

# CytoBase

Report to the Information and Privacy Commissioner Ontario in Respect of Inscyte Corporation's Status as a Prescribed Person under Section 39(1)(c) of the Personal Health Information Protection Act, 2004

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Inscyte Corporation

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Report to the Information and Privacy Commissioner Ontario in respect of CytoBase



## **Background Information**

## About Inscyte Corporation

Inscyte Corporation is a not-for-profit partnership of Ontario medical laboratories. In 1996, Inscyte Corporation began operating "**CytoBase**", a centralized database of patient identified cervical cancer screening test results gathered from member laboratories. The personal health information that Inscyte Corporation collects is used for improving patient care and serves four purposes:

- 1. **CytoBase** provides patient-related 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 the interpretation of new smears. 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 follow-up in the appropriate time frame. Written reminder letters are delivered to physician offices by member laboratories courier networks.
- 4. Personal health information in **CytoBase** is periodically aggregated to produce statistics describing the utilization and trends of cervical cancer screening in Ontario.

Inscyte Corporation also provides a secure online service for primary care providers. This service is called "CytoBase for Clinicians" and permits authorized physicians, nurse practitioners and midwives to access screening histories and follow-up status on individual patients within their care.

Ontario Regulation 329/04 made under the *Personal Health Information Protection Act, 2004* (the Act) designates Inscyte Corporation in respect of CytoBase as a Prescribed Person under section 39(1)(c) of the Act.

## About Artificial Intelligence in Medicine Inc.

Artificial Intelligence In Medicine Inc. (AIM) is a privately held software engineering firm located in Toronto, Ontario. AIM develops information technology solutions for healthcare industry with a special focus on cancer research and prevention. AIM has clients throughout Canada and the U.S.

Inscyte Corporation has contracted AIM for the maintenance, upgrades, quality assurance, and administrative work required in the day-to-day operations of the CytoBase system since its inception in 1996. The CytoBase database is physically located at AIM's secure datacenter. AIM is also responsible for maintaining the network reporting infrastructure (i.e. laboratory connections) for CytoBase and hosting the Inscyte website and the "CytoBase for Clinicians" online application.

Since AIM works in the healthcare domain its staff routinely handles personal health information, not only that of Inscyte Corporation, but from many other clients as well. As such, AIM itself has a comprehensive privacy and security program in place. This program implements Inscyte Corporation's Privacy & Security Policies and Procedures.

## **Contact Information**

Please direct all inquiries to:

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## Part 1 – Privacy Documentation

#### 1. Privacy Policy in Respect of Inscyte Corporation's Status as a Prescribed Person

Inscyte Corporation has a comprehensive Privacy Policy in effect in relation to personal health information it receives and uses with respect to its status as a prescribed person under Ontario's Personal Health Information Protection Act, 2004 ("the Act"). The Privacy Policy is articulated in two overarching documents: Inscyte's *Privacy Code* and its *Privacy & Security Policies and Procedures Manual.* 

#### Status under the Act

The Privacy Policy describes Inscyte Corporation a prescribed person under the Act and the duties and responsibilities that arise as a result of this designation. The Privacy Policy indicates that Inscyte Corporation has implemented policies, procedures and practices to protect the privacy of individuals whose personal health information it receives and to maintain the confidentiality of that information and that these policies, procedures and practices are subject to review by the Information and Privacy Commissioner of Ontario every three years.

The Privacy Policy describes Inscyte's commitment to comply with the provisions of the Act and its regulation, and describes Inscyte's accountability framework for ensuring compliance with the Act and its regulation, and for ensuring compliance with its privacy & security policies and procedures.

#### Privacy and Security Accountability Framework

The President of Inscyte Corporation is ultimately accountable for ensuring compliance with the Act and its regulation, and for ensuring compliance with Inscyte's Privacy & Security Policies and Procedures. The President reports to the Board of Directors of Inscyte Corporation, which is comprised of representatives of the medical laboratories (health information custodians) that provide personal health information to Inscyte Corporation.

The Privacy Policy identifies the position of Privacy Officer as having day-to-day authority to manage the privacy program and AIM's Security Officer as having day-to-day authority to manage the security program. The Privacy Policy also defines the responsibilities of these positions. Inscyte's Privacy Officer reports to the President of Inscyte. AIM's Security Officer reports to the Chief Executive Officer of AIM. AIM, as agent of Inscyte, is responsible for implementing Inscyte's Privacy Policy. AIM's Chief Executive Officer is accountable to the President of Inscyte for ensuring AIM's compliance with Inscyte's privacy & security policies and procedures.

## Collection of Personal Health Information

The Privacy Policy describes the purpose for which Inscyte collects personal health information, the type of personal health information it collects, and the organizations from which it collects the information. The Privacy Policy further specifies that the collection of personal health information must be consistent with the collection of personal health information permitted by the Act and its regulation.

The Privacy Policy states that Inscyte will not collect personal health information if other information will serve the purpose. The Privacy Policy also states that Inscyte only collects personal health information for its stated purpose and that it collects the minimum amount of personal health information required to fulfill its stated purpose. Inscyte's privacy & security policies and procedures ensure that both the amount and the type of personal health information collected is limited to that which is reasonably necessary for its stated purpose.

Inscyte's Privacy Policy includes the requirement to maintain a list of its data holdings of personal health information and identifies the Privacy Officer as the contact for obtaining further information in relation to the purposes, data elements, and data sources of each data holding.

#### Use of Personal Health Information

The Privacy Policy also describes the purpose for which Inscyte uses personal health information and includes policies and procedures that distinguish between the use of personal health information under section 39(1)(c) of the Act and the use of de-identified and/or aggregate information. The Privacy Policy also states that Inscyte Corporation does not use personal health information for research purposes. As such, Inscyte does not disclose personal health information to researchers or agents. The Privacy Policy further specifies that the use of personal health information must be consistent with the uses of personal health information permitted by the Act and its regulation.

The Privacy Policy states that Inscyte will not to use personal health information if other information will serve the purpose and will not to use more personal health information than is reasonably necessary to meet the purpose. Policies and procedures have been implemented in this regard to establish limits on the use of personal health information from CytoBase by participating laboratories and other organizations.

## Disclosure of Personal Health Information

The Privacy Policy identifies the purposes for which personal health information is disclosed, the organizations to whom information is disclosed and the requirements that must be satisfied prior to such disclosures. Inscyte ensures that each disclosure is consistent with the disclosures of personal health information permitted by the Act and its regulation.



The Privacy Policy distinguishes between the purpose for which and the circumstances in which personal health information is disclosed and the purposes for which and the circumstances in which de-identified and/or aggregate information is disclosed. The privacy policies and procedures address methods of de-identification and aggregation to ensure that the information could not be utilized, either alone or with other information, to identify an individual. Inscyte's policy is to review all de-identified and/or aggregate information prior to disclosure to ensure that it is not reasonably foreseeable in the circumstances that the information could be utilized, either alone or with other information, to identify an individual. Furthermore, Inscyte's policy states that it will not disclose personal health information if other information will serve the purpose and that it will not disclosure.

#### Secure Retention, Transfer and Disposal of Records of Personal Health Information

The Privacy Policy addresses the secure retention of records of personal health information in paper and electronic format, including the acceptable use of portable media and mobile devices for the collection, transfer, and storage of personal health information. The Privacy Policy addresses the permitted retention periods and specifies methods for the secure transfer and destruction of personal health information depending on the media on which it is stored.

#### Implementation of Administrative, Technical and Physical Safeguards

The Privacy Policy also specifies Inscyte's security measures to safeguard personal health information and protect the privacy of individuals to whom the information pertains. The policies and procedures cover administrative, physical and technical security controls implemented to protect personal health from unauthorized access, copying, modification, use, disclosure, theft, loss and improper disposal.

#### Inquiries, Concerns or Complaints Related to Information Practices

The Privacy Policy identifies the Privacy Officer of Inscyte as the contact to whom individuals may direct inquiries, concerns or complaints related to the privacy policies, procedures and practices of Inscyte and questions related to Inscyte's compliance with the Act and its regulation. The Privacy Policy specifies that the contact information will be provided on Inscyte's website and that a standard Inquiry or Compliance Challenge form will be made available to the public for lodging inquiries or complaints.

The Privacy Policy also states that individuals may direct complaints regarding Inscyte's compliance with the Act and its regulation to the Information and Privacy Commissioner of Ontario and that Inscyte will provide the mailing address and contact information for the Information and Privacy Commissioner of Ontario.

## Transparency of Practices in Respect of Personal Health Information

The Privacy Policy commits Inscyte to be transparent about its practices in respect of handling personal health information and states that Inscyte shall make its Privacy Policy (Privacy Code and Privacy & Security Policies and Procedures Manual), together with FAQs and other relevant documents, freely available to the public from its website.

## 2. Policy and Procedures for Ongoing Review of Privacy Policies, Procedures and Practices

Inscyte's Privacy & Security Policies and Procedures Manual includes policies and procedures governing the regular review of its privacy policies, procedures and practices. The policies state that Inscyte shall review its privacy program at minimum on an annual basis, or more frequently should there be changes in technology, best practices, the Act and its regulation. The policies further state that a review of relevant policies and procedures shall be taken following a breach of privacy or security to determine if modifications to the policies and procedures are necessary to avert a similar breach in the future.

The policies state that it is the responsibility of the Privacy Officer to initiate a review process, that a committee shall be organized to carry out the review, and that in the event that proposed changes represent a material change to daily operations, the results and recommendations of the review will be reported to the President of Inscyte and CEO of AIM Inc. for review and approval before the changes are implemented.

The policies state that the review process shall take into account any orders, guidelines, fact sheets and best practices issued by the Information and Privacy Commissioner of Ontario under the Act and its regulation; evolving industry privacy standards and best practices; amendments to the Act and its regulation relevant to the prescribed person or prescribed entity; and recommendations arising from privacy and security audits, privacy impact assessments and investigations into privacy complaints, privacy breaches and information security breaches. The review process also addresses whether the existing privacy policies and procedures continue to be consistent with actual practices and whether there is consistency between and among the privacy and security policies, procedures and practices implemented.

The policies describe the procedure for amending and documenting policies and procedures and for communicating the amendments to agents and the public. Amended policies and procedures result in a revision of Inscyte's Privacy & Security Policies and Procedures Manual, which is made available through AIM's internal business network and to the public on Inscyte's website.

Compliance with the Privacy & Security Policies and Procedures is mandatory for all agents of Inscyte. Compliance is monitored by Inscyte's Privacy Officer and Security Officer. The Privacy Policy specifies that a contravention of the policies and procedures constitutes a breach and



includes policies and procedures for corrective actions to be taken in the event of noncompliance.

The Privacy Policy includes policies and procedures governing Inscyte's privacy audit program. The policies state that Inscyte shall conduct an annual privacy audit that involves reviewing its inventory of personal health information holdings; reviewing access rights and uses of the personal health information; reviewing privacy logs for completeness and accuracy, including the Log of Privacy Training Sessions and Attendance, Log of Privacy Breaches, Log of Privacy Complaints, Log of Security Breaches, Log of Transfers of personal health information, Log of Data Holdings and Log of Individual's Access to personal health information.

In addition, Inscyte's policy is to conduct a monthly random audit of computers, servers, and agent workspaces to detect potential breaches and non-compliance with its policies and procedures.

#### 3. Policy on the Transparency of Privacy Policies, Procedures and Practices

Inscyte's Privacy Policy states that Inscyte is committed to maintaining the transparency of its privacy and security practices by making the following information available freely and openly to the public on its website:

- 1. Privacy Code
- 2. Privacy & Security Policies and Procedures
- 3. Privacy Brochure
- 4. Answers to Frequently Asked Questions (FAQ)
- 5. Documentation related to the review of Inscyte Corporation by the Information and Privacy Commissioner of Ontario in respect of Inscyte's policies, procedures and practices implemented to protect the privacy of individuals whose personal health information it holds and to maintain the confidentiality of that information
- 6. A list of the data holdings of personal health information maintained by Inscyte
- 7. A summary of privacy impact assessments
- 8. The name, title, mailing address and contact information of the persons(s) to whom inquiries, concerns or complaints regarding compliance with the privacy policies, procedures and practices implemented and regarding compliance with the Act and its regulation may be directed

In addition, the policy specifies the minimum content of Inscyte Corporation's Privacy Brochure as follows:

- 1. The status of Inscyte Corporation under the Act
- 2. Inscyte's obligations under the Act
- 3. The type of personal health information collected



- 4. The organizations from which personal health information is collected
- 5. The purpose for which personal health information is collected
- 6. The purpose for which personal health information is used
- 7. The circumstances under which personal health information is disclosed
- 8. The entities to whom personal information is disclosed
- 9. Summary of administrative, physical and technical security controls including the steps taken to protect personal health information against theft, loss and unauthorized use or disclosure and to protect records of personal health information against unauthorized copying, modification or disposal
- 10. The name and/or title, mailing address and contact information of the person(s) to whom inquiries, concerns or complaints regarding compliance with the privacy policies, procedures and practices implemented and regarding compliance with the Act and its regulation may be directed

The policy in respect to the transparency of policies and procedures states that the President of Inscyte is responsible for ensuring that the above information is published on Inscyte's website.

