received REB approval, sponsors and institutions are unlikely to be interested in seeking judicial intervention. At least notionally, prospective participants are the most likely to be aggrieved by a research approval process tainted by procedural irregularities. However, such persons are exceedingly unlikely to be aware of the presence of such irregularities. As well, they will frequently constitute an undefined class with no clear person or group who is able or willing to obtain standing on their behalf. The capacity to shoulder the financial cost of litigating the matter may act as an additional barrier.

VI. Conclusion

REBs have, for many years, carried out a critical public decision-making function, and yet there has been little recognition that they may well be within the reach of the "long arm of administrative law." This represents a substantial oversight since administrative law principles can play a pivotal role in defining the rights of research stakeholders and the procedural responsibilities of REBs. The considerable body of administrative law, which has evolved over the course of many decades, can contribute to the REB decision-making process in a variety of ways: (1) where the procedural rules contained in the relevant regulatory instruments (e.g., TCPS, GCP, and *Clinical Trial Regulations*) are ambiguous or vague, administrative law can clarify the nature of the procedural obligation; (2) where these rules are silent on a procedural matter, administrative law can fill the void; (3) where the rules are consistent with administrative law requirements, there is added pressure on REBs to obey them; and (4) where the rules are inconsistent[95], consideration may need to be given to eliminating this inconsistency.[96]

Additionally, administrative law offers the potential for judicial oversight of the exercise of REB decision-making power in some circumstances. While judicial scrutiny is likely to be only infrequently engaged, an awareness of the potential for court supervision may nonetheless act as a catalyst for REBs to take action to ensure that their procedural houses are in order.

In view of the applicability of administrative law requirements, it is recommended that policy makers tasked with reforming the existing research governance regime consider administrative law principles when designing (or redesigning) the decision-making process to be employed in the ethical review of research involving human participants. It is further recommended that information about relevant administrative law principles be included in all programs designed to educate research stakeholders and REB members about the research approval process.

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1. Kathleen Cranley Glass & Trudo Lemmens, "Conflict of Interest and the Commercialization of Biomedical Research: What is the Role of Research Ethics Review?" in Timothy A. Caulfield & Bryn Williams-Jones, eds., *The Commercialization of Genetic Research: Ethical, Legal, and Policy Issues* (Kluwer Academic/Plenum Publishers: New York, 1999) at 85.
2. See *e.g.* Simon Verdun-Jones & David Weisstub, "The Regulation of Biomedical Research Experimentation in Canada: Developing an Effective Apparatus for the Implementation of Ethical Principles in a Scientific Milieu" (1997) 28 Ottawa L. Rev. 297.
3. Tri-Council, *Tri-Council Policy Statement on Ethical Conduct for Research Involving Humans* (*with updates of May 200 and September 2002*) (Ottawa:

Tri-Council, 1998), online: <http://www.pre.ethics.gc.ca/english/pdf/TCPS%20June2003_E.pdf>.

4. International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use, Guideline for Good Clinical Practice E6, online: <http://www.hc-sc.gc.ca/hpfb-dgpsa/tpd-dpt/e6_e.html>[GCP].
5. This paper is strictly concerned with enforcement of the public law duties familiar to administrative law. We recognize that Canadian law provides other means by which guidelines, or "soft law", may become the source of enforceable performance standards, most particularly through negligence actions. See Angela Campbell & Kathleen Cranley Glass, "The Legal Status of Clinical and Ethics Policies, Codes, and Guidelines in Medical Practice and Research" (2001) 46 McGill L.J. 472-89. For a recent Supreme Court of Canada statement concerning the interaction between performance of regulatory duties and civil liability (in the context of Quebec civil law), see *Finney v. Barreau du Quebec*, [2004] SCC 36.
6. *Regulations Amending the Food and Drug Regulations (1024 – Clinical Trials),* P.C. 2001-1042, C. Gaz. 2001.II.1116 . These regulations were made under the *Food and Drugs* Act, R.S.C. 1985, c. F-27 [*Clinical Trial Regulations*].
7. *Health Information Act*, R.S.A. 2000, c. H-5, and *Personal Health Information Protection Act*, S.O. 2004, c. 3, Schedule A, (to be proclaimed, November 4, 2004).
8. *Medical Profession Act*, R.S.A. 2000, c. M-11; *Medical Act*, R.S.Q., M-9.
9. *Civil Code of Quebec*, R.S.Q. 1991, c. C-64, Art. 21.
10. Our paper is not the first to note that the processes governing ethics review have implications in administrative law. See *e.g.* Bernard Dickens, "Governance Relations in Biomedical Research" (2000) Law Commission of Canada at 12. Dickens states:

