Information and Privacy Commissioner,
Ontario, Canada

Commissaire à l'information et à la protection de la vie privée,
Ontario, Canada

ORDER PO-3930

Appeal PA17-123-2

University Health Network

February 25, 2019

Summary: This order deals with an access request made under the *Freedom of Information and Protection of Privacy Act (FIPPA)* to the University Health Network (the UHN) for records related to communications with Health Canada and statistical information about a specific drug. The UHN identified three records as responsive to the request and withheld all three pursuant to the exclusion in section 65(8.1)(c) (research) of *FIPPA*. The requester appealed the UHN's decision and raised the issue of reasonable search during the mediation of the appeal.

In this order, the adjudicator determines that one of the records is excluded from the scope of *FIPPA* pursuant to section 65(8.1)(c). She notes that the other two records at issue may contain "personal health information" (as defined in the *Personal Health Information Protection Act*) of individuals other than the appellant and that as a result, the appellant may not have a right of access to this information under *FIPPA*, or may only have a right of access under *FIPPA* to the remaining information after severing the personal health information. However, the adjudicator finds that it is unnecessary to address this issue because it is clear that both of the remaining records would also be excluded from the scope of *FIPPA* under section 65(8.1)(c).

With regard to the reasonableness of the UHN's search for records, the adjudicator concludes that some of the additional records the appellant asserts exist would be excluded from *FIPPA* pursuant to section 65(8.1)(c). Consequently, no useful purpose would be served in ordering the UHN to conduct further searches for those records. Moreover, she finds that the UHN provided sufficient evidence to establish that it conducted a reasonable search for responsive records.

Statutes Considered: *Freedom of Information and Protection of Privacy Act*, R.S.O. 1990, c. F. 31, as amended, ss. 24 and 65(8.1)(c), *Personal Health Information Protection Act, 2004,* S.O 2004, c. 3, ss. 4(1), 8(1), 8(4), and 52.

OVERVIEW:

[1] A requester made the following request for information to the University Health Network (the UHN) pursuant to the *Freedom of Information and Protection of Privacy Act* (*FIPPA*):

> Provide 2012 to present records that:
>
> 1. The pre-New Drug submission (believe to be #021825) re [a specific drug] of [two doctors] of University Health Network hospital; meeting internally or with Health Canada on that submission; and communications [or] exchanges on its deficiencies or other matters with Health Canada in the 2012-2015 period before the drug's licencing (there was a June 6, 2012 meeting #155181)
>
> 2. Provide adverse drug reactions and side effects reports or fatality/mortality reports re [a specific drug], including those sent to Health Canada and including a summary of such reports before 2012.
>
> 3. Provide statistics on the use of [a specific drug], before and after licensing.

[2] The UHN identified three records as responsive to the request. The records consist of spreadsheets and a letter. The UHN notified an affected party pursuant to section 28(1) of *FIPPA* that the disclosure of the records may affect its interests. The affected party provided representations to the UHN regarding the potential disclosure of the records.

[3] The UHN subsequently issued a decision denying the requester access to the records on the basis that they are excluded from *FIPPA* by section 65(8.1)(c) (research).

[4] The requester (now the appellant) appealed the UHN's access decision to this office. During mediation, the appellant also asserted that additional responsive records ought to exist. These issues were not resolved at mediation and the matters proceeded to the inquiry stage of the appeal process where an adjudicator may conduct an inquiry under *FIPPA*.

[5] An adjudicator commenced an inquiry by sending the UHN a Notice of Inquiry setting out the facts and issues in the appeal and seeking its representations on the matters at issue. The UHN provided representations, which were shared with the appellant in accordance with *Practice Direction Number 7*. The appellant responded to the UHN's representations and the adjudicator offered the UHN an opportunity to reply. The appellant then provided a sur-reply. The appeal was then transferred to me to continue the inquiry.

[6] For the reasons that follow, I find that one of the records is excluded from the scope of *FIPPA* pursuant to the research-related exclusion in section 65(8.1)(c). I note that the other two records may contain "personal health information," as defined in the *Personal Health Information Protection Act* (PHIPA), of individuals other than the appellant and that as a result, the appellant may not have a right of access under *FIPPA*, or may have a right of access to only the information remaining after severing the personal health information. However, I find that it is unnecessary to address this issue because it is clear that both of the remaining records would also both be excluded from the scope of *FIPPA* under section 65(8.1)(c).