## 4. Policy and Procedures for the Collection of Personal Health Information

Inscyte has policies and procedures that identify the purposes for which personal health information is collected, the nature of the personal health information that is collected, the health information custodians from whom the personal health information is collected and the secure manner in which personal health information is collected. Since CytoBase is an electronic medical record of cervical cancer screening tests/results the nature of the personal health information collected and the purpose for which it is collected does not change over time.

The Privacy Policy states that Inscyte Corporation collects patient identified laboratory test results pertaining to the screening and follow-up of cervical cancer for the purpose of improving patient care in Ontario by:

- 1. Compiling longitudinal patient screening histories and providing these to participating laboratories for quality improvement purposes when performing new tests.
- 2. Notifying primary care providers about overdue patient follow-up activities.
- 3. Supporting the Ontario Cervical Cancer Screening Program (operated by Cancer Care Ontario).
- 4. Producing aggregate statistics describing cervical cancer screening patterns and trends in Ontario.

Inscyte's policies articulate a commitment not to collect personal health information unless the collection is permitted by the Act and its regulation, not to collect personal health information if other information will serve the purpose and not to collect more personal health information



than is reasonably necessary to meet the purpose. Inscyte only collects personal health information that is required for its stated purposes and does not collect more personal health information than is necessary to meet the stated purposes.

Personal health information is collected on an on-going daily basis from participating laboratories that perform the screening and follow-up tests. Inscyte requires participating laboratories to comply with its policies and procedures by executing a legally binding Data Sharing Agreement with each participating laboratory. Compliance with these agreements is enforced by the Inscyte Board of Directors, which is comprised of representatives from each of the participating laboratories. Inscyte also has a legally binding agreement with AIM Inc. for the on-going operations and support of the CytoBase system that requires AIM Inc., as its Agent, to implement and comply with Inscyte's privacy & security policies and procedures. Compliance with this agreement is also enforced by the Board of Directors of Inscyte which includes a representative from AIM Inc.

Compliance with the policies and procedures for the collection of personal health information are audited in accordance with Inscyte's policies and procedures in respect of privacy audits, which state that privacy audits are carried out at minimum on an annual basis and identifies the Privacy Officer of Inscyte and AIM's Security Officer as being responsible for conducting the audits and for ensuring day-to-day compliance with the privacy & security policies and procedures.

Inscyte's policies and procedures for managing privacy breaches require that agents of Inscyte and participating laboratories notify the Privacy Officer of Inscyte at the first reasonable opportunity if a breach, or suspected breach, of privacy has occurred. The definition of a breach of privacy includes the failure to comply with Inscyte's privacy & security policies and procedures.

#### Review and Approval Process

The policy and procedures state that the President of Inscyte is responsible for reviewing and determining whether to approve the collection of personal health information and to execute a Data Sharing Agreement with the provider of the information prior to the collection of personal health information. Executing a Data Sharing Agreement requires the approval of the Board of Directors of Inscyte.

The policy and procedures set out the criteria that must be considered for determining whether to approve the collection of personal health information. The criteria require that the collection is permitted under the Act and its regulation and that any and all conditions or restrictions set out in the Act and its regulation have been satisfied. The criteria also require determining whether other information, such as de-identified and/or aggregate information, will serve the identified purpose such that no more personal health information is being requested than is reasonably necessary to meet the identified purpose.



The Privacy Policy states that collection of personal health information requires executing a Data Sharing Agreement between Inscyte and the provider(s) of the information. As such, the ultimate decision of whether or not to approve the collection of personal health information rests with the Board of Inscyte and the provider of the information, taking into account the criteria that must be considered in the review and approval process. The decision to approve or deny a request for the collection of personal information is communicated and documented by the parties during the process of establishing a Data Sharing Agreement.

#### Conditions or Restrictions on the Approval

The policy and procedures state that no personal health information shall be collected in the absence of a legally binding Data Sharing Agreement between Inscyte Corporation and the provider of the information and that all Data Sharing Agreements shall have regard to the requirements of the Act and its regulation. Furthermore, the policies require that each data holding be documented with a Statement of Purpose, a Statement of Permitted Use, and a Statement of Retention. It is the responsibility of the President of Inscyte to ensure that these conditions have been met prior to the collection of personal health information.

#### Secure Retention

Inscyte's Privacy Policy requires that records of personal health information are retained in a secure manner and includes policies and procedures addressing and restricting the secure storage of personal health information on paper records, portable media, mobile devices, email, and computer file/database systems. The personal health information collected by Inscyte is stored in the CytoBase database system housed within a secure datacenter with restricted access in accordance with the policies and procedures for the secure retention of personal health information.

#### Secure Transfer

Inscyte's Privacy Policy requires that records of personal health information are transferred in a secure manner and includes policies and procedures addressing and restricting the secure transfer of personal health information using paper records, portable media, mobile devices, email, and computer file/database systems. The day-to-day collection of personal health information from participating laboratories is accomplished by secure encrypted electronic transfer which does not involve human intervention in accordance with the policies and procedures for the secure transfer of personal health information.

#### Secure Return or Disposal

The policy and procedures identify the Privacy Officer of Inscyte as being responsible for ensuring that records of personal health information that have been collected are either securely returned or securely destroyed upon expiry of the retention period as documented in



the Statement of Retention for the data holding of the personal health information in question. In general, the personal health information in CytoBase is retained in perpetuity.

The Privacy Policy states that records of personal health information that are to be returned to the organization from which they were collected must be returned in accordance with the policies and procedures for the secure transfer of personal health information.

The Privacy Policy states that records of personal health information that are to be destroyed at the expiry of the retention period must be destroyed in accordance with the policies and procedures for the secure disposal of personal health information.

## 5. List of Data Holdings Containing Personal Health Information

Inscyte Corporation retains an up-to-date list and summary description of the data holdings of personal health information maintained by Inscyte.

## 6. Policy and Procedures for Statements of Purpose for Data Holdings Containing Personal Health Information

Inscyte Corporation has policies and procedures governing the creation, review, amendment and approval of statements of purpose for data holdings containing personal health information. The policy and procedures require the statements of purpose to describe the purpose of the data holding, the personal health information contained in the data holding, the source(s) of the personal health information and the need for the personal health information in relation to the identified purpose.

The policy and procedures specify that the Privacy Officer is responsible for maintaining up-todate statements of purpose and describe the process to be followed in completing the statements of purpose for the data holdings containing personal health information. The policy and procedures require that the source(s) of the data holdings be consulted in completing the statements of purpose and specify that the President of Inscyte is responsible for approving the statements of purpose. The day-to-day authority to manage the privacy program in respect of the statements of purpose has been delegated to the Privacy Officer.

The policy and procedures state that statements of purpose are made available to the health information custodians from whom personal health information is collected—in particular, the medical laboratories that provide test results to CytoBase.

The policy and procedures require that the statements of purpose be reviewed in conjunction with regular annual reviews of the privacy program to ensure their continued accuracy and in order to ensure that the personal health information collected for purposes of the data holding is still necessary for the identified purposes. The policies and procedures specify that the Privacy Officer is responsible for the annual review of statement of purpose and the process to be followed in reviewing the statements of purpose and in amending the statements of purpose. The policy and procedures require that the source(s) of the data holdings be consulted when amending the statements of purpose and specify that the President of Inscyte is responsible for approving amended statements of purpose. The policy and procedures state that amended statements of purpose are to be made available to the health information custodians from whom personal health information is collected—in particular, the medical laboratories that provide test results to CytoBase.

Inscyte requires is agents to comply with the policy and procedures. Compliance is monitored by the Privacy Officer in accordance with Inscyte's policies and procedures in respect of ongoing privacy/security audits, which addresses the consequences of breach. The policy and procedures stipulate that audits are performed on a monthly basis. The Security Officer is responsible for conducting the audits and the Privacy Officer is responsible for ensuring compliance with the policy and its procedures.

The policy and procedures require agents to notify the Privacy Officer of Inscyte at the first reasonable opportunity of a breach or potential breach of privacy, in accordance with Inscyte's policies and procedures for identifying a breach of privacy, reporting a breach of privacy and actions to be taken following a breach of privacy.

## 7. Statements of Purpose for Data Holdings Containing Personal Health Information

Inscyte's policies and procedures require that a statement of purpose be documented and retained in the privacy document archives for each data holding containing personal health information, identifying the purpose of the data holding, the personal health information contained in the data holding, the source(s) of the personal health information and the need for the personal health information in relation to the identified purpose.

## 8. Policy and Procedures for Limiting Agent Access to and Use of Personal Health Information

Inscyte Corporation has policies and procedures in place to limit access to and use of personal health information by its agents. The policies and procedures prescribe that access and use of personal health information shall be limited to select individuals on the basis of the "need to know" principal. The policies and procedures further stipulate that the scope of personal health information used in day-to-day work shall be limited to the least identifiable information and minimum amount of information required to complete the work.

Inscyte's policy and procedures limit the scope of work requiring access to personal health information to a narrow set of specific tasks having to do with the manual correction of lab reports, producing monthly follow-up notification letters for Ontario healthcare practitioners,



and performing authorized data linkages with health information custodians or other prescribed persons or entities.

CytoBase is a centralized electronic medical record and owing to the highly limited scope of work that requires access to personal health information, only a few individuals are granted access to CytoBase. Furthermore these individuals are granted different functional privileges to prevent a single individual from compromising personal health information.

For all other purposes and in all other circumstances, the policy and procedures require agents to access and use de-identified and/or aggregate information in accordance with Inscyte's policies and procedures regarding the de-identification of personal health information and limits on the aggregation of data. These policies and procedures explicitly prohibit access to and use of personal health information if other information, such as de-identified and/or aggregate information, will serve the identified purpose and prohibit access to or use of more personal health information than is reasonably necessary to meet the identified purpose.

The policies and procedures also prohibit agents from using de-identified and/or aggregate information, either alone or with other information, to identify an individual. This includes attempting to decrypt information that is encrypted, attempting to identify an individual based on unencrypted information and attempting to identify an individual based on prior knowledge.

#### **Review and Approval Process**

Inscyte Corporation's policies and procedures specify that the Privacy Officer is ultimately responsible for reviewing and approving or denying requests for individuals to obtain access to personal health information.

Inscyte's policies and procedures stipulate that access to personal health information shall be granted to an agent of Inscyte Corporation for the purpose of database maintenance and generating follow-up reminders, or to a health care practitioner (physician, nurse practitioner, or midwife) as a user of the online CytoBase for Clinicians service.

The policies and procedures specify that in approving or denying a request for access to personal health information, Inscyte Corporation shall satisfy itself that:

- The individual making the request routinely requires access to and use of personal health information on an ongoing basis or for a specified period for his or her employment, contractual or other responsibilities;
- The purpose for which access to and use of personal health information is requested is permitted by the Act and its regulation;



- The purpose for which access to and use of personal health information is requested cannot reasonably be accomplished without personal health information;
- De-identified and/or aggregate information will not serve the purpose; and
- No more personal health information will be accessed and used than is reasonably necessary to meet the identified purpose.

Furthermore, the policies state that an agent of Inscyte Corporation shall be granted access provided that the individual has executed a *Personal Health Information Confidentiality and Non-Disclosure Agreement*, and that the individual has received privacy and security awareness training. The policies and procedures specify the documentation required and its content and require that this documentation be reviewed by the Privacy Officer prior to granting access, and that the documentation be retained in perpetuity in Inscyte Corporations privacy document archives.

In regards to CytoBase for Clinicians, the policies specify a formal application process to be followed that requires healthcare practitioners to fill out a standard application form describing the applicant's identity, contact information, and place of work; providing his/her related professional license number; and providing photographic ID. The approval process requires verification of the person's identity and standing with his/her applicable licensing body. The Privacy Officer is responsible for reviewing and approving/denying applications. Users of the CytoBase for Clinicians online application must renew their applications on an annual basis.

The policy and procedures also state that decisions approving or denying the request for access to and use of personal health information and the reasons for the decisions are documented and retained in Inscyte's privacy document archives; provide the format for the documentation and methods of communication; specify that all decisions shall be communicated to the Privacy Officer and to the individual applying for access; and that the Privacy Officer is responsible for ensuring that all documentation is kept up-to-date and accurate.

#### Conditions or Restrictions on the Approval

Inscyte's policies and procedures stipulate that access to personal health information shall be granted to an agent of Inscyte Corporation for the purpose of database maintenance and generating follow-up reminders, or to a health care practitioner (physician, nurse practitioner, or midwife) as a user of the online CytoBase for Clinicians service.

Those agents of Inscyte Corporation who are granted access to personal health information are permitted to read, create, update or delete personal health information in accordance with procedures governing these actions, which require documented instructions from source



laboratories in to modify personal health information. The policies state that agents of Inscyte Corporation cannot modify personal health information without express written instructions from the source(s) of these data. Inscyte's policy states that agent access rights remain in effect for the duration of a person's employment although access rights may be terminated earlier at the direction of the Privacy Officer, or in the event that an individual is found to be in breach of privacy or security.

