Information and Privacy
Commissioner/Ontario
Commissaire à l'information
et à la protection de la vie privée/Ontario

ORDER PO-2693

Appeals PA07-76, PA07-77, PA07-78 and PA07-79

McMaster University

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NATURE OF THE APPEAL:

McMaster University (the University) received requests under the *Freedom of Information and Protection of Privacy Act* (the *Act*) for the following information:

Request 2006-017	A list of clinical trials involving McMaster staff, facilities or its Research Ethics Board which have been suspended due to safety concerns, such list to cover the last five years.
Request 2006-018	The number of deaths which have occurred in clinical trials overseen by McMaster researchers or involving McMaster facilities or McMaster's Research Ethics Board, such list to cover the last five years.
Request 2006-019	The number of adverse events in clinical trials overseen, or supervised by McMaster researchers or involving McMaster facilities or McMaster's Research Ethics Board for the last two years.
Request 2006-020	A list of all clinical trials with subjects who are children under 18, aboriginal people, seniors, people who are incarcerated and other vulnerable populations, including an outline of the project or product being tested.

On January 22, 2007, the University issued its decision that the *Act* did not apply to Request 2006-17 pursuant to section 65(8.1)(a) of the *Act*. On January 23, 2007, the University issued its decision the *Act* also did not apply to Requests 2006-18, 2006-19 and 2006-20 pursuant to section 65(8.1)(a) of the *Act*.

On February 23, 2007, the requester (now the appellant) appealed the University's decision to this office and four appeal files were opened. In addition to seeking a review of the University's decision that section 65(8.1)(a) of the *Act* applies to the responsive records, the appellant raised the application of the exception to section 65(8.1) in section 65(9) of the *Act*.

On March 7, 2007, this office sent four separate Requests for Documentation to the University. The Requests for Documentation notified the University that this office had received notices of appeal regarding its decisions. The Requests for Documentation also directed the University to send specified documentation, including copies of the records, to assist this office in determining how to stream the appeal. In response to the Requests for Documentation, the University's legal counsel wrote to this office and stated that:

> … on a plain reading of the legislation the Commissioner lacks jurisdiction *ab initio* in respect to collection, use and discharge of such information and records falling within Section 65(8.1)(a) and accordingly, any administrative process in respect thereof.

These appeals were then assigned to me as adjudicator. Under the *Act*, the adjudication of an appeal takes the form of an inquiry. I sent a Notice of Inquiry to the University, initially,

inviting representations on the application of section 65(8.1)(a). I also asked for copies of the records and other materials sought in the Requests for Documentation. The University responded to the Notice of Inquiry with correspondence that continued to deny the authority of this office to examine whether section 65(8.1)(a) applies to the records, and denied my request for documentation. The University also expressly declined to provide representations.

As a result, I issued Interim Order PO-2601-I. In that decision, I found that the Commissioner has the authority to conduct an inquiry in relation to whether the requested records are excluded under section 65(8.1)(a). I ordered the University to produce "all materials required by the Requests for Documentation in these appeals, including all records responsive to the four requests…." The University did not do so.

The Commissioner subsequently began an application for judicial review in the nature of *mandamus*, in order to compel compliance with Order PO-2601-I. The University then commenced an additional application for judicial review in the nature of *certiorari*, seeking to have Order PO-2601-I quashed.

Before these matters proceeded to a hearing, the University offered to allow this office to inspect a representative sample of records on the basis that a suitable representative sample would permit the inquiry to proceed without the necessity of producing all of the responsive records in relation to all of the relevant clinical trials. I attended at the University and reviewed the representative sample. The records that contain responsive information are described below. I am satisfied that these records constitute a proper representative sample and that they provide sufficient context to permit me to adjudicate the issues in these appeals.

Accordingly, I have stayed Order PO-2601-I. The parties to the judicial review applications have adjourned the applications to a date to be fixed by the Registrar, pending the successful conclusion of this matter without further need to enforce Order PO-2601-I.

After inspecting the sample records, I sent a new Notice of Inquiry to the University, inviting it to provide representations on the issues in these appeals. The University responded with representations detailing their interpretation of section 65(8.1) and its application to the records in issue. I then provided the non-confidential portions of the University's representations to the appellant, who was provided with an opportunity to provide representations, which she did.

RECORDS:

When I attended at the University to review the sample records, the Associate Dean of Research at the University provided a detailed review of the course of a clinical trial, in order to provide contextual background. I then reviewed the group of records produced by the University, which relate to one particular clinical trial identified by the University. This clinical trial was chosen because it was a study that had been suspended, in which both adverse events and death had occurred, meaning that this particular study contains information that would be responsive to requests 2006-017, 018 and 019 (using the University's request numbers). The records shown to

me included application forms, proposed study amendments, annual reporting, adverse event reporting, Research Ethics Board (REB) minutes in which the study closure was reported, the study completion form and the peer-reviewed publication of the study results (a public record). Most of these, other than the peer-reviewed publication, are presented to the REB, and they most often consist of completed standard forms.

The Associate Dean of Research also indicated that the University is involved in approximately 1,500 to 2,000 ongoing clinical trials or studies at any given time at Hamilton Health Sciences, and additional studies totaling about one-quarter of that number at St. Joseph's Health Care. The records for each study are maintained chronologically, and there is no straightforward way to extract the requested information without searching through the records for each study that was active during the time periods identified in the requests.