[7] With regard to the reasonableness of the UHN's search for responsive records, I find that some of the additional records the appellant asserts exist would also be excluded from *FIPPA* pursuant to section 65(8.1)(c). Consequently, no useful purpose would be served in ordering the UHN to conduct further searches for those records. Moreover, I uphold the reasonableness of the UHN's search for responsive records and decline to order any further searches.

RECORDS:

[8] The UHN withheld all three of the records it identified as responsive to the appellant's request in full. The following chart provides a description of the records at issue:

Record Number	Number of Pages	Description of Contents
1	5	A letter from a doctor to a drug company
2	9	Pages 1-2 and 5-9: Spreadsheets with rows and columns including individuals' names and data related to their use of a particular medication Page 3: A list of information related to the spreadsheets
3	11	Pages 1-2: Spreadsheets and a graph all containing dates and

		numerical data Pages 3-4 and 7-11: Spreadsheets with rows and columns including individuals' names and data related to their use of a particular medication Page 5-6: A list of information related to the spreadsheets

PRELIMINARY MATTER:

[9] In its initial representations, the UHN submits that Records 2 and 3 contain the personal health information of individuals who participated in a "Compassionate Use Program" related to a specific drug. "Personal health information" is defined in sections 4(1)(a) and (b) of *PHIPA* to include the following:

> identifying information about an individual in oral or recorded form, if the information,
>
> > (a) relates to the physical or mental health of the individual, including information that consists of the health history of the individual's family,
> >
> > (b) relates to the providing of health care to the individual, including the identification of a person as a provider of health care to the individual,

[10] Records 2 and 3 contain the names of individuals together with information about their use of a particular medication. While this may qualify as personal health information, the parties did not make full representations on this issue and I have determined that it is not necessary for me to address it for the reasons that follow.

[11] As a public hospital, the UHN is both an institution under *FIPPA* and a health information custodian under *PHIPA*.[1] *PHIPA* sets out rules governing access to records of personal health information, and the entitlement of a person to make a request for access to such records.

[12] Pursuant to section 52 of PHIPA, the right of access to personal health

[1] See the definitions of "institution" and "hospital" in section 2(1) of FIPPA, and also section 3(1)4i of *PHIPA*, as well as Order PO-3751.

information belongs to the individual to whom the information relates.[2] *PHIPA* does not otherwise provide any right of access to records of personal health information.[3]

[13] Furthermore, section 8(1) of *PHIPA* specifies that, except in specified circumstances, *FIPPA* does not apply to personal health information in the custody or control of a health information custodian.[4] However, section 8(4) of PHIPA preserves rights of access under *FIPPA* if all of the personal health information in a record of personal health information can reasonably be severed.

[14] The information in Records 2 and 3 does not relate to the appellant. It follows that if I found that these records contained personal health information, the next step would be determine whether any information could reasonably be severed from the records of personal health information such that the appellant may have a right of access to the remainder under *FIPPA*.

[15] However, even if the records are records of personal health information under *PHIPA*, and even if section 8(4) would preserve a right of access to some information in the records under *FIPPA*, it is unnecessary for me to make findings under those sections. For reasons that I set out below, it is clear to me that Records 2 and 3 would both be excluded from the scope of *FIPPA* in any event, pursuant to the research exclusion at section 65(8.1)(c). Given that Records 2 and 3 would be excluded from *FIPPA*, it is not necessary to consider the issue of whether there is personal health information in these records and if so, whether that information could reasonably be severed.

ISSUES:

A. Does section 65(8.1)(c) exclude the records at issue from *FIPPA*?

B. What is the scope of the appellant's request? Did the UHN conduct a reasonable search for records?

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[2] Pursuant to sections 5(1), 23 and 25 of *PHIPA* a "substitute decision-maker" authorized to make a request for access on an individual's behalf may also have a right of access to personal health information.
[3] PHIPA Decision 27, at para. 22.
[4] A "health information custodian" is defined in section 3 of *PHIPA*.

