

Inscyte Corporation

Privacy Code

Relating to the collection, protection, use, and
disclosure of personal health information

Revision 2.0
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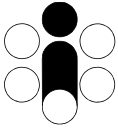
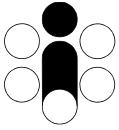


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About Inscyte Corporation and CytoBase

Cervical cancer is a slowly progressing disease that can be treated and even prevented if it is detected sufficiently early. There are several medical tests that can reveal conditions that could potentially develop into cervical cancer. The most common of these is the “Pap” test. Since early detection can often lead to a cure, women are encouraged to have a Pap test performed on a regular basis. In the event that an abnormal result is obtained it is then important that appropriate follow-up actions be taken, in the appropriate time frame, to treat the abnormality.

Since cervical cancer can be prevented if abnormalities are detected and treated early, a comprehensive information system is needed to track the history of test results on individual women over time.

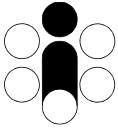
Inscyte Corporation was formed to develop and operate such an information system. It is part of an on-going collaborative effort to reduce the incidence and mortality from cervical cancer for the ultimate benefit of Ontario women. Inscyte Corporation is a not-for-profit partnership of medical laboratories and Cancer Care Ontario – a planning and research organization that advises the Ontario government on all aspects of cancer care. In 1996, Inscyte Corporation began operating “CytoBase”, a computerized database of patient identified cervical cytology and related test results. When a laboratory reports your test results to your physician, a copy of the results is sent electronically to CytoBase.

Your personal health information serves four very important purposes:

1. CytoBase provides your historical test results to laboratory personnel that are reading new Pap tests, regardless of where in Ontario the previous tests were performed. Since cervical cancer is a slowly progressing disease, the availability of historical results on individual women is important in producing accurate results. Also historical results are essential for laboratory quality assurance and for planning patient follow-up.
2. CytoBase supports the work of the Ontario Cervical Cancer Screening Program, which is administered by Cancer Care Ontario (CCO). Personal health information contained in CytoBase is provided periodically to CCO for purposes of analysis and compiling statistical information with respect to the management, evaluation, monitoring, allocation of resources or planning for the cancer system.
3. CytoBase produces monthly physician reminder letters to ensure that women are tested at appropriate intervals and that women with abnormal results receive appropriate follow-up in the prescribed time frame. Written reminder letters are delivered to physician offices by the participating laboratories.
4. Personal health information in CytoBase is aggregated and analyzed to produce statistics describing the characteristics of cervical cancer screening in Ontario.

Inscyte Corporation also provides a secure online service for your doctor. This service is called “CytoBase for Clinicians” and permits authorized physicians or nurse practitioners to access screening histories and follow-up status only on individuals within their care.

Ontario Regulation 329/04 made under the Personal Health Information Protection Act, 2004 designates Inscyte Corporation in respect of CytoBase as a registry of personal health information under section 39(1)(c) of the Personal Health Information Protection Act, 2004. This means that Inscyte Corporation in respect of CytoBase can obtain personal health information and use and disclose this personal health information for the purposes of facilitating or improving the provision of health care without having to obtain



the consent of individuals to whom the personal health information relates and can use and disclose this personal health information, again without consent, for other purposes permitted by the *Personal Health Information Protection Act, 2004*. It also means that Inscyte Corporation must implement practices and procedures to protect the privacy of individuals whose personal health information it receives and to maintain the confidentiality of that information and that these practices and procedures must be reviewed by the Information and Privacy Commissioner/Ontario every three years.

What is Personal Health Information?

Ontario's *Personal Health Information Protection Act, 2004* states that "personal health information" is identifying information about an individual in oral or recorded form, if the information,

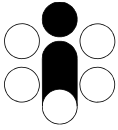
- (a) Relates to the physical or mental health of the individual, including information that consists of the health history of the individual's family,
- (b) Relates to the providing of health care to the individual, including the identification of a person as a provider of health care to the individual,
- (c) Is a plan of service within the meaning of the *Long-Term Care Act, 1994* for the individual,
- (d) Relates to payments or eligibility for health care in respect of the individual,
- (e) Relates to the donation by the individual of any body part or bodily substance of the individual or is derived from the testing or examination of any such body part or bodily substance,
- (f) Is the individual's health number, or
- (g) Identifies an individual's substitute decision-maker.

