



Advisory Opinion 14-003

This is an opinion of the Commissioner of Administration issued pursuant to Minnesota Statutes, section 13.072 (2013). It is based on the facts and information available to the Commissioner as described below.

Facts and Procedural History:

On March 5, 2014, the Information Policy Analysis Division (IPAD) received a letter dated same, from Carl Elliott. In his letter, Mr. Elliott asked the Commissioner to issue an advisory opinion about his right to gain access to certain data that the University of Minnesota (the University) maintains.

IPAD, on behalf of the Commissioner, wrote to Susan McKinney, data practices responsible authority for the University, in response to Mr. Elliott's request. The purposes of this letter, dated March 17, 2014, were to inform her of Mr. Elliott's request and to ask her to provide information or support for the University's position. On April 2, 2014, IPAD received a response, dated same, from Tracy Smith, attorney for the University.

A summary of the facts as Mr. Elliott provided them follows. In his opinion request to the Commissioner, he wrote:

In [my October 20, 2013 data] request, I asked for the minutes of any IRB [Institutional Review Board] meeting in which Serious Adverse Events were discussed for studies conducted by [four psychiatrists]... I also asked for any correspondence regarding Continuing Review of these studies, and the minutes of any IRB Executive Committee meeting in which these Serious Adverse Events in these studies were discussed.

On October 28, 2013, Mr. Elliott followed his October 20, 2013, request with a request for: "the Form 1572, all Adverse Event reports and any other correspondence from the [CLEARS study]."

Mr. Elliott continued:

Despite a number of email reminders, I did not receive an answer to this request for four weeks. On November 21, I was told that in order to get this information I would need to send a check for a total of approximately \$9,419, not including photocopying costs.

...On December 1, I asked [to inspect the data], and on December 12, I narrowed my request considerably in order to speed things up... After several more reminders, I was finally allowed to inspect the records for a single study on January 8, 2014.

On January 11, I asked again about a visual inspection of the Serious Adverse Event Reports for a particular study: the so-called CLEARS study, which was conducted by AstraZeneca. On

January 14, I was notified that AstraZeneca had marked the study as “proprietary” and that the company was being contacted for permission. It has been seven weeks since then, and I have still not gotten a reply.

In the meantime, I have repeatedly asked when I will be allowed to see the Serious Adverse Event reports and/or Continuing Review reports for the other studies conducted by [the two psychiatrists], but I have still not been allowed to see them, or even received a response.

Issue:

Based on Mr. Elliott’s opinion request, the Commissioner agreed to address the following issue:

Pursuant to Minnesota Statutes, Chapter 13, did the University of Minnesota respond appropriately to a request for data related to Institutional Review Boards, specifically: studies, reports, meeting minutes and correspondence?

Discussion:

As a preliminary matter, the Commissioner wishes to note that Mr. Elliott has made a number of data requests to the University throughout the past year, which are documented in the University’s response to the Commissioner’s letter. While the other requests provide relevant context to the University’s response, this opinion focuses on the University’s response to the October 20, 2013, request and the follow-up request on October 28, 2013, referenced in Mr. Elliott’s letter to the Commissioner.

Pursuant to Minnesota Statutes, section 13.03, subdivision 2(a), when a government entity receives a request from an individual who is not the subject of the data, the entity is required to respond in an appropriate and prompt manner, and within a reasonable time. (See also, Minnesota Rules, part 1205.0300.) Although the Legislature did not define “reasonable time,” the Commissioner has stated in previous opinions that it is relative to the nature or complexity of the request and amount of data requested. (See Advisory Opinions 98-040 and 02-020.)

Further, previously issued advisory opinions have established that, when responding to data requests, government entities should respond in one of three ways: (1) provide the data; (2) advise that the data are classified such as to deny the requesting person access; or (3) inform the requestor that the data do not exist.

Section 13.03, subdivision 3(f), provides:

If the responsible authority or designee determines that the requested data is classified so as to deny the requesting person access, the responsible authority or designee shall inform the requesting person of the determination either orally at the time of the request, or in writing as soon after that time as possible, and shall cite the specific statutory section, temporary classification, or specific provision of federal law on which the determination is based.

