Information and Privacy Commissioner,
Ontario, Canada

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

ORDER PO-4360

Appeal PA21-00439

Humber River Hospital

March 13, 2023

Summary: Humber River Hospital (the hospital) received a request for records relating to a clinical trial of [a specified test] of a named company. The hospital issued a decision denying access to the responsive records on the basis that they were excluded from the *Act* by section 65(8.1)(c) (research/clinical trials exclusion). As provided for in section 65(9) of the *Act*, the hospital disclosed the subject matter and the amount of funding associated with the clinical trial. In this order, the adjudicator upholds the hospital's decision that the responsive records are excluded from the *Act* by section 65(8.1)(c) and dismisses the appeal.

Statutes Considered: *Freedom of Information and Protection of Privacy Act*, R.S.O. 1990, c. F.31, section 65(8.1)(c).

Orders and Investigation Reports Considered: Orders PO-2225 and PO-2825.

OVERVIEW:

[1] Following discontinuation of a clinical trial, the appellant, the representative of a company that develops diagnostic tests, made the following request to the Humber River Hospital (the hospital) under the *Freedom of Information and Protection of Privacy Act* (the *Act*):

> Please produce all records in relation to the clinical trial of [a specified test] of [named company]. The principal investigator in relation to this clinical trial was [named individual].

[2] The hospital issued a decision denying the appellant access to the responsive records on the basis that they were excluded from the *Act* by section 65(8.1)(c) (research exclusion). As provided for in section 65(9) of the *Act*, the hospital disclosed the subject matter and the amount of funding associated with the clinical trial.

[3] The appellant appealed the hospital's decision to the Information and Privacy Commissioner of Ontario (the IPC).

[4] During mediation, the mediator discussed the appeal with the appellant and the hospital. The appellant challenged the hospital's position that section 65(8.1)(c) of the *Act* excluded the responsive records from the *Act*. The hospital confirmed its decision and the appellant advised that he wished to proceed to the adjudication stage of the appeal process.[1]

[5] The original adjudicator assigned to the appeal decided to conduct an inquiry and invited representations from the parties which were shared in accordance with the IPC's *Code of Procedure*.

[6] Subsequently, I was assigned to this appeal. I provided the hospital with the appellant's representations, inviting it to provide a reply. The hospital did not provide any further representations.

[7] In this order, I find that the research exclusion at section 65(8.1)(c) of the *Act* applies to the responsive records and dismiss the appeal.

RECORDS:

[8] There were six records identified by the hospital, concerning the clinical trial referenced in the request.

DISCUSSION:

[9] The sole issue before me is whether the section 65(8.1)(c) exclusion, for records respecting or associated with research or teaching, applies to records identified as responsive to the appellant's request.

[10] Section 65(8.1) of the *Act* excludes certain records relating to research and teaching from the *Act*. As a result, the *Act*'s access scheme does not apply to them. The

[1] The appellant also claimed that there was a public interest in the disclosure of the records. However, the public interest override is not an issue before me because it cannot apply to override an exclusion: see section 23 of the *Act*.

purpose of this provision is to protect academic freedom and competitiveness.[2]

[11] The burden of proof lies upon the hospital to establish that the exclusion applies to any responsive records.[3]

[12] The hospital relies specifically on section 65(8.1)(c) which states:

> This *Act* does not apply,
>
> > 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

[13] Sections 65(9) and (10) create exceptions to the exclusion found at section 65(8.1). As stated above, the hospital has already disclosed the information relating to the clinical trials in accordance with these section 65(9). Section 65(10) states:

> 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).

[14] Research has been defined in past IPC orders 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." The research must be able to be linked to specific, identifiable research projects conducted or proposed by a specific faculty member, employee or associate of an educational institution.[4]

[15] The research exclusion is to be narrowly construed, and legislative intent must be kept in mind when interpreting the meaning of the word "research" in sections 65(8.1) (c).

