Protecting privacy. Promoting transparency.

Order F14-46

UNIVERSITY OF BRITISH COLUMBIA

Hamish Flanagan
Adjudicator

November 4, 2014

CanLII Cite: 2014 BCIPC 50
Quicklaw Cite: [2014] B.C.I.P.C.D. No. 50

Summary: The applicant requested access to University of British Columbia Research Ethics Board records related to clinical trials. The adjudicator determined that the responsive records are outside the scope of FIPPA because the records contain research information of UBC researchers under s. 3(1)(e) of FIPPA.

Statutes Considered: *Freedom of Information and Protection of Privacy Act*, s. 3(1)(e).

Authorities Considered: B.C.: Order F12-03, 2012 BCIPC 3 (CanLII); Order F10-42, 2010 CanLII 77328 (BC IPC); Order 00-36, 2000 CanLII 14401 (BC IPC); Order F10-42, 2010 CanLII 77328 (BC IPC); Order F10-43, 2010 CanLII 77330 (BC IPC); Order F11-21, 2011 BCIPC 27 (CanLII).
Ont.: Order PO-2693, 2008 CanLII 36902 (ON IPC).

INTRODUCTION

[1] The applicant requested access to University of British Columbia ("UBC") Research Ethics Board ("REB") records related to clinical trials for the period from 1972 to the date of his request.

[2] The purpose of UBC's REBs, which maintain the requested records, is to review the ethical acceptability of any research involving humans conducted

under the auspices of UBC, including clinical trials.[1] REBs can approve, reject, propose modifications to or terminate clinical trials.[2] UBC REBs have standard processes for applications for research approval and post approval activities that are supported by various application and amendment forms. It is the forms and related records submitted to UBC REBs relating to clinical trials that are at issue in this inquiry.

[3] UBC denied access to the responsive records on the basis that they fall within s. 3(1)(e) of the *Freedom of Information and Protection of Privacy Act* ("FIPPA"), which provides that records containing research information of researchers at post-secondary education institutions are outside the scope of FIPPA. The applicant requested that the Office of the Information and Privacy Commissioner ("OIPC") review UBC's decision to deny access to the information. Mediation was unsuccessful and the applicant requested that the matter proceed to an inquiry.

ISSUE

[4] The issue for this inquiry is whether the requested records contain research information of researchers for the purposes of s. 3(1)(e) of FIPPA and are therefore outside the scope of the applicants request for records under FIPPA.

[5] FIPPA is silent on the burden of proof regarding the issue of whether records are excluded from the scope of FIPPA under s. 3(1)(e). As stated in previous orders, in such a situation it is in the interests of the parties to provide argument and evidence to support their positions,[3] and they did so.

DISCUSSION

[6] **Records in issue––**The records in issue are records held by UBC REBs related to clinical trials for the period from 1972 to the date of the applicant's request. UBC says that REB records for any particular clinical trial vary depending on several factors, including the type of study and the year of the study. However, UBC described the responsive records as follows:

1) "REB Forms", comprising completed application forms and post-approval activity forms;
2) "Other documents" related to the commencement, ongoing conduct, or closure, of the clinical trial. These include:

[1] Clinical trials are investigations into the human response to exposure to a variety of factors, including drugs and medical devices: Initial submission of UBC at para. 40. See also Order PO-2693, 2008 CanLII 36902 (ON IPC) at para. 43.
[2] Affidavit of UBC's Director, Research Ethics at para. 5.
[3] F10-42, 2010 CanLII 77328 (BC IPC) at para. 7.

a. sample case report forms;

b. information given to trial participants, including informed consent forms;

c. questionnaires administered to participants; and

d. "no objection" letters from regulatory bodies. [4]

[7] The "other documents" all identify the research study and contain information produced for and submitted to a REB about the study, such as the research purpose, methodology and results. UBC says these documents are part of the documents Health Canada considers essential clinical trial documents,[5] and that these documents are not made available to the public.[6]

[8] UBC did not provide all of the records to the OIPC for this inquiry, saying that it was self-evident that the records in issue met the s. 3(1)(e) requirements based on previous orders, and citing the very large volume of responsive records. Instead, UBC provided blank forms for a range of the REB Forms. The blank forms contain detailed instructions that provide considerable guidance about the content required for a completed form.[7] I note that while the blank forms provided to me have no doubt changed in format over time, the purpose and general content of the forms remains the same. Therefore, while I do not have blank forms that traverse the time period of the request, I am satisfied that the forms I do have provide a good indication of the general content of submissions to REBs over the years. UBC also provided detailed descriptions of the records in its submissions and affidavit evidence, and offered the OIPC the opportunity to inspect a sample of the records in issue as required. Consistent with the approach to these types of records in previous orders,[8] I requested and received from UBC a representative sample of the "other documents" for review to help to determine the s. 3(1)(e) issue.