DISCUSSION:

A. Does section 65(8.1)(c) exclude the records at issue from *FIPPA*?

[16] Section 65(8.1) excludes certain research-related records from *FIPPA*. The relevant part of that section states:

> This Act does not apply,
>
> …
>
> > (c) to a record respecting or associated with research, including clinical trials, conducted or proposed by an employee of a hospital or by a person associated with a hospital; or

[17] Past decisions of this office have defined research 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."[5] The research must be referable to specific, identifiable research projects conducted or proposed by an employee or person associated with a hospital.[6]

[18] This office has also stated that this section applies where it is reasonable to conclude that there is "some connection" between the record and the specific, identifiable "research conducted or proposed by an employee of a hospital or by a person associated with a hospital."[7]

[19] Previous orders have emphasized the importance of considering the purposes of *FIPPA* as a context for interpreting the research exclusions under section 65(8.1).[8] In Order PO-3365, the adjudicator concluded that the legislative intent with regard to section 65(8.1)(c) was to protect the academic freedom and competitiveness of hospital-based research.

[20] If the exclusion in section 65(8.1)(c) applies to records at issue, they will be totally excluded from the access and privacy provisions of *FIPPA*.[9]

The UHN's representations

[21] The UHN says that section 65(8.1)(c) applies to all three of the records at issue

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[5] Orders PO-2693 and PO-3365.
[6] Order PO-2942; see also *Ontario (Attorney General) v. Toronto Star*, 2010 ONSC 991 (Div. Ct.).
[7] Orders PO-2693 and PO-3365.
[8] Orders PO-2693, PO-2942 and PO-3365.
[9] Order PO-3365.

because they relate to a clinical research study. It submits that it was involved in a "Compassionate Use Program" where a group of patients were provided access to a drug and the drug's efficacy was studied and monitored (the Program). It says that the records it identified as responsive to the appellant's request are comprised of two spreadsheets detailing patient participation in the Program (Records 2 and 3) and a report from a doctor (the Doctor) to a drug company about the results of the study conducted in relation to the Program (Record 1).

[22] The UHN submits that the Doctor's findings regarding the patients' participation in the Program are currently summarized in a research paper that, at the time the UHN made its initial representations for this inquiry, was awaiting approval and subsequent publication. The UHN says that because the records at issue relate to a "clinical research study," they are excluded from *FIPPA* pursuant to section 65(8.1)(c).

[23] In support of its assertion that the records at issue relate to a clinical research study, the UHN provided copies of two UHN "Research Ethics Board" approvals for "access to retrospective data for research purposes" related to the drug it says was monitored and studied during the Program.

The appellant's representations

[24] The appellant says that section 65(8.1)(c) of *FIPPA* does not apply to the information at issue because the UHN was not conducting a clinical research trial. The appellant submits that the data collected through the Program was not intended to be a "research driven program nor a clinical study" and therefore cannot be considered hospital research.

[25] The appellant further asserts that the UHN Research Ethics Board approvals to collect data on the drug "hardly constitutes hospital research" as they are not accompanied by convincing evidence of a "scientific controlled hospital clinical trial ever being in place or any evidence of the necessary consent forms from patients that is a basic element needed for this collection to be considered hospital research."

[26] The appellant makes a number of further representations which I understand to be aimed at establishing that the records at issue were not part of "any clinical legitimate research study." He says that incidents of adverse effects and risks were not reported to the Research Ethics Board and that the manner in which the UHN used the Program circumvented acceptable hospital research and was "a long way from what constitutes clinical trials and hospital research."

The UHN's reply and the appellant's sur-reply

[27] In reply, the UHN asserts that it had a responsibility to both monitor and study the patients that participated in the Program. It says that the patients were studied in both an individual and group manner and that the Doctor monitored the patients' reactions to the drug and prepared a research paper based on the results of the

Program.

[28] In sur-reply, the appellant reiterates his earlier submission that the activities of the Doctor did not constitute a "legitimate clinical trial" or "acceptable hospital research." He notes that the UHN has not provided detailed UHN Research Ethics Board submissions or an affidavit from the Doctor to support its claim that its activities, or those of the Doctor, in relation to the Program, constituted hospital research.