    > In addition, their [REB] influence over prospective investigators' work and careers might give investigators legal rights or legitimate expectations of their proper constitution and functioning, concerning, for instance, adequate records of their deliberations, avoidance or disclosure of members' conflict of interest, and affording investigators opportunities to make representations before negative decisions are finalized.

11. Certain provinces have codified, and to a limited extent modified, the common law of administrative law through statute: see *e.g.* Alberta's *Administrative Procedures Act*, R.S.A. 2000, c. A-3, and Ontario's *Statutory Powers Procedure Act*, R.S.O. 1990, c. S-22.
12. See *Knight v. Indian Head School Division No. 19*, [1990] 1 S.C.R. 653.
13. Public research institutions like universities and hospitals have broad responsibility for the ethical conduct of human participant research which may attract various administrative law duties. However, this paper focuses on the duties likely faced by REBs, as the principal decision-making vehicle chosen by these institutions to discharge their responsibility for preventive ethics review of research activities.
14. David Mullan, *Essentials of Canadian Law: Administrative Law* (Toronto: Irwin Law, 2001) at 4 [Mullan, *Essentials of Canadian Law*]. See also Donald Brown & John Evans, *Judicial Review of Administrative Action in Canada* (Canvasback: 1998) at 1:2256: "Because of extensive government funding and regulation, and the public character of their functions, universities and hospitals have acquired definite 'public' qualities."
15. Daniel Nelson, "Judicial Review in the Community of Scholars: A Short History of *Kulchyski v. Trent University*", (2004) Educ. & L.J. 367 provides a good review of the approaches historically taken by courts to university decision-making.
16. *Canadian Charter of Rights and Freedoms*, Part I of the *Constitution Act, 1982*, being Schedule B to the *Canada Act, 1982* (U.K.), 1982, c. 11 [*Charter*]. See *McKinney v. University of Guelph* [1990] 3 S.C.R. 229; *Harrison v. University of British Columbia* [1990] 3 S.C.R. 451; *Stoffman v. Vancouver General Hospital* [1990] 3 S.C.R. 483.
17. [1997] 3 S.C.R. 624.
18. TCPS, *supra* note 3 at art. 1.2.
19. See discussion in Part IV, below.
20. *Canadian Institutes of Health Research Act,* S.C. 2000, c. 6; *Natural Sciences and Engineering Research Council Act*, R.S.C. 1985, c. N-21; *Social Sciences and Humanities Research Act*, R.S.C. 1985, c. S-12.
21. *Canadian Institutes of Health Research Act, ibid.*at s. 5: "For the purpose of achieving its objective, the powers and functions of the CIHR are to:

    > (d) monitor, analyze and evaluate issues, including ethical issues, pertaining to health or health research.

22. The University of Alberta serves as an example. The University's General Faculties Council (GFC), the body delegated under the province's *Post-Secondary*

Learning Act to govern the University's academic affairs has adopted "University Standards for the Protection of Human Research Participants" as section 66 of the GFC Policy Manual. The Policy obliges faculty members engaging in human participant research to obtain the prior approval of one of two REBs, depending on their area of research. One of these is the Health Research Ethics Board ("HREB"). The policy applies to all research coming with its terms, not only that funded by CIHR, SSHRC, or NSERC. The Policy employs the TCPS as a minimum procedural and substantive standard. The Policy provides an appeal of REB, "in the last resort", to the University Committee on Human Research Ethics, in the office of the Vice-President (Research).