During the meeting, I asked whether there were any electronic records that might contain the requested information. The University representatives responded that the REB maintains a database of clinical trials or studies. This database only contains the REB number assigned to the study, the full name of the study, the name of the sponsor and the name of the principal researcher. Based on the names of the studies identified in this database, which could identify target groups, some of the information contained in the database relates to request 2006-020.

I was also advised that several public databases would likely contain some responsive information. As a pre-requisite for research to be published in the journals represented by the International Committee of Medical Journal Editors (ICMJE), the clinical trial must be registered in the National Institute of Health database: www.clinicaltrials.gov. Those studies receiving funding from the Canadian Institute for Health Research must register with http://www.controlled-trials.com/ (the International Standard Randomized Controlled Trial Number (ISRCTN) Register). Both of these databases are available to the public but they do not include all studies involving the University. As well, they only contain limited information such as that included in the University's database of clinical trials or studies. In any event, these databases are owned and operated by independent bodies. They are clearly not within McMaster's custody or control and they are therefore outside the scope of this appeal.

As a practical matter, and based on the records I have observed and the explanation provided concerning the way clinical trials and studies are conducted (as set out in greater detail under the heading, "Search for Responsive Records/Scope of Request" below), I am satisfied that the University does not have a "list" of clinical trials which have been suspended due to safety concerns in the past five years (request 2006-017), nor does it have records that aggregate the number of deaths or adverse events in clinical trials during the time periods indicated (requests 2006-018 and 019). In order to obtain this information, it is therefore necessary to look at the specific records in which these events are recorded and/or reported (Orders M-493, M-530). I have concluded that, in these appeals, these records (which generally use standard forms that are the same for all clinical trials) are as follows:

- Annual Progress Report to REB

- Suspect Adverse Reaction Report to REB
- Local Serious Adverse Event Report to REB
- Study Completion Report to REB.

In my view, although adverse events are sometimes reported in minutes of REB meetings, the number is not specified, nor the particulars of the event (including whether it was a death or some other adverse event). Accordingly, the minutes do not provide the particulars necessary to adequately respond to the requests. I have decided not to include them in the responsive records for that reason, and also because the relevant information is fully captured in the records listed above.

In addition to the above records, there can also be "non-local" serious adverse event reports to the REB, which would be used in the case of an adverse event at a non-local centre, reflecting the fact that some studies occur in several different sites across Canada or even internationally. This would be the equivalent of the local serious adverse event form mentioned above for studies that occur in several different centres.

Turning to the fourth request (2006-020), for access to a "… list of all clinical trials with subjects who are children under 18, aboriginal people, seniors, people who are incarcerated and other vulnerable populations," I am satisfied, as stated in the Notice of Inquiry, that the University does not have such a list. As for the request itself, it is not clear whether it seeks to identify studies that specifically target these groups, or those that merely include such individuals as subjects. In either event, the following records provide relevant information:

- Application form for review by REB (description of participants on page 8)
- Database of Studies (containing only the REB number, the full name of the study, as well as the names of the sponsor and principal researcher for each study, as noted previously).

Accordingly, I have decided that the following comprise the responsive records:

- Annual Progress Report to REB
- Suspect Adverse Reaction Report to REB
- Local (or Non-Local) Serious Adverse Event Report to REB
- Study Completion Report to REB
- Application form for review by REB (description of participants on page 8)
- Database of Studies.

In the Notice of Inquiry, I indicated that I would adjudicate these appeals based on the sample versions of these records shown to me by the University. However, in her representations, the appellant provided submissions concerning the existence of additional records with respect to the first three requests (2006-017, 2006-018 and 2006-019). In the interest of fairness and completeness, therefore, I will provide a ruling on those arguments under the heading, "Search for Responsive Records/Scope of Request" later in this order.

DISCUSSION:

SECTION 65(8.1)(a)

As stated above, the University claims that section 65(8.1)(a) excludes the records from the *Act*. Sections 65(9) and (10) set out exceptions to the exclusion at section 65(8.1). These sections state:

> (8.1) This Act does not apply,
>
> (a) to a record respecting or associated with research conducted or proposed by an employee of an educational institution or by a person associated with an educational institution;
>
> . . .
>
> (9) Despite subsection (8.1), the head of the educational institution shall disclose the subject-matter and amount of funding being received with respect to the research referred to in that subsection.
>
> (10) Despite subsection (8.1), this Act does apply to evaluative or opinion material compiled in respect of teaching materials or research only to the extent that is necessary for the purpose of subclause 49 (c.1) (i).

This provision was enacted when the University, along with other universities in Ontario, became institutions under the *Act*. As explained in more detail below, the purpose of the provision is to protect academic freedom and competitiveness.

In this decision and Order PO-2694, issued concurrently, I am applying section 65(8.1)(a) for the first time. This requires me to assess the meaning of the section as a whole, in the context of the *Act*, and the meaning of several terms found in the section. The Supreme Court of Canada indicates that legislative purpose must be taken into account in statutory interpretation. For example, in *Rizzo v. Rizzo Shoes Ltd.*, [1998] 1 S.C.R. 27, Justice Bastarache states as follows (at para. 21):

> Although much has been written about the interpretation of legislation [citations omitted], Elmer Driedger in *Construction of Statutes* (2nd ed. 1983) best encapsulates the approach upon which I prefer to rely. He recognizes that statutory interpretation cannot be founded on the wording of the legislation alone. At p. 87 he states:
>
> > Today there is only one principle or approach, namely, the words of an Act are to be read in their entire context and in their

> grammatical and ordinary sense *harmoniously with the scheme of the Act, the object of the Act, and the intention of Parliament*. [My emphasis.]