[9] **Scope of FIPPA––** Section 3(1) of FIPPA provides that FIPPA applies to all records in the custody or under the control of a public body other than the classes of records described in ss. 3(1)(a) to (k). Section 3(1)(e) is relevant for this inquiry. It excludes research material of researchers at post-secondary educational institutions from the scope of FIPPA, and states:

---

[4] UBC initial submission at paras. 27-28; 30.

[5] Affidavit of UBC's Director, Research Ethics at para. 8b. Exhibit C to the Affidavit contains a copy of Health Canada's list of essential clinical trial documents published in its *Good Clinical Practice: Consolidated Guideline* document.

[6] Affidavit of UBC's Director, Research Ethics at para. 9.

[7] Exhibit A and B to the Affidavit of UBC's Director, Research Ethics contains a Clinical Application Form (effective December 15, 2012) and several types of Post Approval Activities Form blank templates, including a form for seeking amendments to a study and a form for advising the REB of the completion of a clinical study.

[8] See Order F12-03, 2012 BCIPC 3 (CanLII).

> 3(1) This Act applies to all records in the custody or under the control of a public body, including court administration records, but does not apply to the following:
>
> ...
>
> (e) a record containing teaching materials or research information of
>
> (i) a faculty member, as defined in the College and Institute Act and the University Act, of a post-secondary educational body,
>
> (ii) a teaching assistant or research assistant employed at a post-secondary educational body, or
>
> (iii) other persons teaching or carrying out research at a post-secondary educational body;

[10] In Order 00-36,[9] former Commissioner Loukidelis identified the purpose of s. 3(1)(e) as being to protect individual academic endeavour by protecting research information from disclosure to those who might exploit it to the disadvantage of the researcher, such as by depriving the researcher of the ability to assert and verify priority when publishing or otherwise disseminating the research results.[10]

[11] For s. 3(1)(e) to apply to exclude the records from the scope of FIPPA, the records must contain "research information" of a UBC faculty member, teaching assistant, research assistant or other persons teaching or carrying out research at UBC.

Does the information constitute "research information"?

[12] In Order F11-21,[11] Adjudicator Fedorak set out that to be research, information must be the product of scientific or systematic research, with the researcher needing to take a critical approach to their evidence. Further, the evaluation of the evidence must derive something meaningful, such as new knowledge, principles, theories or facts. I adopt this as the requirement for research information and apply it here.

---

[9] 2000 CanLII 14401 (BC IPC).

[10] See also Order F10-42, 2010 CanLII 77328 (BC IPC), F10-43, 2010 CanLII 77330 (BC IPC) and Order F12-03, 2012 BCIPC 3 (CanLII) which agree with Order 00-36 that this is the purpose of s. 3(1)(e). This statement was also quoted with approval in Ontario Order 2693, 2008 CanLII 36902 (ON IPC).

[11] 2011 BCIPC 27 (CanLII), paras. 32-46, adopted in Order F12-03 2012 BCIPC No. 3(CanLII) at para. 9.

[13] Previous orders have addressed whether similar types of records to those at issue here contain research information for the purposes of FIPPA; all concluded that these types of records contain research information. In Orders F12-03, F10-42 and F10-43 the responsive records contained proposals and related documents submitted to REBs. In each case the records were found to contain research information for the purposes of s. 3(1)(e). Further, in Ontario Order PO-2693, Senior Adjudicator Higgins found that records submitted to REBs for clinical trials comprised research information.[12]

[14] The responsive records here comprise the same type of information as the orders above, namely application forms and other documents submitted to REBs identifying the research study and containing information about the purpose, methodology and results of the research.

[15] I note also the observation in Order F11-21 that submitting research proposals to the scrutiny of a REB (or other body of professionals with expertise in evaluating the theoretical and methodological soundness of research proposals and their potential for creating new knowledge) is a way to ensure that proposals meet the criteria of "research" under FIPPA.[13] The records at issue in this inquiry include records that serve precisely that function of allowing scrutiny of the proposed trials.