Users of the CytoBase for Clinicians service are only granted the ability to read personal health information. As part of the application process, these individuals also agree to only retrieve and review information on persons within their care, and not to browse the database. Inscyte's policies state that individual access to CytoBase for Clinicians online service expires on an annual basis and requires renewal in accordance with the application process.

Inscyte's policies and procedures also state that an agent of Inscyte shall not access or use personal health information except as necessary for his or her employment, contractual or other responsibilities; and shall not access or use personal health information if other information will serve the identified purpose; and shall not access and use more personal health information than is reasonably necessary to meet the identified purpose. Inscyte also ensures that all accesses to and uses of personal health information are permitted by the Act and its regulation.

Inscyte's policies and procedures also restrict its agents and users of CytoBase for Clinicians from disclosure of personal health information to other parties and stipulate that the use and disclosure of the personal health information must be permitted by the Act and its regulation.

## Notification and Termination of Access and Use

Inscyte policies require that Inscyte be notified in writing when an agent has had his/her access rights to CytoBase terminated and stipulate that the notification must contain the name of the individual, his/her position, the date and the reason for the termination. The policies state that it is the responsibility of the Security Officer to inform the Privacy Officer of the termination and to ensure that the termination event is documented in the *Log of Individuals Having Access to PHI*. A summary report of recent changes to staff having access to CytoBase is also prepared by AIM Inc. and presented at Inscyte Board meetings.

Inscyte ensure that the procedures implemented in regard of terminating agent access rights are consistent with its policies and procedures concerning Termination or Cessation of Employment or Contractual Relationship.

Inscyte Corporation also requires that its Agent, AIM Inc. inform Inscyte about changes to the roster of healthcare practitioners having access to the CytoBase for Clinicians online service. This information is communicated to Inscyte's Privacy Officer by AIM's Security Officer at the time a change occurs and is documented in the CytoBase for Clinicians User Account Log. A



summary report of recent changes to the roster is prepared by the Privacy Officer and presented at Inscyte Board meetings.

#### Secure Retention

Inscyte's policy and procedures require that agents of Inscyte granted approval to access and use personal health information to securely retain the records of personal health information in compliance with Inscyte's Policies and Procedures for the Secure Retention of Records of Personal Health Information.

#### Secure Disposal

Inscyte's policy and procedures require that agents of Inscyte granted approval to access and use personal health information to securely dispose of the records of personal health information in compliance with Inscyte's Policy and Procedures for Secure Disposal of Records of Personal Health Information.

#### Tracking Approved Access to and Use of Personal Health Information

Inscyte policies and procedures stipulate that access to and use of personal health information by individuals is to be tracked in a Log of Individuals Having Access to PHI, as well as a Log of Accounts for CytoBase for Clinicians. It is the responsibility of the Privacy Officer to ensure that these logs are maintained up-to-date and accurate. The policies further specify that these logs shall be retained in perpetuity in Inscyte's privacy documentation archives and that its Agent AIM Inc. is responsible for maintaining the archives.

#### *Compliance, Audit and Enforcement*

Inscyte Corporation requires that its agents comply with Inscyte's policies and procedures. To enforce compliance, regular privacy and security audits are carried out at the direction of the Privacy Officer, at minimum on an annual basis, an in accordance with Inscyte's policies and procedures with respect to privacy and security audits. The privacy policies and procedures further set out the consequences of breach.

The purpose of the privacy and security audits is to ensure that agents of Inscyte granted access to and use of personal health information continue to be employed or retained by Inscyte or its agent AIM inc., and continue to require access to the same amount and type of personal health information. The policies and procedures state that it is the responsibility of the Privacy Officer to ensure that regular privacy and security audits are conducted. The policies state that privacy audits shall be conducted at minimum on an annual basis, and that security audits shall be conducted on a monthly basis.

Inscyte's policies and procedures require that agents of Inscyte be vigilant of breaches, and report breaches or suspected breaches of privacy to the Privacy Officer at the first reasonable



opportunity, in accordance with Inscyte's policies and procedures for privacy/security breach management.

## 9. Log of Agents Granted Approval to Access and Use Personal Health Information

Inscyte Corporation maintains a Log of Individuals Having Access to PHI, as well as a Log of Accounts for CytoBase for Clinicians, granted approval to access and use personal health information. The log includes the name of each individual granted approval to access and use personal health information; the data holdings of personal health information to which the individual has been granted approval to access and use; the level or type of access and use granted; the date that access and use was granted; and the termination date (or the date of the next audit) of access to and use of the personal health information.

## 10. Policy and Procedures for the Use of Personal Health Information for Research

Inscyte Corporation's privacy and security policies and procedures state that personal health information in the custody of Inscyte Corporation shall not be disclosed or used to conduct research or support research on individuals or groups of individuals. As such, Inscyte does not accept requests from researchers or research organizations to access and use personal health information for research purposes, and does not have policies and procedures in place to manage such requests.

Inscyte Corporation compiles and discloses de-identified aggregated statistics describing trends in cervical cancer screening in Ontario. The aggregation of data is performed in accordance with Inscyte's policies and procedures for de-identification and aggregation of personal health information to prevent the inadvertent disclosure of a person's identity resulting from a small number of observations in an aggregation, taking into account the recipient of the information and giving regard to section 4(2) of the Act, which states that information is identifying if it identifies an individual or if it is reasonably foreseeable in the circumstances that the information could be utilized, either alone or with other information, to identify an individual.

## **11.** Log of Approved Uses of Personal Health Information for Research

Inscyte Corporation's privacy and security policies and procedures state that personal health information in the custody of Inscyte Corporation shall not be disclosed or used to conduct research or support research on individuals or groups of individuals. As such, Inscyte does not maintain a log of approved uses of personal health information for research purposes.

## 12. Policy and Procedures for Disclosure of Personal Health Information for Purposes Other Than Research

Inscyte's Privacy Policy identifies the purposes for which personal health information is disclosed for purposes other than research, the organizations to whom information can be disclosed, and the requirements that must be satisfied prior to such disclosures. The policies and procedures governing the disclosure of personal health information articulate a commitment by Inscyte Corporation not to disclose personal health information if other information will serve the purpose and not to disclose more personal health information than is reasonably necessary to meet the purpose.

Inscyte Corporation transfers personal health information to its participating laboratories and requires that these laboratories execute a formal Data Sharing Agreement prior to the transfer of personal health information.<sup>1</sup> Inscyte discloses personal health information to Cancer Care Ontario (a prescribed entity under the Act in respect of the Ontario Cervical Cancer Screening Program), and Ontario health information custodians. Inscyte requires that CCO execute a formal Data Sharing Agreement with Inscyte prior to the disclosure of personal health information. Individual health information custodians are required to execute access agreements for use of the CytoBase for Clinicians online service. In these agreements, Inscyte requires the parties to comply with its policies and procedures and to comply with the requirements of the Act. These agreements also describe how and by whom compliance will be enforced and the consequences of breach.

The parties to whom Inscyte discloses personal health information are either health information custodians or prescribed persons/entities under the Act. As such, the party executing a Data Sharing Agreement with Inscyte must also comply with the provisions and requirements of the Act. For this reason, Inscyte does not have policies or procedures in place to audit or verify a party's compliance with Inscyte's privacy policies and procedures, as the party's own policies and procedures and obligations under the Act take precedence.

The terms and conditions of Inscyte's Data Sharing Agreements with parties to whom it discloses personal health information require that the parties notify Inscyte Corporation, at the first reasonable opportunity, if the party breaches or believes there may have been a breach of privacy in respect of personal health information disclosed to the party by Inscyte Corporation.

## Where the Disclosure of Personal Health Information is Permitted

Inscyte Corporation's policies and procedures set out the purposes and the circumstances under which the disclosure of personal health information is permitted. The policies and

<sup>&</sup>lt;sup>1</sup> Inscyte Corporation recognizes that transfers of personal health information to participating laboratories are actually "uses" of personal health information as per the Act, and not disclosures. However, for the purpose of openness and clarity, these transfers are discussed here.



procedures further require that all disclosures of personal health information comply with the Act and its regulation.

#### **Review and Approval Process**

Inscyte's policies and procedures identify the personnel responsible for receiving, reviewing and determining whether to approve or deny a request for the disclosure of personal health information for purposes other than research, and the process that must be followed in this regard, including a description of the documentation that must be completed, provided and/or executed.

The policies require that organizations to whom Inscyte discloses personal health information execute a formal Data Sharing agreement with Inscyte Corporation prior to the disclosure taking place. The President of Inscyte is responsible for executing the data sharing agreements. The President of Inscyte is responsible for determining whether to approve or deny any request for the disclosure of personal health information for purposes other than research for ensuring that the disclosure is permitted by the Act and its regulation and that any and all conditions or restrictions set out in the Act and its regulation have been satisfied.

The policies require that individual healthcare providers seeking access to the CytoBase for Clinicians online service fill out and submit Inscyte's standard application form, for review and approval by Inscyte, prior to gaining a personalized access account. The policies require applicants to provide their full name, address and contact information, professional license information, and photographic identification. The policies specify that individual healthcare providers must provide this information to Inscyte in hardcopy format using Inscyte's standard application forms. The policies specify the criteria for granting an individual access to CytoBase for Clinicians as (a) being a licensed healthcare provider in the province of Ontario engaged in gynecological health, (b) in good standing with his/her licensing authority, (c) providing photographic ID, and (d) agreeing to and signing the terms and conditions of the access agreement, which re-iterates the requirement to maintain patient information private and secure. The policies and procedures also describe the method for verifying personal identity and professional standing. The Privacy Officer is responsible for determining whether to approve or deny any request for access to CytoBase for Clinicians and for ensuring that the disclosure is permitted by the Act and its regulation and that any and all conditions or restrictions set out in the Act and its regulation have been satisfied.

Inscyte's policies state that the minimum criteria for disclosure of personal health information is that the disclosure is permitted under the Act and that any and all conditions or restrictions set out in the Act and its regulation have been satisfied. The policies further require The President of Inscyte and its Privacy Officer to ensure that other information, namely deidentified and/or aggregate information, will not serve the identified purpose of the disclosure and that no more personal health information is being requested than is reasonably necessary to meet the identified purpose.



Inscyte's policies and procedures set out the manner in which decisions approving or denying a request for the disclosure of personal health information for purposes other than research are made, and that the reasons for the decisions are documented. Decisions regarding Data Sharing Agreements are documented in business letters to the organization requesting access to CytoBase information. Decisions regarding applications for access to the CytoBase for Clinicians online service are documented on the application form(s) and communicated to individual applicants. Inscyte maintains copies of all decisions and communications in its privacy document archives.

#### Conditions or Restrictions on the Approval

Inscyte's policies and procedures identify the conditions or restrictions that are required to be satisfied prior to the disclosure of personal health information for purposes other than research, including any documentation and/or agreements that must be completed, provided or executed and the agent(s) or other persons or organizations responsible for completing, providing or executing the documentation and/or agreements. With respect to disclosure of personal health information to an organization, the policy and procedures require a Data Sharing Agreement to be executed in accordance with the Policy and Procedures for the Execution of Data Sharing Agreements and Inscyte's template Data Sharing Agreement prior to any disclosure of personal health information for purposes other than research.

The policy and procedures identify the President of Inscyte as being ultimately responsible for ensuring that any conditions or restrictions that must be satisfied prior to the disclosure of personal health information have in fact been satisfied, including the execution of a formal Data Sharing Agreement or the execution of CytoBase for Clinicians Access Agreements.

#### Secure Transfer

Inscyte's policies and procedures require records of personal health information to be transferred in a secure manner in compliance with its Policy and Procedures for Secure Transfer of Records of Personal Health Information. These policies and procedures set out the minimum acceptable encryption and authentication standards for the secure transfer of personal health information using computing networks, portable media, and mobile devices.

#### Secure Return or Disposal

Inscyte's policies and procedures stipulate that each Data Sharing Agreement set out the retention period and the appropriate methods of return or destruction of personal health information by the recipient upon the expiry of the retention period in the Data Sharing Agreement or the termination or the Data Sharing Agreement itself. Inscyte's policies and procedures set out acceptable methods and procedures for the secure return or destruction of personal heath information on various digital media, mobile devices and paper records.



The policies further stipulate that recipients of personal healthcare information that are required to return or destroy personal health information upon the expiry of the retention period specified in the Data Sharing Agreement, or the termination of the Data Sharing Agreement itself, shall provide to Inscyte a document of *Confirmation of Return and/or Destruction of Personal Health Information*, describing the information holding, the date of return/destruction, the name and title of the person attesting to the return/destruction, and the method of destruction, within ninety business days of the expiry of the retention period in the Data Sharing Agreement, or the termination of the Data Sharing Agreement. In the event that Inscyte does not receive such confirmation in the allotted time period, it is the responsibility of the Privacy Officer to follow-up with the party to obtain such confirmation. In the event that confirmation of return and/or destruction of personal health information cannot be resolved or verified, the policies require the matter to be escalated to the President of Inscyte for resolution, which may include legal action.

Inscyte Corporation's policy is to retain all *Confirmation of Return and/or Destruction of Personal Health Information* documentation in its privacy document archives in perpetuity.