[16] Universities and hospitals were made subject to the *Act* in 2005 and 2012, respectively. The IPC has found that section 65(8.1)(a) protects academic freedom because of the importance of research and innovative study programs in universities.[5] The IPC has held that similar considerations apply in relation to section 65(8.1)(c) in relation to hospitals.[6]

[17] This section applies where there is "some connection" between the record and

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[2] Order PO-2693, *Carleton University v. Information and Privacy Commissioner of Ontario and John Doe, requester*, 2018 ONSC 3696.
[3] See MO-3294-I, PO-4192 and MO-3919-I, for example.
[4] Order PO-2693.
[5] *Carleton University v. Information and Privacy Commissioner of Ontario and John Doe, requester*, 2018 ONSC 3696.
[6] Order PO-3365.

the specific, identifiable "research conducted or proposed by an employee of an educational institution or by a person associated with an educational institution."[7]

[18] Section 65(10) creates an exception to the exclusion set out in section 65(8.1), and provides that the *Act* does apply to the evaluative or opinion material referred to in section 49(c.1)(i).

Representations

[19] The hospital submits that the records at issue in this appeal are associated with research, specifically a clinical trial, conducted by one of its physicians at the hospital. It submits that the responsive records include documents that are typically generated as part of a research project (Research Ethics Board Approval, Research Protocol, Informed Consent, Questionnaire and Poster, Sample of Data Collection sheet, Sections of the Clinical Trial Agreement between the hospital, physician and manufacturer). As such, the hospital submits, the records are excluded from the *Act* as per section 65(8.1) and it was entitled to deny access to them.

[20] The hospital submits that in responding to the request, it understood its responsibility under the *Act* to comply with the exception to this exclusion in section 65(9) and as a result, disclosed the following to the appellant:

- The subject matter of the clinical trial, and
- The total amount of the funding for this clinical trial

[21] The hospital submits that it did not provide any information to the requester based on the exception to the exclusion in section 65(10) of the *Act* because it felt it was not applicable to this clinical trial.

[22] The appellant submits that the exclusion must be interpreted narrowly and that there is no evidentiary basis for the hospital's claim that the records are excluded by section 65(8.1)(c). He submits that the publicly available information, the initial response of the hospital and the identified records confirm that the "purported clinical trial study" was not conducted. The appellant also submits that the clinical study was not proposed by an employee of the hospital as the study was proposed by the company, a not-for- profit entity in furtherance of its own business.

[23] The appellant submits that it would not promote "academic freedom and competitiveness" to withhold the responsive records. In fact, he submits, the subject matter of the study, which would have purportedly been [a specified test,] has failed and proven to not be effective or fit for its purpose.

[24] The appellant submits that he has a concern that the hospital's records list,

[7] Order PO-2942; see also *Ontario* (*Attorney General*) *v. Toronto Star*, 2010 ONSC 991 (Div. Ct.).

provided with its representations, does not refer to all of the responsive information that should exist. He refers to the definition of record in section 2(1) the *Act*. The appellant also refers to two of the company's own news releases concerning the clinical study, the first suggesting the need for the study and the last referring to early lab results not translating well into the clinical environment. The appellant submits that no records have been identified by the hospital concerning the subject matter in either of these releases. He submits that those records, if they exist, would be potentially relevant to the application of the exception provided at section 65(10). He submits that in these news releases, the principal investigator of the study referred to specific facts as well as opinions, yet no records have been identified relating to the subject matter of either release.

[25] The appellant also submits that he is unable to comment on the application of section 65(10) to the identified records because of the apparent evidentiary gap, in that the hospital did not elaborate on how it arrived at a finding that section 65(10) did not apply to the records except stating that it felt it was not applicable to the clinical trial. The appellant suggests that the hospital "has not affirmatively stated whether or not the responsive record would otherwise include records containing evaluations or opinions." As a result, the appellant concludes that he is unable to "meaningfully comment on the substantive issues" in this appeal. The appellant did not discuss how the records might contain the personal information of an individual with the company so that the exception at section 65(10) is triggered.

