

October 31, 2014

VIA ELECTRONIC AND REGULAR MAIL

Dr. Doug Tkachuk, President INSCYTE Corporation 2 Berkeley Street, Suite 403 Toronto, Ontario M5A 2W3

Dear Dr. Tkachuk:

RE: Review of the Report on the Policies and Procedures of the INSCYTE Corporation in respect of CytoBase

Pursuant to subsection 13(2) of Regulation 329/04 of the *Personal Health Information Protection Act, 2004* ("the *Act"*), the Office of the Information and Privacy Commissioner of Ontario (IPC) is responsible for reviewing the practices and procedures implemented by an organization that has been designated as a prescribed person for the purposes of subsection 39(1)(c) of the *Act*, to protect the privacy of individuals whose personal health information it receives, and to protect the confidentiality of that information.

Given the practices and procedures of the INSCYTE Corporation (INSCYTE), a prescribed person within the meaning of the *Act*, were last approved on October 31, 2011, the IPC was again required to review these practices and procedures and advise whether they continue to meet the requirements of the *Act* on or before October 31, 2014.

In accordance with the process set out in the Manual for the Review and Approval of Prescribed Persons and Prescribed Entities ("the Manual"), INSCYTE, as a prescribed person seeking the continued approval of its practices and procedures, submitted a detailed written report and sworn affidavit to the IPC. These documents were to conform to the requirements set out in the Manual.

The IPC has now completed its review of your report and affidavit. Based on this review, I am satisfied that INSCYTE continues to have in place practices and procedures that sufficiently protect the privacy of individuals whose personal health information it receives, that sufficiently maintain the confidentiality of that information and that continue to meet the requirements of the *Act*.

Accordingly, effective October 31, 2014, I am pleased to advise that the practices and procedures of INSCYTE in respect of CytoBase continue to be approved for a further three-year period.

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Attached is an Appendix containing recommendations to further enhance the practices and procedures of INSCYTE, which must be implemented prior to the next legislated review.

I would like to extend my gratitude to you and your staff for the cooperation provided during the course of the review, including the diligence and timeliness in submitting the requested documentation, in responding to requests by my office for further information, and in making the amendments requested.

Sincerely,

Brian Beamish

Commissioner (Acting)

Attach.

cc: Jack Golabek, Privacy Officer

Appendix

- 1. It is recommended that INSCYTE ensure that a review of its policies and procedures are conducted, at a minimum, on an annual basis, as required by the *Manual for the Review and Approval of Prescribed Persons and Prescribed Entities* (the "Manual").
- 2. It is recommended that all new data sharing agreements strictly comply with the requirements of the *Manual's* Template Data Sharing Agreement.

General Note to All Prescribed Persons and Prescribed Entities

The IPC wishes to clarify its expectations regarding the process for the three-year review and approval of prescribed entities and prescribed persons. For future reviews, the IPC will require that you provide your reports for the period spanning from one year prior to the previous approval up to and including October 31st of the year prior to the next expected approval date. Therefore, for the next expected approval date (October 31, 2017), the IPC requires that your reports, especially with regard to your indicators, cover the period from November 1, 2013 up to and including October 31, 2016.

If, at the time of delivering your report, some of the indicators for more recent months are not yet compiled, you will be expected to provide amendments to include the missing data within a reasonable time period after the initial submission of your report. For those prescribed entities and prescribed persons which have provided indicators beyond October 31, 2013 for the current approval, the IPC requires you to simply resubmit, on October 31, 2016, those portions of your indicators which went beyond October 31, 2013 along with new, previously unreported data, as required.