#### Documentation Related to Approved Disclosures of Personal Health Information

Inscyte Corporation's privacy policy stipulates that documentation related to the receipt, review, approval or denial of requests for the disclosure of personal health information for purposes other than research will be retained in perpetuity in Inscyte's privacy document archives and that it is the responsibility of the Privacy Officer to ensure compliance with this policy.

#### Where the Disclosure of Personal Health Information is not Permitted

Inscyte Corporation's privacy policy states that personal health information in its custody shall not be disclosed to any party where the disclosure is not permitted under the Act and expressly prohibits the disclosure of personal health information for non-research purposes, except where required by law.

Where the disclosure of personal health information is not permitted under the Act, Inscyte's privacy policy permits the disclosure of de-identified or aggregated data should such information be acceptable to the recipient. Under these circumstances the de-identification and/or aggregation of data is performed in accordance with Inscyte's policies and procedures for de-identification and aggregation of personal health information to prevent the inadvertent disclosure of a person's identity resulting from a small number of observations in an aggregation, taking into account the recipient of the information and giving regard to section 4(2) of the Act, which states that information is identifying if it identifies an individual or if it is reasonably foreseeable that the information could be utilized, either alone or with other information, to identify an individual.



#### **Review and Approval Process**

Inscyte's policies and procedures identify the Privacy Officer as being responsible for receiving, reviewing and determining whether to recommend to approve or deny a request for the disclosure of de-identified and/or aggregated data. The President of Inscyte is ultimately responsible for authorizing the release of de-identified and/or aggregated data.

Inscyte's policies and procedures set out the requirements that must be satisfied and the criteria that must be considered by the Privacy Officer in determining whether to recommend to approve or deny the request for the disclosure of de-identified and/or aggregate information for purposes other than research. The policies state that the intended use of the de-identified and/or aggregate information must be consistent with the objectives of CytoBase in improving patient care and reducing the burden of cervical cancer. Further the policies require the de-identified and/or aggregate information to be reviewed by the Privacy Officer prior to the disclosure to ensure that the information does not identify an individual and that it is not reasonably foreseeable in the circumstances that the information could be utilized, either alone or with other information, to identify an individual.

Inscyte's policies and procedures require the requester to provide a written *Letter of Request* to the Privacy Officer describing the requester's identity, the scope of de-identified or aggregated information required, and the purpose and/or intended use of this information. The Privacy Officer is responsible for reviewing and qualifying the request using the stated criteria and communicating with the requester during the review process. The President of Inscyte is ultimately responsible for authorizing the release of the de-identified and/or aggregated data. The approval is documented in a *Letter of Authorization* sent to the requester and copied to the Privacy Officer. The Letter of Authorization must also be signed by the receiving party acknowledging and attesting to that the person or organization will not use the de-identified and/or aggregate information, either alone or with other information, to identify an individual. This includes attempting to decrypt information that is encrypted, attempting to identify an individual based on prior knowledge.

Inscyte's policy is to retain communications and reasons for the decision approving or denying the request for the disclosure of de-identified and/or aggregate information for purposes other than research in its privacy document archives in perpetuity.

#### Conditions or Restrictions on the Approval

Inscyte's policies and procedures stipulate that the disclosure of de-identified and/or aggregate information for non-research purposes requires:

a) A *Letter of Request* identifying the requester, the scope of information requested and the intended use of the information;



- b) A review by the Privacy Officer describing the de-identified and/or aggregated information and the risk of identifying an individual if it is reasonably foreseeable that the information could be utilized, either alone or with other information, to identify an individual; and
- c) A *Letter of Authorization* from the President of Inscyte approving the disclosure.
- d) Signed written acknowledgement from the recipient that it will not use the de-identified and/or aggregate information, either alone or with other information, to identify an individual. This includes attempting to decrypt information that is encrypted, attempting to identify an individual based on unencrypted information and attempting to identify an individual based on prior knowledge.

Inscyte's policies and procedures identify the Privacy Officer as being responsible for ensuring that any conditions or restrictions that must be satisfied prior to the disclosure of the deidentified and/or aggregate information have in fact been satisfied, including the execution of the written acknowledgement. Further, the policies and procedures require that the Privacy Officer track receipt of the executed written acknowledgments and retain these in perpetuity in Inscyte's privacy document archives.

## **13.** Policy and Procedures for Disclosure of Personal Health Information for Research Purposes and the Execution of Research Agreements

Inscyte Corporation's privacy and security policies and procedures state that personal health information in the custody of Inscyte Corporation shall not be disclosed or used to conduct research or support research on individuals or groups of individuals. As such, Inscyte does not accept requests from researchers or research organizations to access and use personal health information for research purposes, and does not have policies and procedures in place to manage such requests or execute such requests.

## 14. Template Research Agreement

Inscyte Corporation's privacy and security policies and procedures state that personal health information in the custody of Inscyte Corporation shall not disclosed or used to conduct research or support research on individuals or groups of individuals. As such, Inscyte does not maintain template research agreements.

## **15.** Log of Research Agreements

Inscyte Corporation's privacy and security policies and procedures state that personal health information in the custody of Inscyte Corporation shall not disclosed or used to conduct research or support research on individuals or groups of individuals. As such, Inscyte does not maintain a log of research agreements.

## 16. Policy and Procedures for the Execution of Data Sharing Agreements

Inscyte's privacy policies and procedures require Data Sharing Agreements to be executed between Inscyte and third parties under any circumstance that involves either the collection and/or disclosure of personal health information between the parties, before the collection and/or disclosure of personal health information taking place. The policies and procedures further specify that Data Sharing Agreements may only be executed with parties that are legally permitted to exchange personal health information with Inscyte. In practice this restricts the parties that may enter into a Data Sharing Agreement for the collection/disclosure of personal health information to Ontario health information custodians and prescribed persons/entities under the Act.

The only exception to the requirements for executing a Data Sharing Agreement is the disclosure of personal health information to individual healthcare providers in Ontario via the CytoBase for Clinicians online service, which requires individually signed Access Agreements to be executed between Inscyte and individual providers in place of a Data Sharing Agreement.

The policies and procedures describe the process for executing Data Sharing Agreements and the required content, terms and conditions of these agreements. The policies require that each Data Sharing Agreement describe the purpose for the collection/disclosure; that the purpose is consistent with the objectives and intended use of CytoBase; that the agreement describe the precautions to be taken to secure the information during exchange; the precautions to be taken to secure the information; the limitations on retention of the information; and the requirements for secure return or destruction of the information. The policies also stipulate that Data Sharing Agreements require each party to inform the other, at the first reasonable opportunity, if the party believes a breach of privacy has occurred or may occur.

The policies further specify that it is the responsibility of the President of Inscyte to execute Data Sharing Agreements with third parties prior to the collection/disclosure of personal health information and to ensure that all requirements of Data Sharing Agreements are satisfied, taking into account the approval processes in respect of the policies and procedures for disclosure of personal health information for purposes other than research and/or the policies and procedures for the collection of personal health information.

Inscyte's policies and procedures also require that all executed Data Sharing Agreements are retained in a perpetual Log of Data Sharing Agreement within its privacy document archives. This includes copies of executed and signed agreements. The policies state that it is the responsibility of the Privacy Officer to ensure that the Log of Data Sharing Agreements is maintained up-to-date and complete.

The parties to Inscyte's Data Sharing Agreements are either health information custodians or prescribed persons/entities under the Act. As such, the party executing a Data Sharing





Agreement with Inscyte must also comply with the provisions and requirements of the Act. For this reason, Inscyte does not have policies or procedures in place to audit or verify a party's compliance with Inscyte's privacy policies and procedures, as the party's own policies and procedures and obligations under the Act take precedence.

Inscyte Corporation requires its agents to comply with this policy and its procedures and designates the Privacy Officer as being responsible for enforcing compliance. Inscyte's policies and procedures set out the consequences of breach and stipulate that compliance will be audited on an annual basis at minimum, in accordance with Inscyte's the Policy and Procedures in Respect of Privacy Audits, and designate the Privacy Officer as being responsible for conducting the audits and for ensuring compliance with the policy and its procedures.

Inscyte's policy and procedures require its agents to notify Inscyte at the first reasonable opportunity, in accordance with the Policy and Procedures for Privacy Breach Management, if an agent breaches or believes there may have been a breach of this policy or its procedures.

## **17. Template Data Sharing Agreement**

Inscyte Corporation ensures that a Data Sharing Agreement is executed in the circumstances set out in the Policy and Procedures for the Execution of Data Sharing Agreements. Inscyte's policies and procedures require that a Template Data Sharing Agreement be kept on file and that all Data Sharing Agreements address the following.

#### **General Provisions**

Inscyte's template Data Sharing Agreement describes the status of Inscyte Corporation with respect to CytoBase under the Act and the duties and responsibilities arising from this status. The template agreement provides a definition of personal health information consistent with the Act and its regulation and provides for specifying the precise nature of the personal health information subject to the Data Sharing Agreement. The template Data Sharing Agreement provides for identifying the organization that is collecting personal health information and the organization that is disclosing personal health information pursuant to the agreement.

#### Purposes of Collection, Use and Disclosure

Inscyte's template Data Sharing Agreement identifies the purposes for which the personal health information subject to the Data Sharing Agreement is being collected and for which the personal health information will be used. The Data Sharing Agreements explicitly state whether or not the personal health information collected pursuant to the Data Sharing Agreement will be linked to other information, and if so, the Data Sharing Agreement identifies the nature of the information to which the personal health information will be linked, the source of the information to which the personal health information will be linked, how the linkage will be conducted and why the linkage is required for the identified purposes.

The template Data Sharing Agreement includes an acknowledgement that the personal health information collected pursuant to the Data Sharing Agreement is necessary for the purpose for which it was collected and that other information, namely de-identified and/or aggregate information, will not serve the purpose and that no more personal health information is being collected and will be used than is reasonably necessary to meet the purpose.

The template Data Sharing Agreement also identifies the purposes, if any, for which the personal health information subject to the Data Sharing Agreement may be disclosed and any limitations, conditions or restrictions imposed thereon.

The template Data Sharing Agreement requires the collection, use and disclosure of personal health information subject to the Data Sharing Agreement to comply with the Act and its regulation and sets out the specific statutory authority for each collection, use and disclosure contemplated in the Data Sharing Agreement.

#### Secure Transfer

Inscyte's template Data Sharing Agreement requires the secure transfer of the records of personal health information subject to the Data Sharing Agreement. The Data Sharing Agreement sets out the secure manner in which the records of personal health information will be transferred, including under what conditions and to whom the records will be transferred, and the procedure that will be followed in ensuring that the records are transferred in a secure manner. Inscyte's policies and procedures prescribe acceptable methods for the secure transfer of personal health information in various formats and media.

#### Secure Retention

Inscyte's template Data Sharing Agreement addresses the retention period of personal health information to ensure that the information is retained only for as long as required to fulfill the purpose for which personal health information is collected.

The template Data Sharing Agreement requires that records of personal health information are stored in a secure manner consistent with Inscyte's policies and procedures for the secure storage of personal health information in various formats and media, which address steps to be taken to ensure that the personal health information subject to the Data Sharing Agreement is protected against theft, loss and unauthorized use or disclosure and to ensure that the records of personal health information are protected against unauthorized copying, modification or disposal.

Each instance of a Data Sharing Agreement describes the secure manner in which personal health information will be stored by the parties to the agreement and the steps to be taken to protect the information against theft, loss, unauthorized use or disclosure, copying, modification and disposal.



#### Secure Return or Disposal

Inscyte's template Data Sharing Agreement also addresses whether the records of personal health information subject to the Data Sharing Agreement will be returned in a secure manner or will be disposed of in a secure manner following the retention period set out in the Data Sharing Agreement or following the date of termination of the Data Sharing Agreement, as the case may be.

If the records of personal health information are required to be returned in a secure manner, the Data Sharing Agreement specifies the time frame following the retention period, or the date of termination of the agreement, within which the records of personal health information must be securely returned, that the records should be returned to the Privacy Officer of Inscyte, and the manner of secure return consistent with Inscyte's policies and procedures for the secure transfer of personal health information.

If the records of personal health information are required to be disposed of in a secure manner, the Data Sharing Agreement specifies the time frame following the retention period, or the date of termination of the agreement, within which the records of personal health information must be securely destroyed and a Certificate of Destruction to be sent to the Privacy Officer of Inscyte attesting to the destruction of the records. The Certificate of Destruction must include at minimum: a description of the record set that was destroyed, the date the records were destroyed, the method by which the records were destroyed, the name of the person who destroyed the records, and the name and signature of the person attesting to the destruction of the records.

If the records of personal health information are required to be disposed of in a secure manner, the Data Sharing Agreement further describes acceptable methods of destruction, consistent with Inscyte's Policies and Procedures for the Secure Disposal of Personal Health Information in various formats and media, which are consistent with the Act and its regulations, and give regard to orders issued by the Information and Privacy Commissioner of Ontario under the Act and its regulation, including Order HO-001 and Order HO-006; and with guidelines, fact sheets and best practices issued by the Information and Privacy Commissioner of Ontario pursuant to the Act and its regulation, including Fact Sheet 10: Secure Destruction of Personal Information.