Findings and analysis

[29] Although I have determined that Records 2 and 3 may contain the personal health information of individuals participating in the Program and that as a result, *FIPPA* may not apply, I have considered and referred to all three records at issue in this inquiry because they all relate to the same matters (the Doctor's study and the Program).

[30] For the following reasons, I have determined that all of the records at issue are records respecting or associated with research, including clinical trials, conducted or proposed by an employee of a hospital or by a person associated with a hospital and as a result, they either are, or would be, excluded from *FIPPA* pursuant to section 65(8.1)(c).

[31] I accept the UHN's representations that all three records contain information collected during the Program about the patients' use of the drug. I note that Record 1, the report to the drug company, covers roughly the same timeframe as the spreadsheets in Records 2 and 3 and many of the same medical terms and acronyms from spreadsheets are discussed at length in the report. All three of the records refer to the type of treatment the patients were undergoing and the information in the records supports the UHN's assertion that the patients' reactions to the drug were being monitored and studied.

[32] Although I cannot discuss the specific contents of the records at issue, it is clear from my review of these records that the patients' reactions to a specific drug were being monitored and that the results were being analyzed for the purpose of understanding the effects of the drug. In my view, this type of activity fits within the definition of research (i.e., a systematic investigation designed to develop or establish principles, facts or generalizable knowledge).

[33] The majority of the appellant's submissions, as outlined above, focus on whether the UHN conducted a legitimate clinical trial. The appellant submits that the UHN did not conduct a proper clinical trial, and was therefore not engaged in hospital research as contemplated by section 65(8.1)(c) of *FIPPA*. I do not accept this argument. Section 65(8.1)(c) specifies that "research" includes clinical trials, but it does not say that research is confined to clinical trials. It is not the case that only records respecting or associated with clinical trials are subject to section 65(8.1)(c) and as such, it is not necessary for the UHN to prove that the research was part of a clinical trial. Therefore,

for the reasons set out above, I find that UHN has established that all three records at issue in this inquiry are related to research within the meaning of section 65(8.1)(c).

[34] However, that is not the end of the matter. As noted in Order PO-3365, section 65(8.1)(c) requires that the research be conducted "by an employee" or a "person associated" with a hospital.[10] The affidavit of UHN's Manager of Privacy Operations and Freedom of Information Coordinator specifies that Record 1 was written by the Doctor, who is a full-time medical specialist with the UHN at one of its hospitals and a member of the UHN's research staff at another of its hospitals. I also note the content of Record 1, which I cannot reveal, makes it clear that the Doctor's research was associated with the hospital.

[35] With regard to Records 2 and 3, the UHN's representations state that the data in those records was collected for the purposes of the Doctor's study and it provided approvals from the UHN's Research Ethics Board as evidence in support of that assertion.

[36] Based on the evidence provided by the UHN, I find that all three of the records at issue are associated with research conducted by an employee, or a person associated with, the UHN (in this case, the Doctor). As a result, they either are, or would be, excluded from the scope of *FIPPA* by section 65(8.1)(c).

B. What is the scope of the request? Did the institution conduct a reasonable search for records?

[37] Section 24 of *FIPPA* imposes certain obligations on requesters and institutions when submitting and responding to requests for access to records. This section states, in part:

> (1) A person seeking access to a record shall,
>
> > (a) make a request in writing to the institution that the person believes has custody or control of the record;
> >
> > (b) provide sufficient detail to enable an experienced employee of the institution, upon a reasonable effort, to identify the record;
>
> . . .
>
> (2) If the request does not sufficiently describe the record sought, the institution shall inform the applicant of the defect and shall offer

[10] At para. 39.

> assistance in reformulating the request so as to comply with subsection (1).

[38] Institutions should adopt a liberal interpretation of a request, in order to best serve the purpose and spirit of *FIPPA*. Generally, ambiguity in the request should be resolved in the requester's favour.[11]

[39] To be considered responsive to the request, records must "reasonably relate" to the request.[12]

[40] 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.[13] 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.