[16] I note that the applicant submits that clinical trials are funded and controlled by drug companies to such an extent that the UBC researchers are not in control of any of the intellectual property of the clinical trials and therefore this work does not truly constitute research. UBC disagrees, and submits that the information in the REB records related to clinical trials is research information. This particular argument of the applicant is addressed below when I consider whether the information is "of" the researchers, as required by s. 3(1)(e).

[17] In summary, for the above reasons, I am satisfied that the responsive records clearly constitute the "research information" requirement for the purpose of s. 3(1)(e) of FIPPA.

Does the information belong to UBC researchers?

[18] Order 00-36 emphasized that the purpose of s. 3(1)(e) is to protect individual academic endeavour. It also held that one of the key indicators of the application of s. 3(1)(e) includes whether the information was "generated by identifiable individuals for use in research". This is consistent with Ontario Order PO-2825, which held that:

---

[12] 2008 CanLII 36902 (ON IPC) at paras. 43-46.
[13] F12-03, 2012 BCIPC 3 (CanLII) at para. 9 citing F11-21, 2011 BCIPC 27 (CanLII), at paras. 95-99.

> The research must be referable to specific, identifiable research projects that have been conceived by a specific faculty member, employee or associate of the University.[14]

[19] The records in issue here consist of information about research projects identifiable as belonging to specific UBC researchers. UBC REB's only review research that is conducted by researchers associated with UBC.[15] UBC submits[16] that while research projects usually involve multiple researchers, each project must have a principal investigator who has the primary responsibility for designing and conducting the project and submitting the REB application. This submission is supported by the instructions contained in the blank REB application form provided to me for this inquiry which requires identification of a principal investigator, who "bears the overall responsibility for the conduct of the study…"[17]

[20] Section 3(1)(e) also requires that research information be "of" the researchers. The significance of the word "of" was explained in Order 00-36:

> It should be said that s. 3(1)(e) will not apply simply because someone who happens to be employed by a post-secondary educational body is engaged, under contract or otherwise, to do research for or with a public body such as the CHR. Section 3(1)(e) is intended to protect individual academic endeavour. It will protect the intellectual value in teaching materials or research information developed by an employee of a post-secondary educational body, for her professional purposes, by protecting it from disclosure to those who might exploit it to her disadvantage.
>
> I will give an example of information that would likely not be excluded from the Act under s. 3(1)(e). If an expert on water quality, who happens to be employed by a university, is retained by a local government to conduct water quality tests, the results of those tests will not be "research information of" that person. If the person is retained to develop new methods for water testing (or does so in the course of conducting tests for a public body) and has or retains no intellectual property in the methods she devises, the methods – assuming they truly qualify as "research information" within the meaning of s. 3(1)(e) – will not be research information "of" that person. They will, at best, be research information of the public body and thus will not be excluded from the Act by s. 3(1)(e).[18]

---

[14] Ontario Order PO-2825, 2009 CanLII 50531 (ON IPC), at p. 7. See also Ontario Order PO-2693, 2008 CanLII 36902 (ON IPC).
[15] UBC initial submission at para. 34.
[16] Initial submission at para. 34.
[17] Part 1.1 of Clinical Application Form, Appendix A of affidavit of UBC's Director, Research Ethics.
[18] 2000 CanLII 14401 (BC IPC) at p. 5.

[21] As noted above, the applicant argues that clinical trials are funded and controlled by drug companies to such an extent that the UBC researchers are not in control of any of the intellectual property of the clinical trials and therefore this work does not truly constitute research. In effect the applicant posits that the research information is not "of" the researchers.

[22] UBC acknowledges the role of drug companies as sponsors of clinical trials conducted by UBC researchers. UBC explains that while sponsors may sometimes require protection of their trade secrets or proprietary data, UBC clinical trial agreements with sponsors preserve the academic freedom of researchers, including the ability of researchers to determine the research methodology and to publish the results of their research.[19] I am satisfied based on the evidence before me that UBC clinical trial agreements ensure that researchers retain academic freedom to, among other freedoms, determine their methodology and publish the results of their work, sufficient to satisfy the requirement of s. 3(1)(e) that the records comprise research information of UBC researchers.

CONCLUSION

[23] For the reasons given above, I find that by virtue of s. 3(1)(e), FIPPA does not apply to the records that are the subject of the applicant's request.

November 4, 2014

ORIGINAL SIGNED BY

Hamish Flanagan, Adjudicator

OIPC File No.: F13-53818

[19] UBC submission at paras. 38-42.