#### Notification

Inscyte's template Data Sharing Agreement requires that notification be provided at the first reasonable opportunity if the Data Sharing Agreement has been breached or is suspected to have been breached or if the personal health information subject to the Data Sharing Agreement is stolen, lost or accessed by unauthorized persons or is believed to have been stolen, lost or accessed by unauthorized persons. Inscyte's policies regarding breach management require the notification to be made in writing to the Privacy Officer of Inscyte, and set out the steps to be taken to contain the breach.



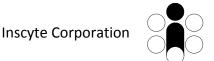
### Consequences of Breach and Monitoring Compliance

The parties to Inscyte's Data Sharing Agreements are either health information custodians or prescribed persons/entities under the Act and must therefore also comply with the provisions and requirements of the Act. For this reason, Inscyte's Data Sharing Agreements do not include provisions for monitoring and auditing compliance of the other party. Instead, the template Data Sharing Agreement stipulates that each party must agree to monitor compliance with the terms and conditions of the data Sharing Agreement in accordance with its own policies and procedures regarding privacy and/or security audits, breach management, containment, and the consequences of breach. Similarly, Inscyte's template Data Sharing Agreements do not require that individual persons who will be given access to personal health information sign an acknowledgment with Inscyte, as these persons will be required to sign confidentiality and non-disclosure agreements with the healthcare custodian or prescribed person/entity that is party to the Data Sharing Agreement.

#### **18.** Log of Data Sharing Agreements

Inscyte Corporation maintains a log of executed Data Sharing Agreements, which includes:

- 1. The name of the organization from which the personal health information is (was) collected and/or to which the personal health information is (was) disclosed;
- 2. The date that the collection or disclosure of personal health information was approved, as the case may be;
- 3. The date that the Data Sharing Agreement was executed;
- 4. The date the personal health information was collected or disclosed, as the case may be;
- 5. The nature of the personal health information subject to the Data Sharing Agreement;
- 6. The retention period for the records of personal health information set out in the Data Sharing Agreement or the date of termination of the Data Sharing Agreement;
- 7. Whether the records of personal health information will be securely returned or will be securely disposed of following the retention period set out in the Data Sharing Agreement or the date of termination of the Data Sharing Agreement; and
- 8. The date the records of personal health information were securely returned or a certificate of destruction was provided or the date by which they must be returned or disposed of.



# **19.** Policy and Procedures for Executing Agreements with Third Party Service Providers in Respect of Personal Health Information

Inscyte's policies require a written agreement to be entered into with third party service providers whenever such services entail access to, or use of personal health information, prior to permitting third party service providers to access and use the personal health information. The policies and procedures require the written agreements to contain the relevant language from Inscyte's Template Agreement for Third Party Service Providers.

The policies and procedures state that the President of Inscyte is responsible for ensuring that a Third Party Service Agreement is executed in all cases where such services involve access to or use of personal health information. This policy does not apply to third party services where access to or use of personal health information is not required.

The policy and procedures specify that Inscyte shall not provide personal health information to a third party service provider if other information, namely de-identified and/or aggregate information, will serve the purpose and will not provide more personal health information than is reasonably necessary to meet the purpose. The Privacy Officer of Inscyte is responsible for making this determination.

The policy and procedures specify that the Privacy Officer is responsible for ensuring that records of personal health information provided to a third party service provider are either securely returned or are securely disposed of, as the case may be, following the termination of the agreement. In the event that records of personal health information are not returned or a confirmation of destruction of the records is not received within the time frame stipulated in the Third Party Service Agreement, it is the responsibility of the Privacy Officer of Inscyte to inform the third party in writing that failure to return or destroy the records in accordance with the terms and conditions of the agreement constitutes a breach of the agreement. If the third party fails to comply after such notification, the matter is escalated to the President of Inscyte, and if compliance is not achieved may result in legal action.

Inscyte's policy requires that a log be maintained of all agreements executed with third party service providers and designates the Privacy Officer as responsible for maintaining the Log of Third Party Service Agreements in Inscyte's privacy document archives, including signed copies of all executed agreements.

The terms and conditions of Inscyte's Third Party Service Agreements require the third party to comply with Inscyte's privacy and security policies and procedures and designate the Privacy Officer of Inscyte as being responsible for monitoring and auditing third party compliance. Compliance will be audited in accordance with Inscyte's policies and procedures in respect of privacy audits, at a frequency specified and agreed to in the Third Party Service Agreement.



The terms and conditions of Inscyte's Third Party Service Agreements require the third party to notify Inscyte, at the first reasonable opportunity, if the third party breaches or believes there may have been a breach of privacy and security as defined in Inscyte's policies and procedures and to comply with Inscyte's breach management policies and procedures.

# 20. Template Agreement for All Third Party Service Providers

Inscyte Corporation maintains a template Third Party Service Agreement to be used with third party services providers whenever the third party will be given access to, or use of, Inscyte's holdings of personal health information in the course of carrying out the work under the service agreement, including those that are contracted to retain, transfer or dispose of records of personal health information.

The template Third Party Service Agreement does not apply to third party service providers who are not permitted access to or use of personal health information but work peripherally with equipment that facilitates the means to collect, use, modify, disclose, or retain personal health information, such as hardware/software vendors, equipment maintenance contractors, network providers, facility maintenance services, etc.

Inscyte's template Third Party Service Agreement addresses the matters set out below.

#### **General Provisions**

The template Third Party Service Agreement describes the status of Inscyte Corporation under the Act and the duties and responsibilities arising from this status. The agreement also identifies whether or not the third party service provider is an agent of Inscyte in providing the services. All third party service providers that are permitted to access and use personal health information in the course of providing services to Inscyte are considered agents of Inscyte.

Third party service providers engaged to work with, maintain or repair equipment that facilitates the means to collect, use, modify, disclose, retain or dispose of personal health information, such as hardware/software vendors, equipment maintenance contractors, network providers and facility maintenance services, etc., are not permitted to access or use personal health information and are not considered agents of Inscyte.

In the event that a third party service provider is an agent of Inscyte, the agreement requires the third party service provider to comply with the provisions of the Act and its regulation, and to comply with Inscyte's privacy and security policies in providing services pursuant to the agreement.

Inscyte's template Third Party Service Agreement includes a definition of personal health information that is consistent with the Act and its regulation. The agreement also specifies the



precise nature of the personal health information that the third party service provider will be permitted to access and use in the course of providing services pursuant to the agreement.

Inscyte's template Third Party Service Agreement also requires that the services provided by the third party service provider be performed in a professional manner, in accordance with industry standards and practices, and by properly trained staff of the third party service provider.

## **Obligations with Respect to Access and Use**

Inscyte's template Third Party Service Agreement identifies the purposes for which the third party service provider is permitted to access and use the personal health information of the prescribed person or prescribed entity and any limitations, conditions or restrictions imposed thereon. Inscyte further ensures that each use identified in the agreement is consistent with the uses of personal health information permitted by the Act and its regulation. The agreement explicitly prohibits the third party service provider from using personal health information except as permitted in the agreement.

The template Third Party Service Agreement also prohibits the third party service provider from using personal health information if other information will serve the purpose and from using more personal health information than is reasonably necessary to meet the purpose.

In the case of third party service providers engaged to work with equipment that facilitates the means to collect, use, modify, disclose, retain or dispose of personal health information, such as hardware/software vendors, equipment maintenance contractors, network providers and facility maintenance services, etc., the agreement prohibits the provider from accessing and/or using personal health information that may be stored on the equipment, and from disclosing the personal health information except as required by law.

## Obligations with Respect to Disclosure

The template Third Party Services Agreement identifies the purposes, if applicable, for which the third party service provider is permitted to disclose the personal health information and the limitations, conditions or restrictions imposed on the disclosure. Specifically, the agreement states that such disclosure must be consistent with the Act and its regulations and comply with Inscyte's policies and procedures for the disclosure of personal health information. The agreement further prohibits the third party from disclosing personal health information except as permitted in the agreement or as required by law, from disclosing personal health information if other information will serve the purpose and, from disclosing more personal health information than is reasonably necessary to meet the purpose.

In the case of third party service providers engaged to work with equipment that facilitates the means to collect, use, modify, disclose, retain or dispose of personal health information, such as



hardware/software vendors, equipment maintenance contractors, network providers and facility maintenance services, etc., the agreement prohibits the provider from accessing and/or using personal health information that may be stored on the equipment, and from disclosing the personal health information except as required by law.

#### Secure Transfer

In the event that a Third Party Services Agreement contemplates the transfer of personal health information between Inscyte and another party, the agreement requires that such transfer of personal health information comply with Inscyte's policies and procedures for the secure transfer of personal health information in various formats and media. Specifically, the agreement sets out the secure manner in which the records will be transferred by the third party service provider, the conditions under which the records will be transferred, to whom the records will be transferred, and the procedures that must be followed by the third party service provider in ensuring that the records are transferred in a secure manner.

In addition, where the retention of records of personal health information or where the disposal of records of personal health information outside the premises of Inscyte is the primary service provided to Inscyte, the agreement requires the third party service provider to provide documentation to Inscyte setting out the date, time and mode of transfer of the records of personal health information and confirming receipt of the records of personal health information by the third party service provider. In these circumstances, the agreement obligates the third party service provider to maintain a detailed inventory of the records of personal health information transferred.

#### Secure Retention

In the event that a Third Party Services Agreement contemplates the retention of personal health information by an agent of Inscyte, the agreement requires that the retention comply with Inscyte's policies and procedures regarding the secure storage and retention of personal health information in various formats and media, and describes the responsibilities of the service provider in securely retaining the records of personal health information.

Where the retention of records of personal health information is the primary service provided to Inscyte by the third party service provider, the agreement obligates the third party service provider to maintain a detailed inventory of the records of personal health information being retained on behalf of Inscyte as well as the methods used to track the records being retained.

## Secure Return or Disposal Following Termination of the Agreement

Inscyte's template Third Party Services Agreement addresses, where applicable, whether records of personal health information will be securely returned to Inscyte or will be disposed of in a secure manner following the termination of the agreement.



In the event that records of personal health information are to be returned to Inscyte the agreement specifies that the records are to be returned to the Privacy Officer of Inscyte, the format and/or media in which the records are to be returned, the time frame following the date of termination of the agreement within which the records must be returned, that the method of returning the records in compliance with Inscyte's policies and procedures regarding the secure transfer of personal health information in various formats and media.

If the event that records of personal health information are to be disposed of in a secure manner, the agreement describes acceptable methods of destruction, consistent with Inscyte's policies and procedures for the secure destruction of personal health information in various formats and media, which are consistent with the Act and its regulations, and give regard to orders issued by the Information and Privacy Commissioner of Ontario under the Act and its regulation, including Order HO-001 and Order HO-006; and with guidelines, fact sheets and best practices issued by the Information and Privacy Commissioner of Ontario pursuant to the Act and its regulation, including Fact Sheet 10: Secure Destruction of Personal Information.

If the records of personal health information are required to be disposed of in a secure manner, the agreement specifies the time frame following the termination of the agreement, within which the records of personal health information must be securely destroyed and a Certificate of Destruction to be sent to the Privacy Officer of Inscyte attesting to the destruction of the records. The Certificate of Destruction must include at minimum: a description of the record set that was destroyed, the date the records were destroyed, the method by which the records were destroyed, the name of the person who destroyed the records, and the name and signature of the person attesting to the destruction of the records.

## Secure Disposal as a Contracted Service

In circumstances where the disposal of records of personal health information is the primary service provided to Inscyte or its agents by the third party service provider, in addition to the requirements above in relation to secure disposal, the agreement sets out the responsibilities of the third party service provider in securely disposing of the records of personal health information, including:

- The time frame within which the records are required to be securely disposed of;
- The precise method by which records in paper and/or electronic format must be securely disposed of, including records retained on various media;
- The conditions pursuant to which the records will be securely disposed of; and
- The person(s) responsible for ensuring the secure disposal of the records.

The agreement also enables Inscyte, at its sole discretion, to witness the secure disposal of the records of personal health information subject to such reasonable terms or conditions as may be required in the circumstances.



# Implementation of Safeguards

Inscyte's template Third Party Services Agreement details the precautions and safeguards that a service provider is required to implement to ensure that personal health information accessed and used in the course of providing services is protected against theft, loss and unauthorized use or disclosure and to ensure that the records of personal health information subject to the agreement are protected against unauthorized copying, modification or disposal. The agreement states that these precautions must be consistent with Inscyte's policies and procedures for the secure storage, transfer and/or destruction of personal health information in various formats and media, as the case may be.

## Training of Agents of the Third Party Service Provider

Inscyte's template Third Party Services Agreement requires that a service provider who is an agent of Inscyte must provide training to its staff regarding the importance of protecting the privacy of individuals whose personal health information is accessed and used in the course of providing services pursuant to the agreement and on the consequences that may arise in the event of a breach of these obligations.