23. See Memorandum of Understanding employed by all three Councils, online: <http://www.nserc.ca/institution/mou_doc_e.htm>.
24. *Harelkin v. University of Regina*, [1979] 2 S.C.R. 651; *Mikkelsen v. University of Saskatchewan* (2000), 191 Sask. R. 53 (Q.B.); *Khan v. University of Toronto* (1995), 130 D.L.R. (4th) 570 (Ont. Div. Ct.).
25. *Paine v. University of Toronto et al.* (1982), 34 O.R. (2d) 770 (C.A.); *Wade v. Strangway*, [1996] B.C.J. No. 450 [QL] (C.A.). The Supreme Court of Canada granted *certiorari* with respect to a disciplinary decision of the Board of Governors of the University of British Columbia in *Kane v. U.B.C.*, [1980] 1 S.C.R. 1105.
26. See Part V, below, for a discussion of the courts' role in judicial review.
27. [1986] A.J. No. 1156 (Q.B.) (QL); aff'd [1988] A.J. No. 545 (C.A.) (QL). See also *Saskatoon District Health Board v.Rosen*, [2001], S.J. No. 457 (C.A.), and *Cimolai v. Children's and Women's Health Centre of British Columbia*, [2003] B.C.J. No. 1313 (C.A.) (QL).
28. See Louise Sanchez-Sweatman, "Hospital Ethics Committees: A Reflection of Medical Model Decision-Making", (1995) Health Law Review 5, and Glenn Griener, "An Ethicist Reflects on the Role of Hospital Ethics Committees", (1995) 4 Health Law Review 3.
29. The authors are not aware of any Canadian case law on this subject. In *R. v. Ethical Committee of St. Mary's Hospital (Manchester)*, [1988] 1 F.L.R. 512 (Q.B.), Schiemann J. dismissed a judicial review application on the basis that the committee served a merely consultative or advisory role.
30. *Supra,* note 6 at 1120.
31. *Ibid.* at 1117 (definition of "research ethics board").
32. See IRBS homepage, online: <http://www.irbservices.com/>.
33. *Supra*, note 6 at 1117.
34. *Ibid.* at 1131.
35. *Ibid.* The Impact Statement contemplates that if an REB denies approval for the clinical site it is reviewing, a Directorate within Health Canada will consider the implications for other sites.
36. *Supra*, note 7.
37. *Health Information Act, supra* note 7 at s. 50(1).
38. Alta. Reg. 69/2001. Section 44 of the Ontario statute sets out a similar regime for ethics review in that province. The statute states that designated REBs are to be "prescribed". As of the time of writing no REBs have been prescribed.
39. See Timothy Caulfield *et al.*, "Research Ethics and the Role of the Professional Bodies: A View from Canada", (2004) Journal of Law, Medicine & Ethics 365, for discussion of the general responsibilities of self-regulatory bodies in this area.
40. *Supra*, note 8.
41. *Health Information Act, supra* note 7.
42. *Ibid.*, By-law 53(8)(e).
43. R.R.Q. YEAR, c. M-9, r. 4.1, s.31:

    > A physician must, before undertaking his research on humans, obtain approval of the project by a research ethics committee that respects existing standards, notably in its composition and procedures. He must also ensure that all those collaborating with him in the research project are informed of his ethical obligations.

44. The term "regulatory instruments" is used in this paper to broadly refer to documents (both legal and extra-legal) that can exert control over the decision-making process employed by REBs.
45. In recent years, courts have, for the most part, stopped drawing a distinction between the principles of procedural fairness and natural justice. See David Mullan, *Administrative Law*, 3rd ed. (Toronto: Carswell, 1996) at 235 [Mullan, *Administrative Law*].
46. Mullan, *Essentials of Canadian Law, supra* note 14 at 7.
47. The Latin term *audi alteram partem* (or "hear the other side") is often used in reference to this arm of the principle of procedural fairness.
48. The second arm also has a corresponding Latin term, *nemo jurdex in sua propria causa debet esse* (no one should be the judge in her or his own cause). See Mullan, *Essentials of Canadian Law*, *supra* note 14 at 232.