About this Document

This document describes Inscyte Corporation's principles and policies relating to the collection, use, disclosure and protection of personal health information.

The principles and policies set forth in this document are guided by the ten principles articulated by the Canadian Standards Association in its *Model Code for the Protection of Personal Information*, the key elements of which are incorporated into Canada's federal *Personal Information Protection and Electronic Documents Act* (PIPEDA), and Ontario's *Personal Health Information Protection Act, 2004*. The principles are:

1. Accountability
2. Identifying Purposes
3. Consent
4. Limiting Collection
5. Limited Use, Disclosure, and Retention
6. Accuracy
7. Safeguards
8. Openness
9. Individual Access



10. Challenging Compliance

This document discusses each of these principles individually as they apply to personal health information in the custody or control of Inscyte Corporation.

Principles & Policies

Principle 1 – Accountability

Inscyte Corporation is responsible for all personal health information under its custody or control. Persons or organizations to which Inscyte Corporation discloses personal health information in accordance with the provisions of the *Personal Health Information Protection Act, 2004*, are responsible for maintaining the privacy and confidentiality of the disclosed personal health information.

Inscyte Corporation uses written contractual data sharing agreements and confidentiality agreements to ensure that personal health information that is disclosed to persons or organizations in accordance with the provisions of the *Personal Health Information Protection Act, 2004*, is protected in a manner consistent with these principles and policies.

The President of Inscyte is responsible for ensuring that the corporation's activities are conducted in accordance with these principles and policies and in accordance with the *Personal Health Information Protection Act, 2004*. The President is accountable to Inscyte Corporation's Board of Directors and to the Information and Privacy Commissioner/Ontario with respect to matters of privacy. The President designates a person or persons to act as Privacy Officer(s) to oversee the organization's compliance with these principles and policies and with the *Personal Health Information Protection Act, 2004*.

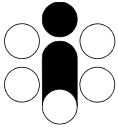
Inscyte Corporation may designate a third party to act as Agent for Inscyte Corporation in carrying out day-to-day work with respect to operating and maintaining the CytoBase system. In this case the Agent is required to execute a written contractual agreement with Inscyte Corporation that sets out the terms and conditions of the agency and includes the requirement that the Agent and the Agent's personnel abide by these principles and policies and with the obligations imposed by the *Personal Health Information Protection Act, 2004*.

Inscyte Corporation has policies and procedures in place to give effect to the principles of:

1. Protection of personal health information
2. Orientation and training in respect to its policies and procedures, as well as reinforcing awareness of privacy and confidentiality issues on a regular basis
3. Receiving and responding to complaints and inquiries
4. Developing and disseminating clear and accurate information regarding Inscyte Corporation's policies and procedures

Principle 2 – Identifying Purposes

Inscyte Corporation identifies the purposes for which it collects and uses personal health information before the personal health information is collected or used and ensures that



such collections and uses are permitted by the *Personal Health Information Protection Act, 2004*.

Inscyte Corporation collects personal health information to maintain a high quality registry of patient identified cervical cancer screening test results for the Province of Ontario.

The personal health information is used for the following purposes:

1. To provide historical screening results of individual patients to authorized laboratory personnel for diagnostic, quality assurance, and follow-up activities.
2. To provide primary care providers (physicians, nurse practitioners) with individual patient historical results and follow-up status.
3. To provide personal health information for research, planning and administrative activities to persons and organizations that are authorized to obtain this personal health information in accordance with the *Personal Health Information Protection Act, 2004*.
4. To compile aggregated statistics describing the characteristics of cervical cancer screening in Ontario.

Any other purpose for the use of personal health information shall be identified and described and a determination shall be made that the use is permitted by the *Personal Health Information Protection Act, 2004*, prior to using personal health information for the new purpose.

Inscyte Corporation publishes information regarding its use of personal health information on its website and provides printed material upon request.

Principle 3 – Consent

As a prescribed registry of personal health information under Ontario's *Personal Health Information Protection Act, 2004*, Inscyte Corporation in respect of CytoBase is not required to obtain individual patient consent for the collection of personal health information or for the use and disclosure of personal health information for the purpose of facilitating or improving the provision of health care under section 39(1)(c) of the *Personal Health Information Protection Act, 2004* and section 13 of *Ontario Regulation 329/04*.