This approach is commonly referred to as the "modern" principle of statutory interpretation. I will refer to it in more detail in my consideration of the meaning of section 65(8.1)(a), below.

I also note that, in *Ontario (Ministry of Correctional Services) v. Goodis*, [2008] O.J. No. 289 (Div. Ct.), Justice Swinton (writing for the panel) expressly applied this approach to the interpretation of section 65(6) and specifically referred to the modern principle as reflected in *Rizzo Shoes* (at para. 21). Section 65(6) is another exclusion from the application of the *Act* (like section 65(8.1)(a)), and applies to labour relations and employment-related records. The Ministry had argued that section 65(6) applied to records describing employee actions, on the basis that those actions could give rise to vicarious liability on the part of the Crown. After setting out the purposes of the *Act* at section 1, Justice Swinton rejected this approach, stating (at para. 26):

> *The interpretation suggested by the Ministry in this case would seriously curtail access to government records and thus undermine the public's right to information about government*. If the interpretation were accepted, it would potentially apply whenever the government is alleged to be vicariously liable because of the actions of its employees. Since government institutions necessarily act through their employees, this would potentially exclude a large number of records and undermine the public accountability purpose of the *Act (Ontario (Ministry of Transportation) v. Ontario (Information and Privacy Commissioner)*, [2005] O.J. No. 4047 (C.A.) (at para. 28). [My emphasis.]

Thus, in my view, the purposes of the *Act* as set out in section 1 are important in the interpretation and application of its provisions, including section 65. Section 1 states, in part, as follows:

> The purposes of this Act are:
>
> (a) to provide a right of access to information under the control of institutions in accordance with the principles that,
>
> (i) information should be available to the public,
>
> (ii) necessary exemptions from the right of access should be limited and specific, and
>
> (iii) decisions on the disclosure of government information should be reviewed independently of government; …

In applying the modern principle of interpretation to section 65(8.1)(a), it is equally important to consider the legislative purpose that underlies the addition of this provision to the *Act*. This amendment was made by means of the *Budget Measures Act, 2005* (Bill 197), and was addressed by M.P.P. Wayne Arthurs on both the second and third readings. Mr. Arthurs was, on both occasions, the Parliamentary Assistant to the Minister of Finance and spoke on behalf of the government in relation to the provisions aimed at adding Ontario universities as institutions under the *Act*. His comments clearly address the purpose of section 65(8.1). At third reading on November 21, 2005, he stated:

> . . . [T]his bill proposes to make Ontario's universities subject to the provisions of the Freedom of Information and Protection of Privacy Act and ensure that Ontario's publicly funded post-secondary institutions are even more transparent and accountable to the people of Ontario. That will be both our universities and our colleges of applied arts and science. *So as not to jeopardize the work being done at these institutions, though, the freedom-of-information provision would take into account and respect academic freedom and competitiveness. Clearly we understand the importance of the university post-secondary sector when it comes to doing research and innovative study programs.* Thus we wouldn't want to jeopardize that academic freedom, or the competitive environment that is created accordingly. [My emphasis.]

I acknowledge the importance of these principles in the interpretation and application of section 65(8.1)(a). However, bearing in mind the purposes of the *Act* in section 1 and the stated legislative purpose of this amendment, I have concluded that the Legislature did not intend to create an exclusion from the application of the *Act* whose reach would be broader than is necessary to accomplish these stated objectives. It is important to note, in that regard, that section 65(8.1)(a) only relates to the question of whether the *Act* applies to the records. If the *Act* is found to apply, this does not automatically lead to disclosure. Where the *Act* applies, the records could be subject to one of the mandatory and/or discretionary exemptions from the right of access, which are found in sections 12 through 22 of the *Act*.

I now turn to the question of the meaning of section 65(8.1)(a) and its application in the present appeals. I will organize the analysis under several headings that refer to terms included in section 65(8.1)(a).

"Research"

To determine whether the records are respecting or associated with research, it is necessary to determine how "research" should be defined.

Although "research" is not a defined term under the *Act*, another statute within the jurisdiction of this office, the *Personal Health Information Protection Act* (*PHIPA*), contains a definition at section 2:

> "research" means a systematic investigation designed to develop or establish principles, facts or generalizable knowledge, or any combination of them, and includes the development, testing and evaluation of research.

This definition is similar to the interpretation of "research" that has been developed in jurisprudence of this office under sections 13(2)(h) and 21(1)(e)(ii) of the *Act* (both of which also mention this term):

> . . . [T]he systematic investigation into and study of materials, sources, etc. in order to establish facts and reach new conclusions [and] ... an endeavour to discover new or to collate old facts etc. by the scientific study or by a course of critical investigation.
>
> (Orders P-666, P-763, and P-1371)

In determining the meaning of "research", I must consider the modern rule of statutory interpretation, referred to in the *Rizzo Shoes* judgment of the Supreme Court of Canada, and the Divisional Court judgment in *Ontario (Ministry of Correctional Services) v. Goodis* (see above). A more recent articulation of the rule appears in *Sullivan and Driedger on the Construction of Statutes*, 4th ed., by Ruth Sullivan (Toronto: Butterworths, 2002) at p. 3:

> [A]fter taking into account all relevant and admissible considerations, the court must adopt an interpretation that is appropriate. An appropriate interpretation is one that can be justified in terms of (a) its plausibility, that is, its compliance with the legislative text; (b) its efficacy, that is, its promotion of the legislative intent; and (c) its acceptability, that is, the outcome complies with legal norms; it is reasonable and just.