[41] *FIPPA* 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.[14] To be responsive, a record must be "reasonably related" to the request.[15]

[42] A reasonable search is one in which an experienced employee knowledgeable in the subject matter of the request expends a reasonable effort to locate records which are reasonably related to the request.[16]

[43] A further search will be ordered if the institution does not provide sufficient evidence to demonstrate that it has made a reasonable effort to identify and locate all of the responsive records within its custody or control.[17]

The UHN's representations

[44] The UHN submits that it conducted a reasonable search for responsive records. It provided an affidavit from its Manager of Privacy Operations and Freedom of Information Coordinator. The Manager says that he contacted the Doctor and asked him to conduct a search in response to the appellant's original request. After clarifying the request with the Manager, the Doctor advised the Manager that he did not locate any records that referenced a "pre-New Drug Submission" to Health Canada. The

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[11] Orders P-134 and P-880.
[12] Orders P-880 and PO-2661.
[13] Orders P-85, P-221 and PO-1954-I.
[14] Orders P-624 and PO-2559.
[15] Order PO-2554.
[16] Orders M-909, PO-2469 and PO-2592.
[17] Order MO-2185.

Doctor also told the Manager that he did not participate in the preparations of any submissions to Health Canada about the drug, though he did attend a meeting with the drug company and Health Canada and gave a presentation in support of the licensing of the drug.

[45] The Manager attested that he then met with the Doctor to discuss the search further with respect to the appellant's request for adverse side effects of the drug and mortality reports. The Doctor told the Manager that information related to those matters was transferred to each patient's "Electronic Medical Record" after the completion of the Program and following Health Canada's approval of the drug in 2015. The UHN explained in its representations that it understood the appellant to be seeking "summary records," rather than information that would be located in individual patient files. The UHN submits that it based this understanding, in part, on the fact that the appellant had made a subsequent request under *FIPPA* for specific patient data for patients taking the drug.

[46] The UHN further stated that although it was involved in the Program, it did not provide any information on the drug's efficacy directly to Health Canada for the purpose of drug licensing. It further stated that while the Doctor made a presentation to Health Canada as a guest of the drug's manufacturer, the UHN has no records of other communications with Health Canada about the drug's deficiencies or other matters.

[47] Finally, the Manager attested that there are no records containing statistics on the use of the drug before or after licensing.

The appellant's representations

[48] In his initial representations, the appellant makes a number of assertions about why he believes additional records should exist. His arguments, in summary, are as follows:

1. The UHN's representations and Exhibits B and C of the Manager's affidavit indicate that the Doctor made at least one presentation as part of the "pre-drug discussions" but no notes or slides related to the presentation have been provided.

2. The Doctor made additional "pre-drug submissions such as [those] to the Research Ethics Board in 2011 and 2012."

3. No reports of adverse side effects and fatality/mortality reports sent by the UHN to Health Canada were provided.

4. Data on the drug's deficiencies, including its toxicity and side effects would have been discussed if the UHN was conducting research or taking samples and compiling statistics for reports.

5. A dossier/data package that the drug company submitted making use of the Doctor's UHN data should exist.

6. Records related to the paper the Doctor was publishing, including a table of contents or other information about the paper, should exist.

[49] The appellant also takes issue with the UHN's decision that some of the information the Doctor identified as potentially responsive to the request was "not relevant" and submits that the UHN should have identified the documents and offered evidence or an affidavit in support of its decision that they were not relevant.

The UHN's reply

[50] In reply, the UHN submits that other than the one presentation made before a Health Canada committee in 2011, the Doctor had no involvement in the preparation of any "pre-drug submissions" and notes that the appellant has not provided any evidence in support of his claim that the Doctor, or the UHN, were further involved in that process.

[51] The UHN further states that it, as an organization, did not participate in the preparation of any "pre-drug submissions," nor was it a participant in the drug's approval process.

[52] With regard to the records that the UHN concluded were not relevant and outside of the scope of the appellant's request, it specifies those records related to funding for an external conference. They also included other records the UHN says were already reviewed when processing other related access requests the appellant previously made under *FIPPA*.

The appellant's sur-reply

[53] In his sur-reply, the appellant takes issue with the UHN's position that the information he is seeking is unavailable. He says that the Doctor's unreleased paper would have had to rely on the data he is seeking and makes the following additional arguments:

> It is difficult to stand by and not receive the adverse drug reports and side effects and fatality/mortality reports (minus their names and personal information) [the Doctor] was obliged to submit and sent to [the drug company] and Health Canada.
>
> Or not to get routine SAP [the Program] patient by patient applications (minus their personal information) [the Doctor] made every six months.
>
> Or generic notes [the Doctor] assembled without patient consent that [the Doctor] intends to publish.