The agreement further requires the service provider to ensure that its agents who will have access to the records of personal health information are aware of and agree to comply with the terms and conditions of the agreement prior to being given access to the personal health information. To this end, the agreement requires agents to sign an acknowledgement, prior to being granted access to the personal health information, indicating that they are aware of and agree to comply with the terms and conditions of the agreement.

## Subcontracting of the Services

In the event that the Third Party Services agreement permits an agent of Inscyte to subcontract certain services to be provided under the agreement, the agreement requires the agent to acknowledge and agree that it will provide Inscyte with advance notice of its intention to do so, that agent will enter into a written agreement with the subcontractor on terms consistent with its obligations to Inscyte, and that a copy of the sub-contract agreement will be provided to Inscyte.

## Notification

Inscyte's template Third Party Services Agreement requires the third party service provider to notify Inscyte at the first reasonable opportunity if there has been a breach or suspected breach of the agreement or if personal health information handled by the third party service provider on behalf of Inscyte is stolen, lost or accessed by unauthorized persons or is believed to have been stolen, lost or accessed by unauthorized persons. The agreement requires that the notification be made to the Privacy Officer of Inscyte, both verbally and in writing, and that under such circumstances Inscyte's policies and procedures for breach management shall come into force.



## Consequences of Breach and Monitoring Compliance

In the event that a third party service provider is an agent of Inscyte, the Third Party Services Agreement indicates that Inscyte may, at any time and at its sole discretion, conduct a review/audit of the practices of the agent to ensure that the agent is in compliance with Inscyte's privacy and security policies and procedures as described in the agreement. The Third Party Services Agreement also describes the consequences of breach of the agreement.

# 21. Log of Agreements with Third Privacy Service Providers

Inscyte maintains a perpetual log of executed agreements with third party service providers in its privacy document archives, which includes:

- The name of the third party service provider;
- The nature of the services provided by the third party service provider that require access to and use of personal health information;
- The date that the agreement with the third party service provider was executed;
- The date that the records of personal health information or access to the records of personal health information, if any, was provided;
- The nature of the personal health information provided or to which access was provided;
- The date of termination of the agreement with the third party service provider;
- Whether the records of personal health information, if any, will be securely returned or will be securely disposed of following the date of termination of the agreement; and
- The date the records of personal health information were securely returned or a certificate of destruction was provided or the date that access to the personal health information was terminated or the date by which the records of personal health information must be returned or disposed of or access terminated.

# 22. Policy and Procedures for the Linkage of Records of Personal Health Information

Inscyte's privacy policy permits linkage of data with external sources provided that the that the linkage is permitted under law, that the purpose of the linkage is consistent with the purpose of CytoBase, and that the other party has executed a Data Sharing Agreement with Inscyte prior to the linkage taking place. Further, the policies state that if the linkage results in a disclosure of personal health information by Inscyte to another person or organization, the linkage is permitted only if the other party is a healthcare custodian or a prescribed entity/person under the Act and its regulations.

In practice, Inscyte Corporation does not receive new requests for data linkage on an on-going basis. At the time of writing, the only on-going linkage occurs with data provided by "P-



Prompt", a service provided to Ontario physician's by Fig.P Software Inc. This is a quarterly linkage where the only information disclosed by Inscyte is a patient's most recent cervical cancer screening test date.

## Review and Approval Process

Inscyte's policies and procedures stipulate that requests for data linkages must be addressed to the President of Inscyte, and designate the President of Inscyte as being ultimately responsible for reviewing requests and approving/denying requests for data linkage. The request procedure requires that requests be submitted in writing to the President of Inscyte describing the purpose of the linkage, the nature of the data elements to be linked and the data elements that will be disclosed by each party to the other as a result of the linkage.

The policy and procedures designate the President of Inscyte as being responsible for reviewing and approving or denying requests for data linkage with CytoBase. The policies state that the minimum criteria used for evaluating requests for data linkage are:

- a) The linkage must be permitted by law, and
- b) The purpose of the linkage must be consistent with Inscyte's policies regarding the collection and use of personal health information, and the general objectives of CytoBase with respect to improving patient care in Ontario.

The policies and procedures require that the decision to approve or deny a request for data linkage be provided by the President of Inscyte to the requesting party in writing, including a documentation of the reason for the decision.

If a request for data linkage is approved, the policies and procedures require that a Data Sharing Agreement be prepared in compliance with Inscyte's policies and procedures in respect of data sharing agreements, and that the Data Sharing Agreement set out the purpose of the linkage, the frequency of the linkage, the nature of data to be linked and disclosed, the retention periods for linked data, and the disposal requirements for the linked data.

#### Conditions or Restrictions on Approval

In the event that linked records of personal health information will be disclosed by Inscyte to another person or organization, the policies and procedures require that the disclosure be approved pursuant to Inscyte's Policies and Procedures for the Disclosure of Personal Health Information For Purposes Other Than Research, and the execution of Data Sharing Agreements.

In the event that the linked records of personal health information will be used by Inscyte Corporation, Inscyte's policies and procedures require that the use be approved pursuant to Inscyte's Policy and Procedures for the Use of Personal Health Information and limiting access to personal health information. Further, Inscyte's policies and procedures state that the linked



records of personal health information will be retained only for as long as required to fulfill the purpose of the linkage, and that thereafter, as soon as practicable, the linked data will be deidentified/aggregated or destroyed in compliance with Inscyte's policies for the deidentification/aggregation or destruction of personal health information, as the case may be.

#### Process for the Linkage of Personal Health Information

Inscyte's policies and procedures in respect of data linkages do not set out any specific process for performing data linkages as these processes may differ depending on the type of data linkage being performed, the frequency of the data linkage, and the desired formats/media of the input and output datasets. The agent(s) responsible for implementing specific processes and performing the data linkage are identified in the Data Sharing Agreement governing the linkage.

#### Retention

Inscyte's policies and procedures require all data linkages to be carried out under a Data Sharing Agreement, which sets out the requirements regarding retention of the linked data by Inscyte and/or the other party, depending on the purpose of the linkage and the intended use of the linked data, and in compliance with Inscyte's Policies and Procedures for Secure Retention of Records of Personal Health Information until they are de-identified and/or aggregated pursuant to the Policy and Procedures with Respect to De-Identification and Aggregation of personal health information.

#### Secure Disposal

Inscyte's policies and procedures require all data linkages to be carried out under a Data Sharing Agreement, which sets out the requirements regarding disposal of linked personal health information by Inscyte and/or the other party, when it is no longer required to fulfill its intended purpose and use, in compliance with Inscyte's Policies and Procedures for the Secure Disposal of Personal Health Information.

#### Compliance, Audit and Enforcement

Inscyte's policies and procedures require all data linkages to be carried out under a Data Sharing Agreement and where the linkage would result in a disclosure of personal health information by Inscyte, the other party must be either health information custodians or prescribed persons/entities under the Act and must therefore also comply with the provisions and requirements of the Act. For this reason, Inscyte's Data Sharing Agreements do not include provisions for monitoring and auditing compliance of the other party. Instead, the Data Sharing Agreement stipulates that each party must agree to monitor compliance with the terms and conditions of the Data Sharing Agreement in accordance with its own policies and procedures regarding privacy and/or security audits, breach management, containment, and the consequences of breach. Further, the Data Sharing Agreement requires each party to notify the other at the first reasonable opportunity, in accordance with the Policy and Procedures for



Privacy Breach Management, if the party breaches or believes there may have been a breach of the terms and conditions of the Data Sharing Agreement.

## Tracking Approved Linkages of Records of Personal Health Information

Inscyte's policies and procedures require that logs be maintained of the linkages of records of personal health information approved by Inscyte and identifies AIM Inc. as the agent responsible for maintaining these logs. The logs of data linkages contain the name of the requester, the date/time the linkage was performed, the name of the individual performing the linkage and the disposition of the linked record set. In circumstances where approved data linkages are performed by on an on-going basis by automated processes, Inscyte's policies and procedures require that an audit trail be maintained specifying the date and time of each record linkage and its disposition.

# 23. Log of Approved Linkages of Records of Personal Health Information

Inscyte Corporation maintains a log of linkages of records of personal health information approved by the prescribed person or prescribed entity. The log includes the name of the person or organization who requested the linkage; the date that the linkage of records of personal health information was approved or denied; and the nature of the records of personal health information linked, the purpose of the linkage, the frequency of the linkage and a copy of (or reference to) the applicable Data Sharing Agreement governing the linkage.

# 24. Policy and Procedures with Respect to De-Identification and Aggregation

Inscyte's privacy policies and procedures state that personal health information shall not be used or disclosed if other information, namely de-identified and/or aggregate information, will serve the identified purpose. To this end Inscyte has also implemented policies and procedures for the de-identification of personal health information in various formats and media, and policies and procedures setting out the limits on the aggregation of statistical information from personal health information. These policies and procedures provide a definition of personal health information consistent with the Act and its regulations.

Inscyte's policies and procedures define de-identified information as information that cannot be used alone, or in conjunction with other information, under reasonable effort, to identify an individual. The policies and procedures specify that de-identification of personal health information requires outright removal or obfuscation (pseudonym-value substitution) of every element of personal health information as defined in the Act and regulations. The policies state that at minimum the following data elements must be removed or obfuscated in the process of de-identification of personal health information:

- a) Patient name, middle name and last name
- b) Patient contact information (address, city, postal code, telephone etc.)
- c) Patient health insurance providers/policy numbers



- d) Patient medical record numbers and/or chart numbers
- e) Patient caregiver names, addresses, contact information
- f) Patient date of birth to be converted to "age at" date where possible
- g) Specimen accession numbers and/or medical report identifiers
- h) Institution, clinic, hospital, laboratory names, addresses, telephone, etc.

Inscyte's policies and procedures specify that encrypted information is not the same as deidentified information because it is subject to decryption. Inscyte's policies and procedures provide examples of acceptable methods of removing and/or obfuscating data to de-identify personal health information in various formats and media, and designate AIM Inc. as agent responsible for the de-identification and aggregation of information.

Inscyte's policies and procedures define aggregated information as information that contains no patient identifying information whatsoever, but rather represents mathematical counts, ratios, rates, etc. of instances of correlated data. Inscyte's policies stipulate that aggregate information with fewer than five (5) observations per aggregation (cell) is not to be disclosed owing to the elevated risk of potential re-identification due to a low occurrence of instances of the correlated data.

Inscyte's policies and procedures designate the Privacy Officer of Inscyte as being responsible for the review and approval of the disclosure of de-identified and/or aggregate information and to assess the risk of inadvertent disclosure of a person's identity, taking into account the recipient of the information and the purpose of the disclosure. In making this assessment, the policies and procedures require the Privacy Officer to take section 4(2) of the Act into consideration, which states that information is identifying if it identifies an individual or if it is reasonably foreseeable in the circumstances that the information could be utilized, either alone or with other information, to identify an individual. The policies and procedures stipulate that if the risk is deemed inappropriate the information shall not be disclosed.

The process in reviewing the de-identified and/or aggregate information and the criteria used in assessing the risk of re-identification includes verification that no directly identifying information persists in the de-identified and/or aggregate data (e.g., name, address, health card number) and that the de-identified and/or aggregate data does not contain information that could be used, with reasonable effort, and with other information to discover a person's identity (e.g., date-of-birth, postal code, gender) taking into account the resources of the party(ies) to whom the de-identified and/or aggregate data are disclosed. Inscyte's policies and procedures suggest using mathematical tools to quantify the risk (probability) of reidentification of an individual under these circumstances.

Inscyte's policies and procedures prohibit agents of Inscyte from using de-identified and/or aggregate information, including information in cell-sizes of less than five, to identify an individual. This includes attempting to decrypt information that is encrypted, attempting to



identify an individual based on unencrypted information and attempting to identify an individual based on prior knowledge.

Inscyte's policies and procedures require that the release of de-identified and/or aggregated information be accompanied by a statement requiring the recipient to acknowledge that the released data will not be used alone or with other information to identify an individual. This is an implied acknowledgment since Inscyte has no mechanism to monitor or enforce this requirement, except insofar as ensuring, to its best ability, that the disclosed de-identified and/or aggregate data does not contain information that could be used, with reasonable effort, and with other information to discover a person's identity.

Inscyte requires its agents to comply with its policies and procedures regarding the deidentification and aggregation of personal health information and designates the Privacy Officer as being responsible for monitoring and ensuring compliance. Inscyte's policy and procedures set out the consequences of breach and stipulate that compliance will be audited at minimum on an annual basis, and that spot security audits will be conducted on a monthly basis. The policy states that is is the responsibility of the Privacy Officer to initiate privacy audits and the responsibility of the Security Officer to initiate security audits at the prescribed intervals. The procedures outline the steps involved and the data and documentation holdings that are to be audited and how the results of the audits are to be documented.

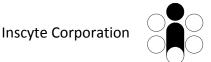
Inscyte's policies and procedures require all agents of Inscyte to be vigilant of and notify Inscyte's Privacy Officer, at the first reasonable opportunity, in accordance with the Policy and Procedures for Privacy Breach Management, if an agent breaches or believes there may have been a breach of this policy or its procedures.