(a) Plausibility or Compliance with Legislative Text

Sullivan states (at p. 123) that to be plausible, an interpretation must be "one the words can reasonably bear." As noted, section 65(8.1) includes the word "research" without any other language to qualify or restrict the plain and ordinary meaning of that word. In Order P-666, Assistant Commissioner Irwin Glasberg turned to the Concise Oxford Dictionary (8th edition) to aid in formulating a definition for "research." In my view, his formulation of the definition of "research" is accurate. However, I have concluded that the definition found in section 2(1) of *PHIPA*, which had not been enacted at the time of Order P-666, is a better articulation of the same concept. As well, it has the advantage of appearing in a statute devoted to privacy and access to information, and also administered by this office. In my view, it is a "plausible" definition.

(b) Promotion of Legislative Intent

I have already referred to the comments made by M.P.P. Wayne Arthurs during the third reading debate on the *Budget Measures Act, 2005* (Bill 197), which enacted section 65(8.1). This extract

from the legislative debates makes it clear that academic freedom and competitiveness must be respected in any interpretation of section 65(8.1)(a) that is adopted, including the meaning ascribed to "research".

It is also evident, based on the legislative text of section 65(8.1), that universities' academic freedom and competitiveness is intended to be protected by the exclusion of certain records from the scope of the *Act*. In my view, an interpretation of "research" that recognizes its ordinary meaning is in keeping with the intention of the Legislature to protect the academic freedom and competitiveness of educational institutions. Given its specificity and comprehensiveness, I have concluded that the definition in *PHIPA* is best suited to achieve this purpose.

(c) Outcome must be Consistent with Legal Norms and be Reasonable and Just

In my view, the definition of "research" in *PHIPA* meets this requirement as well. With respect to the meaning of "legal norms", Ruth Sullivan states as follows in *Sullivan and Driedger* (cited above):

> These norms are found in Constitution Acts, in constitutional and quasi-constitutional legislation and in international law, both customary and conventional. …

This portion of the analysis under the modern principle requires that the *outcome* of the interpretation must meet the expressed standard. Given the stated legislative purpose of respecting academic freedom and competitiveness, I am satisfied that adopting the definition of "research" in *PHIPA* produces a result that is consistent with legal norms and is both reasonable and just. I do not believe that it produces any unfairness, or that any violations of constitutional or quasi-constitutional principles would result. Nor is it inconsistent with the purposes of the *Act* as a whole, as stated in section 1 (reproduced above).

For all these reasons, I conclude that "research" in the context of section 65(8.1) should be defined as "… a systematic investigation designed to develop or establish principles, facts or generalizable knowledge, or any combination of them, and includes the development, testing and evaluation of research."

Before leaving this subject, however, I would also note that the meaning of "research" in the context of section 65 (8.1)(a) is informed by the remaining words of the section. In particular, the section requires that the research be "conducted or proposed by an employee of an educational institution or a person associated with an educational institution." Seen in the context of the purpose of this provision, that is, to protect academic freedom and competitiveness, the use of the words, "conducted or proposed", and the inclusion of specific references to employees or persons associated with the University, leads me to conclude that "research" must be referable to specific, identifiable research projects that have been conceived by a specific faculty member, employee or associate of the University.

In my view, this approach to "research" also complies with the modern rule, as it is an interpretation the words of section 65(8.1)(a) can reasonably bear, and promotes the legislative purpose of protecting the freedom and competitiveness of the University's faculty members and associated individuals. It does not produce an outcome that violates legal norms, and because it protects academic freedom and competitiveness, it is reasonable and just.

In addition, this interpretation finds support in the approach taken to the related provision found at section 3(1)(e) of British Columbia's *Freedom of Information and Protection of Privacy Act*, which excludes "a record containing … research information of employees of a post-secondary educational body" from the application of that statute. I note that Commissioner David Loukidelis stated (in Order 00-36) that "[s]ection 3(1)(e) *is intended to protect individual academic endeavour*." I agree, and in my view, notwithstanding the different wording of the British Columbia exclusion, this approach is equally applicable to section 65(8.1)(a) of the *Act*.

In its representations, the University submits that clinical trials are a well-recognized form of medical research:

> Clinical trials are conducted by McMaster, whether alone or in partnership with a third party for the purpose of answering research questions relating to whether drugs, diagnostic tools, surgical procedures, treatments or other similar interventions are able to help or treat certain medical conditions. . .
>
> . . .
>
> [Clinical trials] are described by the Canadian Institutes of Health Research … as one of "the four pillars of health research: biomedical; clinical; research respecting health systems and services; and the social, cultural, and environmental factors that affect the health of populations." Moreover, most of the records in issue are either reports or applications to the [REB] regarding clinical trials. Since the entire function of the REB is to oversee research with a view to protecting rights, safety and well-being of the human subjects involved, any reports and applications which are submitted to the REB are invariably reports and applications pertaining to research.

The University goes on to argue that there is an implicit recognition in Order HO-004, issued by this office under the authority of the *PHIPA*, that records containing health information relating to participants in medical research studies, which are analogous to clinical trials, are records related to research.

The appellant makes no submissions on whether clinical trials are a form of research. The appellant's argument is that "mere statistical information (number of trials suspended, number of deaths, number of adverse events)" is basic information that was not intended to be excluded when the amendment was enacted:

> It is our understanding that the exemption was crafted for the purpose of protecting actual research records, not statistics on research generally. This is supported by the fact that 65(9) enables disclosure of records pertaining to the subject matter and amount of funding with respect to research.