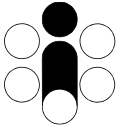
In the event that personal health information is disclosed for research purposes, the disclosure shall be made in accordance with the provisions of section 44 of the *Personal Health Information Protection Act, 2004* and section 16 of *Ontario Regulation 329/04*.

Inscyte Corporation acknowledges that individuals registered in the CytoBase system are entitled to receive notice about the types of personal health information collected, the purposes for which it is used and how it is disclosed. Inscyte Corporation publishes this information on its website and provides printed materials upon request.

Principle 4 – Limiting Collection

Inscyte Corporation limits the amount and types of personal health information that it collects to that which is necessary to fulfill its stated purposes.

Inscyte Corporation will not collect personal health information that is outside of its stated purposes unless the new purpose is permitted or required by law .



Principle 5 – Limiting Use, Disclosure, and Retention

Inscyte Corporation limits the use, disclosure and retention of the personal health information in its custody to that which is necessary to fulfill its stated purposes.

Use

The use of personal health information is limited to the purposes stated in Principle 2. If a new use or purpose for the personal health information is identified the provisions of Principle 2 and Principle 3 shall apply.

Individual staff of Inscyte Corporation and its Agents who use personal health information are required to execute a written Confidentiality and Non-Disclosure Agreement that clearly describes their obligations with respect to protecting patient privacy and protecting the confidentiality of personal health information and stipulates the penalties for breach. This agreement must be executed prior to using the personal health information.

Disclosure

The disclosure of personal health information is limited to the purposes stated in Principle 2. Personal health information is only disclosed where the disclosure of the personal health information is permitted or required by law, including where permitted or required by the *Personal Health Information Protection Act, 2004*.

In general, prior to the disclosure of personal health information, Inscyte Corporation requires a written Data Sharing Agreement to be executed between Inscyte Corporation and the person or organization to which the personal health information will be disclosed.

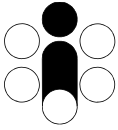
Inscyte Corporation discloses personal health information to health information custodians if the personal health information pertains to patients in their care for the purpose of the management of the health of the individual whose personal health information is being disclosed.

Inscyte Corporation discloses personal health information for research purposes in accordance with Section 44 of the *Personal Health Information Protection Act, 2004* and subject to the provisions of section 16 of *Ontario Regulation 329/04*. This includes:

1. Obtaining a written research application.
2. Obtaining a written research plan that has been prepared in accordance with the requirements of the *Personal Health Information Protection Act, 2004* and *Ontario Regulation 329/04*.
3. Obtaining a copy of the decision of the research ethics board approving the research plan; and
4. Entering into an agreement with the researcher in accordance with section 44 of the *Personal Health Information Protection Act, 2004*.

Inscyte Corporation discloses aggregated data derived from the personal health information in the form of publications (e.g. statistical reports). To minimize the possibility of indirectly identifying an individual, aggregate information of less than five observations per cell is not published.

If Inscyte Corporation receives a concern or complaint by any person, that a recipient of personal health information has made false or misleading statements in the request for personal health information or has violated one or more conditions of a signed



agreement, Inscyte Corporation will investigate. When the concern or complaint is substantiated, Inscyte Corporation will impose sanctions, which may include:

- (a) A written complaint to the individual and/or organization;
- (b) Recovery of personal health information disclosed by Inscyte Corporation;
- (c) Report to an authority having jurisdiction over the individual or organization including, where appropriate, the Information and Privacy Commissioner/Ontario;
- (d) Refusal to disclose personal health information in future; or
- (e) Legal Action

Retention

Personal health information in the custody or control of Inscyte Corporation may be in electronic or paper formats. Personal health information in electronic format is retained for as long as is necessary to fulfill the stated purposes for which it was collected. Paper records are retained for only as long as required to transfer the personal health information to electronic form. Thereafter, paper records are securely destroyed, as are records of personal health information in electronic format, which are both destroyed in such a manner that reconstruction is not reasonably foreseeable in the circumstances.