Analysis and finding

[26] The exclusion at section 65(8.1)(c) is clear and records respecting or associated with research, including clinical trials, conducted or proposed by an employee of the hospital will be excluded from the *Act* with limited exceptions. I find the records at issue are excluded from the scope of the *Act* under section 65(8.1)(c).

[27] This exclusion applies, as noted, in order to protect academic freedom because of the importance of research and innovative study programs in universities. The fact that the study was not successful is not relevant to my determination of whether the records at issue are excluded from the scope of the *Act*.

[28] The appellant submits that because the company proposed the study, the responsive records cannot be excluded under section 65(8.1)(c). The appellant further argues that the hospital initially indicated that the [specified study] was not conducted. Based on my review of the parties' representations and the records, I find that the study was conducted by the hospital. Further, given that the principal investigator was a physician employed by the hospital, I find that the study was conducted by an employee of the hospital, or a person associated with the hospital. Therefore section 65(8.1)(c) applies to the responsive records subject to the exceptions set out in section 65(9) and 65(10).

[29] Given my finding that the hospital conducted the clinical trial, it is not necessary for me make a finding on who proposed it.

[30] Although there are exceptions to this exclusion set out in sections 65(9) and 65(10), the hospital has provided the information required in section 65(9) and the appellant did not take issue with this in its representations.

[31] The appellant suggests that the hospital's submissions concerning section 65(10) not applying to the identified records is inadequate since the hospital did not elaborate on how it arrived at this finding. However, after my review of the records at issue, I find that section 65(10) does not apply to them as they do not contain evaluative or opinion material for the purpose of subclause 49(c.1)(i).

[32] As noted, the exception at section 65(10) provides that the *Act* applies to the evaluative or opinion material referred to in section 49(c.1)(i). Section 49(c.1)(i) creates an exemption to the general right of access to an individual's own personal information held by an institution. Under section 49(c.1)(i), an institution may refuse to disclose evaluative or opinion material compiled to assess teaching materials or research.

[33] With regard to the circumstances of the creation of the records at issue in this appeal, I find that section 49(c.1)(i) does not apply. I find support for this conclusion in Order PO-2825. In that order, the adjudicator determined that section 49(c.1)(i) did not apply to a peer review report on a research proposal submitted to a university by the appellant because he concluded that it did not contain the appellant's personal information according to the definition of the term in section 2(1) of the *Act*. The following excerpt from Order PO-2825 is relevant in this appeal:

> Applying the approach of former Assistant Commissioner Tom Mitchinson in Order PO-2225, and having carefully reviewed the record, I also find that the record was created and exists in an entirely professional context. It includes information relating to the proposed professional scientific work of the appellant as an employee of the University and the comments of the affected party are made in his or her professional capacity as a peer reviewer. I also find that disclosure of the record would not reveal anything of a personal nature about the appellant because there is nothing in the record that would relate to the appellant in his personal capacity and the comments of the affected party about the research proposal do not reach into the personal realm.
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> Accordingly, I find that the record does not contain any information of the appellant that qualifies as his personal information.
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> Because of the wording of the preamble of section 49 ("[a] head may refuse to disclose to the individual to whom the information relates personal information…"), section 49(c.1)(i) can only apply to records

> containing the personal information of the requester, in this case, the appellant (see Order M-352).

[34] I agree with and adopt the analysis in Orders PO-2225 and PO-2825 for the purposes of this appeal. I am satisfied that the records at issue were "created and exist in an entirely professional context," relating as they do to the clinical trial of [the specified test]. The records identified as responsive by the hospital do not contain information that would qualify as "personal information," as that term is defined in section 2(1) of the *Act*. As a result, the section 49(c.1)(i) exemption is not relevant.

[35] The appellant claims that additional records should exist. While the issue of search is not before me, I observe that, given the nature of the access request and my review of the records and submission of the parties, it is likely that any other records, if any exist, are also excluded from the *Act* under section 65(8.1)(c).

[36] In conclusion, I find that the identified records fall within section 65(8.1)(c), and that they are excluded from the *Act*.

ORDER:

The appeal is dismissed.

Original signed by: March 13, 2023
Alec Fadel
Adjudicator