I am satisfied from the records themselves, in particular the protocol and application form for review by the REB, that clinical trials are systematic investigations. The clinical trials at issue in this appeal are designed to develop or establish new therapeutic or diagnostic tools with respect to certain medical conditions. In my view, this qualifies as generalizable knowledge. Accordingly, I find that clinical trials are a form of research. As well, and quite apart from the foregoing legal analysis, it would in my view be extremely difficult, if not impossible, to substantiate the opposite conclusion and find that clinical trials are anything other than research.

"Respecting or Associated with"

Turning to the question of whether the records are "respecting or associated with" research, the University submits that:

> . . . the records in issue easily meet the requirement that they be "respecting or associated with" research, regardless of whether those terms are construed broadly or narrowly. All of the records in issue arise directly from the development and conduct of clinical trials.
>
> For example, the Annual Progress Report, Suspect Adverse Reaction Report, Local Serious Adverse Event Report, and Study Completion Report (identified as being responsive to Requests 2006-017 to 2006-019) are all reports pertaining to specific clinical trials and were all made to the REB for the purpose of recording the progress of the research, the state of completion of the trial and the extent to which adverse events or adverse reactions may have occurred in connection with the clinical trial. Research, in the form of clinical trials is the sole subject of all those reports and all of the reports are substantially connected to that research, both because the content of the reports describes various aspects of the research, because the purpose of the reports is in furtherance of the research and because the recipient of the reports is the REB which is charged with overseeing the research.
>
> Similarly, the records identified as being responsive to Request 2006-020, including the Application Form for review by the Research Ethics Board and the Database of Studies are also records directly relating to proposed or ongoing clinical trials. In the case of the Application Form submitted to the Research Ethics Board, this is a prerequisite for all clinical research trials, since the REB must approve the protocol for the clinical trial (including the description of proposed participants in the trial). Similarly, the Database of Studies is a record developed to list all clinical trials in which the University is involved and includes

> key information relating to clinical trials, such as the Research Ethics Board number for the trial, the full name of the study, the names of the sponsor and principal researcher for each study, etc.
>
> In summary, it is submitted that all of the records in issue are clearly associated with or respecting the clinical trials in the sense of being connected with, having a relationship to, involved with or closely related to those clinical trials.

The appellant makes no submissions as to whether the records are "respecting or associated with" research.

In addition to the legislative context and history of section 65(8.1)(a), the University suggests that guidance as to the interpretation of "associated with" can come from other legal contexts, including criminal and municipal law. In the criminal law context, Hill J. stated in *R. v. Campbell*, (2004) O.J. No. 2151 (S.C.J.), that

> the words "associated with" should be interpreted with the flexibility of dictionary definitions including "connected with", "having relationship to", "involved with", and "closely related to".

The University also cites *Humphreys Funeral Home – A.W. Miles Campbell v. Toronto (City)*, (2007) O.J. No. 824 (S.C.J.), in which "associated with" was considered to mean "connected or circumstantially combined with."

As stated previously, the purpose of section 65(8.1)(a) is to protect academic freedom and competitiveness. While the words "respecting or associated with research" may be broader than a requirement that records actually "contain" research information, I do not accept that the Legislature intended the potentially broad scope ascribed to them by the University.

For the reasons that follow, I have concluded that the words "respecting or associated with" require that there be a substantial connection between the records and actual or proposed research. In my view, the purpose of the section must be considered in assessing whether the connection between the records and the actual or proposed research is sufficient to establish the necessary substantial connection in a particular case.

As well, guidance as to the interpretation of this section can be found in other provisions of the *Act*. When the Legislature enacted section 65(8.1) it did so in the context of the *Act* and it is presumed that the intention was that it would be read in the context of the *Act* as a whole. While the words "respecting or associated with" do not appear elsewhere in the *Act*, some aid in their interpretation can be found in previous orders of this office that interpret the words "in relation to" used in section 65(6), referred to above in my discussion of the *Solicitor General* and *Ministry of Correctional Services v. Goodis* cases.

Section 65(6) states:

> Subject to subsection (7), this Act does not apply to records collected, prepared, maintained or used by or on behalf of an institution *in relation to* any of the following:
>
> > 1. Proceedings or anticipated proceedings before a court, tribunal or other entity relating to labour relations or to the employment of a person by the institution.
> >
> > 2. Negotiations or anticipated negotiations relating to labour relations or to the employment of a person by the institution between the institution and a person, bargaining agent or party to a proceeding or an anticipated proceeding.
> >
> > 3. Meetings, consultations, discussions or communications about labour relations or employment-related matters in which the institution has an interest.

In my view, although the language of section 65(6) is different, an analogy is possible because the words "in relation to" are close enough in meaning to "respecting or associated with," and a finding that these sections apply to a record has the same effect as section 65(6), that is, the records are excluded from the application of the *Act*. Moreover, the French language version of section 65(8.1)(a) uses the word "concernant," which may be translated as "relating to" (Collins Robert French-English Dictionary, 1993) Given that both "relating to" and "in relation to" share a common verb base and preposition, the meaning of "in relation to" in section 65(6) is relevant here.