# 25. Privacy Impact Assessment Policy and Procedures

Inscyte Corporation's policy and procedures state that a Privacy Impact Assessments shall be conducted on existing and proposed data holdings involving personal health information whenever a new or a change to an existing information system, technology or program involving personal health information is contemplated. Specifically, the policies and procedures require a Privacy Impact Assessment to be conducted in the event that:

- (a) There is a proposed change in the scope or type of personal health information to be collected or a proposed change in the use of the personal health information.
- (b) There is a proposed change in the source(s) from which personal health information is collected or to which personal health information is to be disclosed.

The policies also state that Privacy Impact Assessments may not be required in the course of making routine upgrades, repairs, or enhancements to the information and security systems infrastructure, which includes:



- (a) Upgrades to supporting software (e.g. O/S version upgrades)
- (b) Upgrades/repairs/replacement of hardware (e.g. disk drives, power supplies, routers)
- (c) Upgrades to technical security measures (e.g. increasing encryption key strength)
- (d) Re-organization of computing infrastructure (e.g. moving to virtual servers, network storage arrays etc.)

The policies state that under the above circumstances, Privacy Impact Assessments are not required provided that the proposed changes will not materially alter or degrade the existing privacy and/or security measures. The policies state that it is the responsibility of the Security Officer to conduct a risk assessment and advise the Privacy Officer if upgrades and changes to the information system infrastructure could in any way degrade the security measures in place, and that it is the responsibility of the Privacy Officer to review the risk assessments and determine whether or not a Privacy Impact Assessment is required under the circumstances. The policies require the risk assessment and reasons for the determination to be documented in Inscyte's information infrastructure *Asset Inventory* documentation.

The policies state that in the event that new data holdings of personal health information are contemplated or changes to existing information systems, technologies or programs involving personal health information are contemplated, a Privacy Impact Assessment shall be conducted at the conceptual design phase and that the PIA be reviewed and amended, if necessary, during the detailed design and implementation phases. With respect to existing data holdings involving personal health information, the policy and procedures require a timetable to be developed to ensure privacy impact assessments are conducted and designates the Privacy Officer as being responsible for developing the timetable.

Inscyte's policies and procedures require the review of completed Privacy Impact Assessments as part of the annual privacy audit to ensure that the PIAs continue to be accurate and continue to be consistent with the information practices of Inscyte.

The policy and procedures designate the Privacy Officer as being responsible for identifying when privacy impact assessments are required; in identifying when privacy impact assessments are required to be reviewed in accordance with the policy and procedures; in ensuring that privacy impact assessments are conducted and completed; and in ensuring that privacy impact assessments are reviewed and amended, if necessary. The policies designate the Privacy Officer as having been delegated day-to-day authority to manage the privacy program and the Security Officer as having been delegated day-to-day authority to manage the security program in respect of privacy impact assessments.

Inscyte's policy requires the following information, at minimum, to be included in Privacy Impact Assessments:

- The data holding, information system, technology or program at issue;
- The nature and type of personal health information collected, used or disclosed or that is proposed to be collected, used or disclosed;
- The sources of the personal health information;
- The purposes for which the personal health information is collected, used or disclosed or is proposed to be collected, used or disclosed;
- The reason that the personal health information is required for the purposes identified;
- The flows of the personal health information;
- The statutory authority for each collection, use and disclosure of personal health information identified;
- The limitations imposed on the collection, use and disclosure of the personal health information;
- Whether or not the personal health information is or will be linked to other information;
- The retention period for the records of personal health information;
- The secure manner in which the records of personal health information are or will be retained, transferred and disposed of;
- The functionality for logging access, use, modification and disclosure of the personal health information and the functionality to audit logs for unauthorized use or disclosure;
- The risks to the privacy of individuals whose personal health information is or will be part of the data holding, information system, technology or program and an assessment of the risks;
- Recommendations to address and eliminate or reduce the privacy risks identified; and
- The administrative, technical and physical safeguards implemented or proposed to be implemented to protect the personal health information.

Inscyte's policies state that, when required, Privacy Impact Assessments are to be conducted and any recommended remedial or corrective actions are to be taken, and that the Privacy Impact Assessment be suitably amended, before the proposed changes that gave rise to the Privacy Impact Assessment are implemented.

Inscyte's policies and procedures designate the Privacy Officer as being responsible for reviewing the recommendations arising from Privacy Impact Assessments, for establishing timelines to address the recommendations and for delegating work to other agents to implement the recommendations, and for monitoring and ensuring that the recommendations are implemented in a timely and effective manner.

Inscyte's policies and procedures state that Privacy Impact Assessments are to be reviewed as part of regular privacy audits, which are to be conducted at minimum on an annual basis, and that it is the responsibility of the Privacy Officer to initiate privacy audits.



Inscyte's policies and procedures state that Privacy Impact Assessments are to be maintained in perpetuity in the Log of Privacy Impact Assessments in the privacy document archives. This includes privacy impact assessments that have been completed, those that are in progress but no yet completed, and those that have been requested but not yet undertaken. It is the responsibility of the Privacy Officer to ensure that the Log of Privacy Impact Assessments in maintained accurate and up-to-date.

Inscyte requires its agents to comply with its Policies and Procedures in respect of Privacy Impact Assessments. The Privacy Officer is responsible for monitoring and enforcing compliance. The policies and procedures further describe the consequences of breach and that compliance will be audited in accordance with the Inscyte's Policy and Procedures In Respect of Privacy Audits, to be held at minimum on an annual basis, and that the Privacy Officer is responsible for initiating privacy audits.

Inscyte's policies and procedures require all agents of Inscyte to be vigilant of and notify Inscyte's Privacy Officer, at the first reasonable opportunity, in accordance with Inscyte's Policy and Procedures for Privacy Breach Management, if an agent breaches or believes there may have been a breach of this policy or its procedures.

## 26. Log of Privacy Impact Assessments

Inscyte Corporation maintains a Log of Privacy Impact Assessments that includes assessments that have been commissioned but not yet started, assessments that are underway, and assessments that have been completed. The log of Privacy Impact Assessments contains the following information at minimum:

- a) The date the Privacy Impact Assessment was commissioned
- b) The subject (data holding or system) of the Privacy Impact Assessment
- c) The status of the Privacy Impact Assessment (pending, underway, completed)
- d) The name(s) of the individual(s) conducting the assessment
- e) The expected/actual date of completion of the assessment
- f) The recommendations of the assessment
- g) The review status of the recommendations
- h) A description of the manner in which each recommendation will be addressed
- i) The target date for addressing each recommendation

Inscyte's policies and procedures designate the Privacy Officer as being responsible for reviewing the recommendations arising from Privacy Impact Assessments, for establishing timelines to address the recommendations and for delegating work to other agents to implement the recommendations, and for monitoring and ensuring that the recommendations are implemented in a timely and effective manner.

In addition, Inscyte's policies stipulate that recommendations emanating from Privacy Impact Assessments to mitigate identified risks shall be recorded in the Corporate Risk Register, together with anticipated actions and dates that the actions will be completed.

Inscyte Corporation also maintains a Log of Data Holdings of personal health information and an Asset Inventory of information and security systems components. These documents indicate if Privacy Impact Assessments were performed with respect to the data holdings or information and security systems components, and indicate if and when Privacy Impact Assessments were performed on these assets, and the reasons that Privacy Impact Assessments were not performed on these assets, together with the names and dates of the agents responsible for making this determination.

# 27. Policy and Procedures in Respect of Privacy Audits

Inscyte Corporation has developed and implemented policies and procedures in respect of conducting privacy audits to assess compliance with its privacy policies, procedures and practices by Inscyte and its agent(s) permitted to access and use personal health information pursuant to Policy and Procedures for Limiting Agent Access to and Use of Personal Health Information.

Inscyte's policies and procedures state that the purpose of the privacy audit is to monitor the privacy program and document archives to ensure that day-to-day activities are in compliance with Inscyte's Privacy and Security Policies and Procedures and that all related documentation is up-to-date, complete and accurate. The policies further state that the privacy audit is an internal self-assessment tool to collect information to inform the planning and decision-making process regarding the on-going application of privacy legislation to Inscyte's organization. Inscyte Corporation does not conduct audits of its member medical laboratories, health information custodians, or prescribed persons/entities under the Act to whom it discloses, or from whom it collects, personal health information.

Inscyte conducts both privacy audits and security audits. There is only one type of privacy audit. The policies state that the privacy audit shall be conducted on an annual basis, usually in conjunction with the annual review of policies and procedures, typically scheduled in October of each year. The policies state that the annual privacy audit involves:

- a) Reviewing changes to applicable legislation and applicable orders and/or best practice guidelines issued by the Office of the Privacy Commissioner, Ontario
- b) Reviewing the status of personal health information holdings
- c) Reviewing uses of personal health information
- d) Reviewing the status of all security measures, including;
  - a. Status of user accounts to information systems
  - b. Status of personal access cards/keys to secure premises
- e) Reviewing privacy documentation to ascertain completeness and accuracy, including;



- a. Data sharing agreements
- b. Third party service agreements
- c. Log of privacy training sessions and attendance
- d. Log of privacy breaches
- e. Log of privacy complaints
- f. Log of security audits
- g. Log of security breaches
- h. Log of privacy audits
- i. Log of privacy impact assessments
- j. Log of transfers of personal health information
- k. Log of data holdings
- I. Log of individuals having access to personal health information
- m. Corporate risk register
- n. Consolidated log of recommendations

The results of the reviews and any recommendations are documented in the Log of Privacy Audits. The policies stipulate that it is the responsibility of the Privacy Officer to initiate a privacy audit and delegate specific reviews to designated members of Inscyte's or its agent's staff. Inscyte's Privacy Officer has been delegated day-to-day authority to manage the privacy program while the Security Officer has been delegated day-to-day authority to manage the security program.

The process of conducting a privacy audit involves reviewing and assessing the status of the items listed above in relation to the requirements articulated in Inscyte's Privacy & Security Policies and Procedures. The results of each review are required to be documented indicating:

- a) The item under review (e.g. Log of Privacy Breaches)
- b) The name of the reviewer
- c) The date the review was started
- d) Findings with respect to compliance with requirements
- e) Identified issues (if any)
- f) Recommended remedial actions (if any)
- g) The date of completion

Following the review and documentation of each item, the Privacy Officer is responsible for consolidating the review documentation and convening a panel of representatives from Inscyte and its agent(s) to review and discuss the results and make consolidated recommendations to address any privacy or security issues arising. The policy requires that these recommendations are to be documented in the *Consolidated Log of Recommendations* together with actions, target dates and personnel responsible for addressing each recommendation. It is the responsibility of the Privacy Officer to ensure that items within the *Consolidated Log of Recommendations* are acted upon in the required time frames.

At the conclusion of the privacy audit, the policies require the review documentation and consolidated recommendations to be archived in Inscyte's privacy document archives and a copy forwarded to the President of Inscyte within thirty (30) days of completion. Further, the policies require that the privacy audit activity is recorded in the *Log of Privacy Audits*. It is the responsibility of the Privacy Officer to communicate the findings and recommendations of privacy audits to appropriate parties and to ensure that the *Log of Privacy Audits* is complete and up-to-date.

Inscyte's policies and procedures require all agents of Inscyte to be vigilant of and notify Inscyte's Privacy Officer, at the first reasonable opportunity, in accordance with Inscyte's Policy and Procedures for Privacy Breach Management, if an agent breaches or believes there may have been a breach of this policy or its procedures.

# 28. Log of Privacy Audits

Inscyte Corporation maintain a *Log of Privacy Audits* that have been completed. The log contains the following information:

- a) A unique privacy audit number
- b) The date the privacy audit was started
- c) The date the privacy audit was completed
- d) The location of the review documentation
- e) Summary of findings and recommendations

The personnel or agent(s) responsible for addressing each recommendation; the date that each recommendation was or is expected to be addressed; and the manner in which each recommendation was or is expected to be addressed is recorded in Inscyte's *Consolidated Log of Recommendations* referencing the unique privacy audit number as the source of the recommendations.

The policies and procedures state that it is the responsibility of the Privacy Officer to initiate a privacy audit, at minimum on an annual basis, for delegating work to appropriate agents in carrying out the audit, and for ensuring that the audit is completed.

# 29. Policy and Procedures for Privacy Breach Management

Inscyte Corporation has developed and implemented policies and procedures that address the identification, reporting, containment, notification, investigation and remediation of privacy breaches.

The policy defines a "breach of privacy" as:



- a) The collection, use, disclosure, retention or disposal of personal health information that is in contravention of applicable laws, including, but not limited to Ontario's Personal Health Information Protection Act, 2004 and its regulations.
- b) Failure to adhere to Inscyte's Privacy & Security Policies and Procedures
- c) A breach of a contractual agreement for the handling of personal health information such as Confidentiality and Non-Disclosure Agreements with agents of Inscyte or its agent(s) or Data Sharing Agreements with third parties.
- d) Circumstances where personal health information is stolen, lost or subject to unauthorized use or disclosure or where records of personal health information are subject to unauthorized copying, modification or disposal.

The policy and procedures impose a mandatory requirement on Inscyte's agents to notify the Privacy Officer of Inscyte if a privacy breach or suspected privacy breach is discovered. The policies state that this notification is to be made immediately, either verbally or by email.