> UHN does not expect anyone, including peer groups, to have access to or monitor what [the Doctor] collected or how he collected the data, kept it and used it. Or to agree that the "study" data integrity is no longer available and disassembled.

[54] The appellant confirms he is seeking an order to have the UHN conduct a further search and provide responsive records.

Findings and analysis

[55] It is clear from the appellant's representations, in particular his sur-reply (as set out in part above), that he is seeking records related to the study that the Doctor conducted through the Program. I have already concluded that records related to those matters are records respecting or associated with research conducted or proposed by an employee or person associated with a hospital, and are therefore excluded from *FIPPA* pursuant to section 65(8.1)(c).

[56] Previous orders have examined whether an institution should be ordered to conduct further searches for responsive records in cases where records have been found to be excluded from *FIPPA*.[18] For example, in Order MO-1412, the adjudicator was satisfied, based on his treatment of records that had been identified as responsive, that any other records that might exist would, by definition, be treated in the same manner. On that basis, he declined to order a further search. Similar reasoning applies to a number of the records the appellant asserts exist in his representations.

[57] In my view, it is reasonable to conclude that records that have "some connection" to the Doctor's research through the Program at the UHN (i.e. records related to the study he conducted, the data he obtained, the paper he intended to publish, or any notes and/or slides from his presentation) would also fall within the scope of 65(8.1)(c) for the reasons outlined above. Accordingly, I find that no useful purpose would be served in ordering the UHN to conduct further searches for these types of records.

[58] Moreover, I find that the evidence submitted by the UHN demonstrates that it conducted a reasonable search for records. The Manager who conducted the search had the appropriate experience and was familiar with the UHN's record keeping practices. He contacted the Doctor to assist him in locating the responsive records, followed up with the Doctor to clarify the nature of the request and then also met with him to discuss the search findings. The Manager's affidavit also specified that the Doctor had been involved in four previous access requests related to the drug that was the subject matter of this request and as a result, I accept that the Doctor was also

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[18] Orders MO-1412, PO-2105-F and PO-3194.

familiar with the subject matter and location of the responsive records.

[59] As noted above, although an appellant will rarely be in a position to indicate precisely which records have not been identified in an institution's response, the appellant must, nevertheless, provide a reasonable basis for concluding that such records exist. The appellant in this case has not provided that basis. For example, he asserts that additional records should exist regarding communications the UHN had with Health Canada about a "pre-New Drug submission." However, he has not explained the basis for his belief that the UHN or the Doctor were communicating directly with Health Canada and/or sending it reports regarding the drug, nor did he offer satisfactory evidence in support of his assertions that the records he seeks in that regard exist.

[60] Based on my review of Record 1, I accept the UHN's representations that, other than the presentation made before the Health Canada committee, neither the Doctor nor the UHN were involved in the preparation of any "pre-drug submissions." Although I cannot reveal the specific content of Record 1, it is connected to the Doctor's presentation and supports the UHN's assertion that the Doctor did not communicate directly with Health Canada about the drug.

[61] Finally, with regard to the appellant's assertion that the UHN should have provided additional information regarding the records the Manager determined were not responsive to his request, I accept the UHN's evidence that those records were outside the scope of the appellant's request. The UHN says the records related to funding for an external conference and included records that had previously been reviewed when processing the appellant's prior *FIPPA* requests related to the same matters. While it is possible that records reviewed in response to one request could also be relevant to a different request, I understand from the Manager's affidavit that the Doctor had been asked to exclude all records that were previously *provided* in response to the requester's past requests.

[62] For all of the reasons set out above, I find that the UHN conducted a reasonable search for responsive records as required by section 24 of *FIPPA*, and I decline to order the UHN to conduct a further search for responsive records.

ORDER:

For the reasons set out above, I uphold the UHN's decision to deny the appellant access to the records at issue and find that the UHN conducted a reasonable search for responsive records.

Original signed by
Meganne Cameron
Adjudicator

February 25, 2019