Mr. Elliott made his request on October 20, 2013. He made the follow-up request for data about the CLEARs study on October 28, 2013. Despite Mr. Elliott’s assertion that the University did not respond to those requests for four weeks, the University provided the Commissioner with an email dated October 28, 2013, in which Ms. McKinney wrote, “I have received all of your requests. We are working on gathering the information you requested.” On November 21, 2013, Ms. McKinney wrote to Mr. Elliott and provided him with an estimate for the copies he requested, which included the

requests dated October 20, 2013, and October 28, 2013, and a recap of his remaining unresolved data requests. On December 1, 2013, Mr. Elliott responded to that email and changed his request to inspection instead of copies. Mr. Elliott and Ms. McKinney continued to correspond about other data requests and on December 12, 2013, Ms. McKinney provided Mr. Elliott with a list of 83 studies that contained data responsive to his request and offered him the opportunity to choose which studies he wanted to review first. Mr. Elliott and Ms. McKinney continued to be in contact with one another for the remainder of the month on these and other requests.

On January 22, 2014, in reply to an email from Ms. McKinney, Mr. Elliott further refined his request and identified his priorities with regard to inspecting the data. Two days after Mr. Elliot requested this opinion, on March 7, 2014, Ms. McKinney notified Mr. Elliott that the University had hired an individual to assist in fulfilling his October data requests.

On behalf of the University, Ms. Smith, wrote:

It is important to understand the complexity of identifying and locating the records Prof. Elliott requested. Neither serious adverse event reports nor continuing review correspondence are kept together in some central University file organized according to "serious adverse events" reports or "continuing reviews," nor are such documents organized or maintained according to researcher. Rather, the records are organized and maintained according to the IRB protocol for the applicable research project.

Ms. Smith went on to explain the involved process necessary to identify and prepare the relevant data, which include studies for a period of nearly 20 years. She wrote, “[e]ven to find that no records exist in a file requires a careful review of a file.”

Based on the complexity of the request and the fact that the University has been in continual communication with Mr. Elliot, it is the Commissioner’s opinion that the University has acted appropriately in responding to Mr. Elliott’s October 20, 2013, request. It seems reasonable that the request might warrant the time that has elapsed, especially in the context of Mr. Elliott’s various other requests. In her April 2, 2014, letter to the Commissioner, Ms. Smith wrote, “[r]eview of the documents will be completed by next week (the week of April 7), and any public records produced to Prof. Elliott by the end of that week.” If the University has not already done so, the Commissioner encourages it to provide Mr. Elliott with the data as soon as practicable.

With regard to Mr. Elliott’s October 28, 2013, request for data associated with the CLEARs study, Ms. McKinney wrote in a January 14, 2014, email:

The information from the CLEARs study will not be available for you to review this week. The study sponsor, AstraZeneca, has marked the information as proprietary. I am contacting them about your data request and will be back in touch with you as soon as I have more information to share.

In a follow-up letter dated April 22, 2014, Ms. Smith wrote, “since my last response, we have been able to get confirmation from AstraZeneca that it does not assert that the SAEs constitute trade secret information.” She went on to state that the University will provide Mr. Elliott with the reports related to the CLEARs study within the week.

The Commissioner wishes to note that section 13.03, subdivision 3(f), requires an entity to inform a data requester, either orally at the time of the request or in writing shortly thereafter, if the data are classified as not public. Here, the University received Mr. Elliott's request for access to the CLEARs study on October 28, 2014, but did not state that the data were potentially classified as nonpublic until January 14, 2014, and at that time, Ms. McKinney did not assert that the data were classified pursuant to Minnesota Statutes, section 13.37 (trade secret). While the University should have informed Mr. Elliott of the CLEARs study's classification in a timelier manner, given the lengthy, on-going correspondence between the parties, the Commissioner believes that University acted in good faith.

Opinion:

Based on the facts and information provided, the Commissioner's opinion on the issue raised by Mr. Elliott is as follows:

Pursuant to Minnesota Statutes, Chapter 13, the University of Minnesota responded appropriately to a request for data related to Institutional Review Boards, specifically: studies, reports, meeting minutes and correspondence.



Spencer Cronk
Commissioner

April 23, 2014