49. David Phillip Jones & Anne S. de Villars, *Principles of Administrative Law*, 4th ed. (Toronto: Thomson Canada Ltd., 2004) at 367.
50. TCPS, *supra* note 3 at i.6 (Introduction).
51. *Ibid*.
52. *Ibid.*
53. Examples of such requirements are:

> The REB shall function impartially, provide a fair hearing to those involved and provide reasoned and appropriately documented opinions and decisions. The REB shall accommodate reasonable requests from researchers to participate in discussions about their proposals, but not be present when the REB is making its decisions. When a REB is considering a negative decision, it shall provide the researcher with all the reasons for doing so and give the researcher an opportunity to reply before making a final decision. (art. 1.9)
>
> [REBs are obligated] to be guided by principles of natural and procedural justice in their decision-making. Such principles include providing a reasonable opportunity to be heard, an explanation of the reasons for opinions or decisions, and the opportunity for rebuttal, fair and impartial judgement, and reasoned and written grounds for the decisions. (art. 1.10 and accompanying commentary)
>
> Researchers and REB members shall disclose actual, perceived or potential conflicts of interest to the REB. (art. 4.1)
>
> [REBs need] to act, and been seen to be acting, fairly and reasonably. (art. 1.8 and accompanying commentary)

54. With Health Canada's adoption of the GCP, the inclusion of procedural requirements in the *Clinical Trial Regulations* may have been deemed unnecessary. However, the relegation of important procedural requirements relating to REB decision-making to a guideline document is remarkable.
55. For the sake of precision, it is noted that the GCP actually uses the terms Institutional Review Boards and Independent Ethics Committees to refer to the decision-making bodies which carryout the same general functions that the TCPS has assigned to REBs.
56. These include the requirements that researchers be given the opportunity to furnish information to the REB on any aspect of their research proposals (s. 3.2.5) and that only REB members who are independent of the researcher and research sponsor "should" participate in the decision-making process respecting the research protocol (s. 3.2.1).
57. TCPS, *supra* note 3 at art. 1.9.
58. GCP, *supra* note 4 at s. 3.2.5.
59. See discussion under Part V.
60. Trudo Lemmens & Benjamin Freedman, "Ethics Review for Sale? Conflict of Interest and Commercial Research Review Boards" (2000) 78 The Milbank Quarterly 547 at 555.
61. GCP, *supra* note 4 at s. 3.2.1.
62. TCPS, *supra* note 3 at art. 1.12.
63. *Ibid.* at art. 4.1.
64. *Ibid.* at s. 4(B).
65. *Ibid.*
66. *Ibid.* at art. 1.2.
67. *Ibid.* at s. 4(B).
68. *Ibid.* at s. 4(C).
69. Sara Blake, *Administrative Law in Canada*, 3rd ed. (Markham, Ont.: Butterworths 2001) at 94.
70. *Ibid.*
71. See Jones & de Villars, *supra* note 49 at 373 for other situations that may lead to a reasonable apprehension of bias.
72. The TCPS, *supra* note 3 at s. 4(A), sets out two suggested tests "for assessing the potential implications of apparent or real conflicts of interest": (1) would an outside observer question the ability of the individual to make a proper decision despite possible considerations of private or personal interests; and (2) would the public believe that the trust relationship between the relevant parties be reasonably maintained if they had accurate information on the potential sources of conflict of interest? The first of these two tests loosely approximates the established administrative law test for bias. That said, there is not complete concordance; for example, the administrative law test expressly acknowledges that the improper influences can be unintentional.
73. These questions are posed in Glass & Lemmens, *supra* note 1 at 90. Glass & Lemmens note that strong personal interests of maintaining collegiality or job security can exist in such situations.
74. Lemmens & Freedman, *supra* note 60 at 556. The authors note that the "closer an entity approaches judicial decision-making, the stricter the rules of conflict of interest are."
75. *Ibid*.
76. Blake, *supra* note 69 at 95.
77. *Ibid.* at 78. In support of this statement, Blake cites *Bailey v. Langley Local Board of Health*, [1982] 2 W.W.R. 76 (B.C.S.C.). In that case, the Court quashed the decision of a Board of Health because three of the five members of the Board had been absent from part

of the hearing and, despite their absence, took part in the final discussions leading to the vote.