In Order MO-2024-I, I reviewed the jurisprudence of this office on the meaning of "in relation to" in section 52(3) of the *Municipal Freedom of Information and Protection of Privacy Act* (the municipal *Act*), the equivalent of section 65(6) of the *Act*. The appellant in that appeal sought access to the total amount paid by the City of Toronto to a law firm defending a lawsuit brought by a former employee. The City denied access on the basis that the records were excluded by section 52(3)1 of the municipal *Act*. I stated:

> The consequence of a finding that section 52(3)1 applies is a serious one – the total exclusion of the record from the scope of the access and privacy provisions of the *Act*. In this case, as the appellant points out, the record relates to the expenditure of public funds to defend a legal action. This type of information has a strong connection to government accountability, which the Supreme Court of Canada refers to as an "overarching" purpose of access legislation (see *Dagg v. Canada (Minister of Finance)* (1997), 148 D.L.R. (4th) 385 (S.C.C.)). In my view, this purpose, which relates to the right of public access to government-held

> records identified in sections 1 and 4 of the *Act*, must be kept in mind in assessing the proper meaning of "in relation to" in this case.
>
> …
>
> As noted above, the term "in relation to" in section 52(3) has previously been defined as "for the purpose of, as a result of, or substantially connected to" [Order P-1223]. In my view, meeting this definition requires more than a superficial connection between the creation, preparation, maintenance and/or use of the records and the labour relations or employment-related proceedings or anticipated proceedings. For example, the preparation of the record would have to be more than an incidental result of the proceedings, and would have to have some substantive connection to the actual conduct of the proceedings in order to meet the requirement that preparation (or, for that matter, collection, maintenance and/or use) be "in relation to" proceedings. This interpretation would also apply under sections 52(3)2 and 3, which require that the collection, preparation, maintenance and/or use of the records be "in relation to" either negotiations or anticipated negotiations, or to meetings, consultations, discussions or communications about labour relations or employment-related matters in which the institution has an interest.
>
> In this case, I acknowledge that, but for the proceedings, this record would never have been created. However, in my view, the City's record of payments to a law firm, and particularly the total amount paid, is too remote to qualify as being "in relation" to proceedings for which the law firm was retained by the City. This record, which the City states was prepared by its Clerk, appears to be extracts from the City's accounting records, which were created and maintained for accounting reasons that have nothing to do with the proceedings. Based on my examination of the record, there is no obvious relationship between it and the actual conduct of the proceedings, nor is any such relationship explained by the City in its representations.
>
> I therefore find that requirement 2 is not met, and section 52(3)1 does not apply.

Having considered all the authorities referred to above, including the dictionary definitions cited, and the French version of the provision, I conclude that "respecting or associated with" has a similar meaning to "in relation to" in previous decisions of this office. All these phrases describe a similar degree of connection. In my view, like "in relation to", "respecting or associated with" should be interpreted to mean "for the purpose of, as a result of, or substantially connected to." Also, and similar to the cautionary note in Order MO-2024-I, meeting this definition requires more than a superficial connection between the records and the research in question. Whether or not the records at issue are "respecting or associated with" research turns on an examination of the records. To justify a finding that records are "respecting or associated with" research, there must be a substantial connection between the content of a particular record, on the one hand, and

specific, identifiable research actually conducted or proposed by an employee of the University or a person associated with the University.

This interpretation is supported by the purposes of both the *Act* and this particular amendment. Applying an overbroad definition would frustrate the fundamental purpose of the *Act* to provide a right of access to information in the custody of institutions, without any justification referable to the stated purpose of adding this section to the *Act*, namely the protection of academic freedom and competitiveness. In this regard, I am mindful of the similar concerns expressed by Justice Swinton in *Ministry of Correctional Services v. Goodis* (cited and quoted more fully above) that "[i]f the interpretation were accepted, it would potentially exclude a large number of records and undermine the public accountability purpose of the *Act*."

I also find that this interpretation meets the requirements of the modern principle, which requires an appropriate interpretation, that is, one that can be justified in terms of (a) its plausibility, that is, its compliance with the legislative text; (b) its efficacy, that is, its promotion of the legislative intent; and (c) its acceptability, that is, the outcome complies with legal norms; it is reasonable and just. In my view, there is no doubt that an interpretation requiring a substantial connection between the records and actual or proposed research is one that the words of the statute can reasonably bear, and is therefore plausible. As I have just observed, it promotes the purpose of the *Act* as a whole, while respecting the intent of the Legislature to protect academic freedom and competitiveness. Accordingly, in my view, it is "efficacious." There is nothing to suggest that the outcome of this interpretation would violate legal norms, and in my view, it is a just and reasonable approach, and therefore acceptable.

I have carefully reviewed the records at issue and I find that they consist of information "respecting or associated with" research. Most of the records are submitted to the REB in relation to a particular trial or study. Clearly, the completed forms in relation to clinical trials are an integral part of conducting a particular research project or study, and are therefore "substantially connected to" research. My examination of the sample records indicates that they set out highly textured details of actual research and the manner in which it has proceeded in a particular clinical trial.

In particular, the records that are responsive to the first three requests all contain results of research in terms of the number and nature of adverse events that had occurred as a result of a particular intervention.

The records that are responsive to the fourth request also contain details of ongoing research projects. The application form submitted to the REB contains extensive details about the research project and the methodology to be used. The database of studies is maintained by the REB, and contains details such as the REB number, the sponsor, and the name of each study. While a list showing the names of a group of studies may not always have a sufficient connection with actual research to qualify as "respecting or associated with research", I am satisfied that this is the case here because of the information contained in the database and the fact that it is maintained by the REB.

In my view, these are precisely the kinds of records the Legislature had in mind when formulating this exclusion with the purpose of protecting academic freedom and competitiveness.

To conclude, I am satisfied that all of the responsive records are "respecting or associated with" research.