In the event that additional personal health information is collected for a new purpose, this personal health information is subject to the provisions of principles 2, 3 and 4, and will be retained for only as long as required by the new purpose. If the additional personal health information is no longer required it shall be de-identified or securely destroyed.

Inscyte Corporation has formal procedures for the secure retention, destruction, and de-identification of personal health information.

Principle 6 – Accuracy

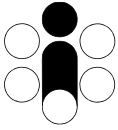
The personal health information in the custody or control of Inscyte Corporation is as accurate, complete, and up-to-date as is necessary to fulfill its stated purposes. Organizations and institutions that provide personal health information to Inscyte Corporation are required to ensure that the personal health information being provided meets with Inscyte Corporation's requirements relating to timeliness of submission, completeness, format and accuracy.

Since the personal health information is used in the care of individual patients, Inscyte Corporation implements formalized quality assurance and quality control procedures to monitor and assess the timeliness, completeness and accuracy of the personal health information it receives as an on-going activity.

Principle 7 – Safeguards

Inscyte Corporation considers all personal health information in its custody to be highly sensitive and implements appropriate safeguards to protect the personal health information against theft, loss and unauthorized access, use, disclosure, copying, modification or disposal.

The safeguards in place include:



Inscyte Corporation

1. Physical Security Controls: e.g. locked facility with tracked card access, locked filing cabinets and restricted access to offices, external video monitoring.
2. Organizational Security Controls; e.g. employee confidentiality and non-disclosure agreements, data sharing agreements and security system audit procedures.
3. Technical Security Controls; e.g. password/account user authentication, role-based restrictions, network encryption, audit trails, intrusion detection, fault tolerance, backup and recovery procedures.

Inscyte Corporation also has procedures in place for the de-identification, secure disposal and secure destruction of personal health information to prevent unauthorized parties from gaining access to the personal health information.

A complete description of Inscyte's safeguards is contained in the document entitled "CytoBase Security Controls and Performance" available from Inscyte Corporation or its Agents.

Principle 8 – Openness

Inscyte Corporation makes information about its policies and practices with respect to the handling and protection of personal health information readily available on its website at www.inscyte.org and in printed format upon request.

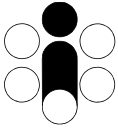
The information available includes:

1. Contact information for person(s) that are accountable for Inscyte Corporation's policies and practices and to whom complaints or inquiries can be forwarded.
2. A brochure describing Inscyte Corporation and CytoBase.
3. Answers to frequently asked questions about privacy practices.
4. A description of the nature of the personal health information held by Inscyte Corporation.
5. A description of the purposes for which the personal health information is collected and a list of organizations from which personal health information is obtained.
6. This Privacy Code.
7. Procedures for requesting information about the existence, use and disclosure of personal health information held by Inscyte Corporation.
8. Procedures for challenging compliance with this Privacy Code.

Principle 9 – Individual Access

Inscyte Corporation will provide information to an individual about the existence, use, and disclosure of the personal health information held on that individual provided that:

1. The individual submits a written request
2. The individual provides acceptable proof of identity
3. Inscyte Corporation is not legally prevented from providing the information
4. The information is not subject to solicitor-client or litigation privilege



An individual will be able to challenge the accuracy and completeness of the personal health information and have it amended as appropriate. Since Inscyte Corporation does not amend the personal health information it receives, such challenges will be referred for resolution to the institution or organization from which the personal health information was originally received.

Principle 10 – Challenging Compliance

An individual will be able to address a challenge concerning compliance with the above principles and policies to the designated individuals accountable for Inscyte Corporation's compliance. These individuals are the President and the Privacy Officer(s) of Inscyte Corporation.

Inscyte Corporation will investigate all complaints and will inform individuals who make inquiries or lodge complaints of the relevant complaint resolution process.

If a complaint is deemed justified, Inscyte Corporation will take appropriate measures including, if necessary, amending its policies and procedures.

In addition, an individual will be able to address a challenge concerning compliance by Inscyte Corporation with the above principles and policies by making a complaint to the Information and Privacy Commissioner/Ontario at:

Information and Privacy Commissioner/Ontario
2 Bloor Street East
Suite 1400
Toronto, Ontario
M4W 1A8

Telephone: 416-326-3333 or 1-800-387-0073