78. *Ibid.* at 78.
79. The word "hearing" is used in the TCPS in relation to protocol review meetings conducted by REBs. See *supra* note 3 at art. 1.9.
80. Mullan, *Administrative Law*, *supra* note 45 at 187.
81. See *Ford v. Canada (National Parole Board)* (1984), 12 Admin. L.R. 266 (F.C.T.D.) at 270.
82. Blake, *supra* note 69 at 80.
83. TCPS, *supra* note 3 at art. 1.7.
84. Jones & de Villars, *supra* note 49 at 545.
85. TCPS, *supra* note 3 at art. 1.10.
86. *Ibid.* at art. 1.11, as am. by May 2000 update.
87. However, appeal procedures are referenced in Section 3.3, which reads:

> 3.3 The [REB] should establish, document in writing, and follow its procedures, which should include: ...
>
> > 3.3.9 Ensuring that the [REB] promptly notify in writing the investigator/institution concerning: ...
> >
> > > c. Procedures foe appeal of its decisions /opinions.

88. See Jones & de Villars, *supra* note 49 at c. 13, 15 for a general discussion of these issues.
89. See *ibid*. for a discussion of these remedies, including prohibition, which can be used to stop a tribunal from "embarking upon or continuing upon a procedure for which it has no jurisdiction" (at 580), and *mandamus* which "compels the performance of a statutory duty owed to the applicant" (at 585).
90. In this regard, Blake, *supra* note 69 at 193, states, "facts that, in one context, may raise a reasonable apprehension of bias, may not be of concern in another context."
91. Mullen, *Essentials of Canadian Law, supra* note 14 at 330.
92. Jones & de Villars, *supra* note 49 at 408. Similarly, Blake, *supra* note 69 notes at 107: "[T]he bias of one tribunal member can taint the whole decision, even though a majority of members were not biased. It is assumed that the biased member influenced the other members."
93. Jones & de Villars, *supra* note 49 at 588.
94. Jones & de Villars, *supra* note 49 at 588-89 indicates that not just any concerned citizen is entitled to challenge a tribunal's decision: "In order to possess standing to obtain one of the prerogative remedies, an applicant must be 'aggrieved', 'affected' or have some other 'sufficient interest'. In general, mere busy-bodies need not apply." This reflects the traditional common law position on the matter of standing. However, the Supreme Court of Canada's ruling in *Finlay v. Canada (Minister of Finance)*, [1986] 2 S.C.R. 607 has offered greater promise to those persons who seek standing to challenge a decision made by a public decision-maker by allowing for the possibility of a grant of "public interest standing". According to Jones & de Villars, at 592-593, public interest standing may be granted where an applicant raises a "serious issue as to the invalidity of the decisions complained of", demonstrates "a genuine interest in the matter", "and another reasonable and effective way to bring the issue before the court" is not available.

    Whether a person or group representing the interests of (prospective) participants would be able to obtain standing is unclear. An application for public interest standing may have a reasonable prospect of success where the REB has, in approving a biomedical research project, clearly acted in a procedurally unfair manner and the project will expose research participants to substantial risks. If the person or group was deemed to be a proper representative of the interests of prospective research participants, we believe a genuine interest in the matter could be established. We are also satisfied that there may well be no other reasonable and effective way to bring the issue before the court.
95. Legislated inconsistency with the common law is permissible; however, overriding a common law procedural protection should only be done when there is a rational basis to do so.
96. The authors would like to thank Jocelyn Downie for suggesting these four concise summary points.