"Conducted or Proposed by an Employee or Person Associated with an Educational Institution"

In my view, the inclusion of the words, "conducted or proposed by an employee of an educational institution or a person associated with an educational institution" in this section is significant. Those same words inform my conclusion, above, that the term "research" must be referable to specific, identifiable research projects that have been conceived by a specific faculty member, employee or associate of the University.

As well, the inclusion of these words requires consideration of whether research has actually been conducted, or is being conducted, or alternatively, whether the research has been proposed. In some instances, research will be proposed by means of an application to an overseeing body such as an ethics board, while in other cases, such approval may not be required. Where research has not yet begun, the question of whether it has been "proposed" will therefore depend on the facts and context of a particular request.

Clearly, the records at issue relate to research that is being or has been conducted, given that they are about ongoing clinical studies.

In addition, in the context of this appeal, it is necessary to analyze the relationship between those conducting or proposing the research to determine whether they are employees of, or associated with, the University.

In Order PO-2641, Assistant Commissioner Brian Beamish considered the definition of employee in determining whether the President of a university is an employee of the university:

> In arriving at my conclusions, I have considered the definition of "employee" found in Black's Law Dictionary (6th. ed.). "Employee" is defined as:
>
> > A person in the service of another under any contract of hire, express or implied, oral or written, where the employer has the power or right to control and direct the employee in the material details of how the work is to be performed . . . One who works for an employer; a person working for salary or wages. Generally when a person for whom the services are performed has right to control and direct the individual who performs the services not only as to result to be accomplished by work but also as to details

> and means by which result is accomplished, individual subject to direction is an "employee".

Order P-244 set out relevant factors that may be considered in deciding whether or not a person is an employee or an independent contractor. These include:

- the level of control and supervision exercised by the person requiring the work to be done, with respect to how the work is to be performed, in what setting and under what conditions, the hours of work, as well as the results of the work; and

- whether the work was part of the essential ongoing operation of the employer.

Researchers in university settings frequently collaborate with colleagues at other universities, as well as third parties, such as pharmaceutical companies. The affidavit of the University's Associate Dean of Research explains that research questions generally originate from either a McMaster faculty member, from a faculty member of another educational institution, or from a private sector third party, who subsequently develops the research question into a proposed protocol for conducting the clinical trial. Furthermore, the "vast majority" of research is conducted off-site, such as at an affiliated teaching hospital.

Section 65(8.1)(a) also encompasses research that was proposed, developed and/or conducted by a non-employee at an off-site location, provided that person is "associated with" an educational institution.

As discussed above, to be "associated with" the educational institution there must be a substantial connection between the individual and the educational institution.

The University's representations discuss the various people involved with the records and their relationship with the University. The representations on whether the research is conducted or proposed by an employee or person associated with the University can be distilled to the following points:

- The REB, only has jurisdiction to review and oversee clinical trials that are conducted or proposed by McMaster employees or persons associated with McMaster;

- All clinical trials require a local Principal Investigator who is a member in good standing of the medical staff of Hamilton Health Sciences/McMaster;

- The Clinical Chief and Administrative Director of the McMaster department or program to be involved in the research must confirm they have the space, personnel and resources to support the research; and

- The REB records in issue must be completed by the local Principal Investigator concerning the clinical trial in respect to the aspects of the clinical trial carried out at McMaster or its affiliated teaching hospitals.

Regardless of whether the researchers are actual employees or not, I am satisfied that the research in question is conducted or proposed by individuals who are all "associated with" the University. For the reasons that follow, I find that the researchers who complete and submit the responsive records that relate to the first three requests have a substantial connection to McMaster. The records all must be either filled out or signed by the principal investigator of the study. The principal investigator must be a member in good standing of Hamilton Health Sciences/McMaster. As noted on its website, Hamilton Health Sciences is "affiliated" with McMaster. Also, the REB receives those records from the principal investigator and the REB has exclusive jurisdiction only over McMaster clinical trials, which denotes a significant connection between the person completing the form and McMaster. Accordingly, I find that the research referred to in the first three requests is conducted by persons who are "associated with" the University.

With respect to the records that are responsive to the fourth request, the application form for Review requires the principal investigator to agree to be responsible for the research done locally, and I have just found that the principal investigator must be associated with the University. The last record at issue is the Database of Studies. This record is created by the REB at McMaster and contains the REB file number, the name of the study as well as the names of the sponsor and principal researcher. I therefore find that, because the REB's jurisdiction is limited to clinical trials performed by McMaster, the clinical trials referred to in that record are research projects conducted by investigators who are "associated with" the University.

To summarize, I have found that the records are respecting or associated with research being conducted by employees or persons associated with the University. Accordingly, subject to discussion of the exceptions to the section 65(8.1) exclusion found at sections 65(9) and (10) (below), I find that the responsive records meet the requirements of section 65(8.1)(a), and are therefore excluded from the scope of the *Act*.

Sections 65(9) and 65(10)

Sections 65(9) and (10) set out exceptions to the section 65(8.1) exclusions, meaning that if either applies, the information in question would be subject to the *Act*.

I find that the information contained in the records and the information sought does not relate to the amount of funding being received, which is a required element in section 65(9). Nor do the records contain evaluative or opinion material compiled in respect of research that would also be

subject to the section 49(c.1) exemption, as required for section 65(10) to apply. The potentially relevant part of section 49(c.1) applies to confidential evaluative material compiled solely for the purpose of evaluating the research of an employee or person associated with the University. While some of the records may contain evaluative material, this is not their sole purpose. For the foregoing reasons, therefore, I find that the section 65(9) and (10) exceptions to the section 65(8.1)(a) exclusion do not apply.

Accordingly, the records are excluded from the scope of the *Act* under section 65(8.1)(a).

SEARCH FOR RESPONSIVE RECORDS / SCOPE OF REQUEST

As noted above, the appellant has provided submissions to the effect that additional records should exist in relation to requests 2006-017, 2006-018 and 2006-019. Specifically, she maintains that it would be likely for the University to maintain these records in a "list" format or in aggregated form to facilitate inspections by Health Canada (or other regulatory bodies). She also submits that "it would ordinarily be in the interests of an REB to retain information in a fashion that would allow ongoing accounting of general safety of clinical trials conducted under the auspices of the institution."

Where a requester claims that additional records exist beyond those identified by the institution, the issue to be decided is whether the institution has conducted a reasonable search for records as required by section 24 (Orders P-85, P-221, PO-1954-I). If I am satisfied that the search carried out was reasonable in the circumstances, I will uphold the institution's decision. If I am not satisfied, I may order further searches.

The *Act* does not require the institution to prove with absolute certainty that further records do not exist. However, the institution must provide sufficient evidence to show that it has made a reasonable effort to identify and locate responsive records (Orders PO-1744, P-624).

A reasonable search is one in which an experienced employee expending reasonable effort conducts a search to identify any records that are reasonably related to the request (Order M-909).

In this case, as well as suggesting that aggregate records should exist, as noted above, the appellant also argues that the following records should exist and are responsive to the first three requests, concerning the total number of studies that have been suspended, the number of deaths and the number of adverse events:

- notification to Health Canada, the sponsor, the REB, or the trial participants of the discontinuance of a clinical trial;

- under Health Canada regulations, REBs have to know how many serious adverse events they have had and have to keep records as to how they dealt with those events.

The appellant also points out that other universities, such as the University of Western Ontario, assemble information on suspensions, deaths and adverse events cumulatively and publish that information as part of ethical and institutional oversight.

As part of its representations in these appeals, McMaster provided a detailed affidavit sworn by its Associate Dean of Research, explaining at length the clinical trial process and how records are stored. As well, when I visited McMaster to inspect the sample records, the Associate Dean of Research answered questions around the storage of records, particularly in electronic format.

From my inspection of the sample records, it is clear that those I have identified as responsive contain the information identified by the appellant and summarized in the two bullet points above. In particular, notification of discontinuance is dealt with by means of the Study Completion Report. Serious adverse events, and the REB's response to them, are recorded in the Local (or Non-Local) Serious Adverse Event Report. This form is provided to the REB, which completes a section indicating whether further review took place. As well, the number of such events during the year for each study is reported to the REB in the Annual Progress Report.

I also note that, while not all clinical trials must abide by Health Canada regulations (depending on the jurisdiction involved), all must provide notification of adverse events, including deaths, to the REB.

With respect to the creation of aggregate statistics (as the appellant indicates is done by the University of Western Ontario), I am advised that McMaster does not compile its information that way. The affidavit of the University's Associate Dean of Research explains that the records are contained within the individual clinical trial file and in chronological order. Comprehensive lists or databases of aggregate total numbers of adverse events do not exist. I note that the Health Canada guidelines provided by the appellant do not indicate a prescribed manner in which clinical trial records must be kept. While aggregate statistics may facilitate inspections and transparency, there is no requirement that this information be compiled that way. The only record that contains a total number of adverse events is the Study Completion Form, and those forms are only present for individual clinical trials that have been completed or terminated.

I have carefully reviewed the University's representations and the evidence that the University has provided to support its position that it conducted a reasonable search. I also have carefully reviewed the appellant's reasons, set out in her representations, for believing there are further responsive records.

In this appeal, the University explained at the on-site meeting that no aggregate statistics exist and each clinical trial would contain similar forms to the samples provided. In my view, the sample records identified above as comprising the responsive records are, in fact, responsive. The University is involved in approximately 1,500 to 2,000 clinical trials at its own Health Sciences Centre, and additional studies at St. Joseph's Health Care. Each clinical trial has its own file, which is organized chronologically. This was the case with the sample records, and on the evidence provided to me, I am satisfied that all clinical trials are organized in a similar

manner. Accordingly, I have concluded that aggregated records of the type referred to by the appellant do not exist with respect to McMaster's clinical trials.

As well, it is important to recognize that in circumstances where a record containing the form of information sought by the requester (in this case, a list or other aggregated statistical information) does not exist, the University is not obligated to tally its statistics and create a new record (Order P-50).

With respect to the other kinds of records referred to by the appellant, that is, notification to Health Canada, the sponsor, the REB, or the trial participants of the discontinuance of a clinical trial, I am not satisfied that they would contain any further responsive information than those I have already identified as responsive. Moreover, given that they are prepared as part of a clinical trial, I find that they have the necessary substantial connection to be records "respecting or associated with research". As already noted, these clinical trials are conducted by persons associated with McMaster. Accordingly, such records would be excluded from the scope of the *Act* under section 65(8.1)(a), and even if I found them to be responsive, no purpose would be served by ordering the University to search for them.

Based on the foregoing analysis, I am satisfied that the University has conducted reasonable search to locate responsive records.

CONCLUSION

As I have found that the responsive records are excluded from the scope of the *Act* under section 65(8.1)(a), and that the University conducted a reasonable search for records, this appeal is dismissed.

ORDER:

1. I uphold the University's decision to withhold the records in their entirety.

2. I uphold the University's search for responsive records as reasonable.

Original signed by: July 16, 2008
John Higgins
Senior Adjudicator