The policies state that Upon discovery of a breach of privacy (or suspected breach of privacy) the following actions shall be taken:

- 1. Notify the Privacy Officer and Security Officer
- 2. Assess the incident
- 3. Contain the breach
- 4. Initiate a Privacy Breach Report
- 5. Notify appropriate parties
- 6. Investigate and remediate the breach
- 7. Complete the Privacy Breach Report and submit to Privacy Officer for sign-off
- 8. Approve and sign-off of the Privacy Breach Report
- 9. Approve and act on recommendations for mitigating strategies

Inscyte's policies state that depending on the nature and severity of the breach, these actions may have to be undertaken simultaneously, or in very short succession.

Inscyte's policies and procedures stipulate that the first course of action upon discovery of a breach or possible breach of privacy is to assess the incident to determine whether a privacy breach has in fact occurred and if so, what, if any, personal health information has been breached. This determination can be made by any agent of Inscyte.

The policies and procedures stipulate that in the event that personal health information has been breached the immediate action to be taken is to contain the breach. The policies and procedures provide guidelines with respect to containment procedures, depending on the format and media of the personal health information that has been breached, to ensure that steps are taken to protect the personal health information from further theft, loss or unauthorized use or disclosure, copying, modification or disposal. The procedures require,



where possible, that the records of personal health information be retrieved and returned to Inscyte to be retained in secure storage or disposed of in a secure manner.

The containment procedures further require that steps be taken to ensure that additional privacy breaches cannot occur through the same mechanism by assessing whether the breach would allow unauthorized access to any other information and taking necessary actions to prevent recurrence, such as shutting down computer servers, networks etc.

It is the responsibility of the Privacy Officer to review the containment measures and assess if the breach has been fully contained and that all personal health information that can be retrieved has been retrieved and returned to secure storage or securely disposed of. It is the responsibility of the Security Officer to ensure that security measures that may have been compromised are either disabled or reset to prevent recurrence of the breach.

Inscyte's policies and procedure require a *Privacy Breach Report* to be initiated and completed for all incidence of breach or suspected breach, regardless of the severity or consequences of the breach. The policies set out the minimum content of a *Privacy Breach Report* as follows:

- (a) Unique report number
- (b) The date the breach was reported to Inscyte
- (c) The name of the person(s) reporting the breach
- (d) The name of the author(s) of the report (investigators)
- (e) The date/time of the breach incident (or estimate thereof)
- (f) The evidence of breach (what lead to the discovery of breach)
- (g) The nature/source of the personal health information involved
- (h) The amount of personal health information involved (or estimate thereof)
- (i) The format of the personal health information (paper, media, etc.)
- (j) The location of the personal health information
- (k) The nature of the breach (or potential breach) categorized as one or more of:
  - a. Inappropriate collection/receipt of personal health information
  - b. Inappropriate use of personal health information
  - c. Inappropriate disclosure of personal health information
  - d. Inappropriate retention of personal health information
  - e. Inappropriate disposal of personal health information
  - f. Failure to follow prescribed policies and/or procedures
  - g. Failure to adhere to contractual terms and conditions
- (I) Who perpetrated the breach (internal/external)
- (m) The motivation/cause for the breach (e.g. accidental, purposeful)
- (n) The mechanism of the breach (i.e. method, process failure, etc.)
- (o) Containment procedures taken and dates (what was done to contain the breach)
- (p) Likelihood of disclosure of personal health information to unauthorized parties
- (q) List of parties and personnel contacted/notified



- (r) Indication if affected persons were contacted (names & dates)
- (s) Indication if IPC was contacted (date)
- (t) Remedial actions taken and recommendations for mitigating strategies
- (u) Privacy Officer sign-off and date

It is the responsibility of the Privacy Officer to ensure that a *Privacy Breach Report* is initiated in all cases within five (5) business days of receiving notification, and to delegate investigation activities to appropriate personnel. It is the responsibility of the Privacy Officer to ensure that all breaches are investigated and that reports are completed in a reasonable time frame. It is the responsibility of the Privacy Officer to sign-off and approve of Privacy Breach Reports and resulting recommendations for mitigating strategies to prevent similar breaches from occurring in the future. The policies further state that the Privacy Breach Report provides the contact information of the Privacy Officer.

In the event that there is reasonable cause to believe that personal health information has been disclosed to unauthorized parties, or is likely to be disclosed as a consequence of the breach, Inscyte's breach management policy requires the Privacy Officer to immediately notify the President of Inscyte about the breach, either verbally or by email and to provide a copy of the interim *Privacy Breach Report*. The policy states that is subsequently the responsibility of the President of Inscyte to notify, at the first reasonable opportunity, the health information custodians or parties to data sharing agreements affected/impacted by the breach, and to notify the Office of the Information and Privacy Commissioner of Ontario. This notification can be made verbally, by email or in writing, with a copy of the interim Privacy Breach Report.

The Privacy Officer of Inscyte has been delegated day-to-day authority to manage the privacy program. As such, it is the responsibility of the Privacy Officer to assign appropriate personnel to investigate and document each incident of breach. The investigation process requires addressing each section of the *Privacy Breach Report* using any appropriate means such as document reviews, interviews, site visits, inspections etc. This includes making recommendations for mitigating strategies to prevent similar breaches from occurring in the future. The investigators are responsible for preparing the *Privacy Breach Report* and submitting it to the Privacy Officer for review and final approval.

Upon approval recommendations made in a *Privacy Breach Report* are recorded in Inscyte's *Consolidated Log of Recommendations,* citing the report number as the source of the recommendations and specifying the actions to be taken to implement the recommendations, the personnel responsible for carrying out the actions, and the target date(s) of completion.

Inscyte's policies and procedures distinguish between a breach of privacy and a breach of security. Inscyte's policies define a "breach of security" as:



- a) An unauthorized person gaining access to, or attempting to gain access to, secured premises or secured information, by any means whatsoever.
- b) An act that compromises the confidentiality, integrity (accuracy and completeness) or availability of secured information.

Inscyte's policy states that although a breach of security can occur without a consequential breach of privacy (and vice-versa) the process to be followed in identifying, reporting, containing, notifying, investigating and remediating a security breach is the same as that for a privacy breach, and if in the course of the investigation of a security breach it is discovered that a privacy breach may also have occurred, then the policies and procedures in respect of managing a privacy breach also apply.

Inscyte's policy and procedure require that a perpetual *Log of Privacy Breaches* be maintained in its privacy document archives containing a summary listing of privacy breaches and the complete *Privacy Breach Report* on each incident. The policy designates the Privacy Officer as being responsible for ensuring that the log is accurate and up-to-date, and for tracking that the recommendations arising from the investigation of privacy breaches are addressed within the identified timelines.

Inscyte's policies and procedures require all agents of Inscyte to be vigilant of and notify Inscyte's Privacy Officer, at the first reasonable opportunity, in accordance with Inscyte's Policy and Procedures for Privacy Breach Management, if an agent breaches or believes there may have been a breach of this policy or its procedures. The policies and procedures also set out the consequences of breach. Inscyte's policy stipulates that compliance will be audited in accordance with its Policy and Procedures In Respect of Privacy Audits, which set out the frequency with which the policy and procedures are audited and designate the Privacy Officer as being responsible for conducting the audit and for ensuring compliance with Inscyte's policy and its procedures.

In developing its policies and procedures, Inscyte has given regard to the guidelines produced by the Information and Privacy Commissioner of Ontario entitled "What to do When Faced With a Privacy Breach: Guidelines for the Health Sector."

# **30. Log of Privacy Breaches**

Inscyte Corporation maintains a perpetual *Log of Privacy Breaches* in its privacy document archives containing a summary listing of privacy breaches and the complete *Privacy Breach Report* on each incident. The information in the log includes:

- a) The date the privacy breach was reported;
- b) The date that the privacy breach was identified or suspected;
- c) Whether the privacy breach was internal or external;



- d) The nature of the personal health information that was the subject matter of the privacy breach and the nature and extent of the privacy breach;
- e) The date that the privacy breach was contained and the nature of the containment measures;
- f) The date that the health information custodian or other organization that disclosed the personal health information to the prescribed person or prescribed entity was notified;
- g) The date that the investigation of the privacy breach was completed;
- h) The agent(s) responsible for conducting the investigation;
- i) The recommendations arising from the investigation;

The following information is retained in Inscyte's *Consolidated Log of Recommendations* for each incident of breach:

- a) The recommendation description together with the reference to the Privacy Breach Report number from which the recommendations emanated.
- b) The personnel responsible for addressing each recommendation;
- c) The date each recommendation was or is expected to be addressed; and
- d) The manner in which each recommendation was or is expected to be addressed.

# **31.** Policy and Procedures for Privacy Complaints

Inscyte Corporation has developed and implemented policies and procedures to address the process to be followed in receiving, documenting, tracking, investigating, remediating and responding to privacy complaints. The policies define a "privacy complaint" as being a concern or complaint relating to the privacy policies, procedures and practices implemented by Inscyte Corporation and related to Inscyte Corporation's compliance with the Act and its regulation.

The policy states that Inscyte shall make its complaint process and standard *Privacy Compliance Challenge Form* freely available to the public on its website together with the contact information of the President of Inscyte and the Privacy Officer of Inscyte, designated as the individuals to whom all complaints should be addressed. The policies further state that all filed complaints shall be brought to the attention of the President. In addition, Inscyte's policy states that individuals shall also be advised that they may make a complaint regarding Inscyte's compliance with the Act and its regulation to the Information and Privacy Commissioner of Ontario and that the mailing address and contact information for the Information and Privacy Commissioner of Ontario shall be provided on Inscyte's public website.

The policy and procedures establish the process to be followed in receiving privacy complaints. All complaints must be documented using Inscyte's standard *Privacy Compliance Challenge Form* and include supporting information and/or other documentation relevant to the complaint. The procedures require that a complainant provide this information to the President or Privacy Officer of Inscyte in paper or electronic format.



The policy states that Inscyte Corporation will investigate all complaints. It is the responsibility of the President of Inscyte to delegate duties to appropriate agents of Inscyte to investigate a complaint (e.g. carry out document reviews, interviews, site visits, inspections) and to make recommendations regarding actions to be taken to resolve the complaint. The policies require that all investigations are to be documented using Inscyte's standard *Complaint Investigation and Resolution Form*. It is also the responsibility of the President of Inscyte, at the first reasonable opportunity, to notify any related parties to the complaint, which may include related health information custodians, ministries of government and the Office of the Information and Privacy Commissioner of Ontario.

The policies state that all complaints shall be investigated in a timely manner, which may involve seeking additional information from the complainant and consultation with affected parties. The policies require that the complainant be notified, in writing, of the investigation undertaken, what the investigation will consist of, whether the complainant will be contacted for further information about the complaint, the time frame expected for resolution, and the contact information of the person(s) to whom the complainant may make inquiries regarding the progress and status of the investigation. The policy identifies the agent responsible for sending out the above-noted letter and the time-frame within which the letter will be sent to the individual. Further, the policies state that the individual making the privacy complaint shall also be advised that he or she may make a complaint to the Information and Privacy Commissioner of Ontario if there are reasonable grounds to believe that the Act or its regulation has been or is about to be contravened and the contact information for the Information and Privacy Commissioner of Ontario shall also be provided.

In the event that an investigation into a privacy complaint reveals that a breach of privacy or potential breach of privacy has occurred then the provisions of Inscyte's policies and procedures regarding breach management shall take effect and the breach shall be contained, managed and remediated in accordance with those policies and procedures in addition to the process of resolving the privacy complaint.

Inscyte's policies state that at the conclusion of a complaint investigation a written report shall be prepared describing the results of the investigation together with recommendations regarding actions to be taken to resolve the complaint. This report shall be provided to the complainant and all related parties, including, if applicable, the Office of the Information and Privacy Commissioner of Ontario. It is the responsibility of the President of Inscyte to ensure that the report is delivered to the appropriate parties in a timely manner.

The policies state that upon conclusion of the investigation, if a complaint is deemed justified, Inscyte Corporation will take appropriate and reasonable measures to remedy and resolve the complaint including, if necessary, amending its *Privacy & Security Policies and Procedures*. It is



the responsibility of the President of Inscyte to make this determination. The policies require that the measures taken with respect to the resolution of a complaint shall be communicated to the complainant, affected parties and, if applicable, to the Office of the Information and Privacy Commissioner of Ontario, in a *Letter of Complaint Resolution*, containing the measures taken and the dates of implementation. It is the responsibility of the President of Inscyte to ensure that the *Letter of Complaint Resolution* is delivered to the complainant and appropriate parties in a timely manner.

Inscyte's Privacy & Security Policies and Procedures stipulate that Inscyte's Privacy Officer has been delegated day-to-day authority to manage the privacy program while the Security Officer has been delegated day-to-day authority to manage the security program. It is the responsibility of the Privacy Officer to ensure that recommendations for changes to the privacy and security practices emanating from complaint investigations are acted upon and recorded in Inscyte's *Consolidated Log of Recommendations* including:

- a) The recommendation description together with the reference to the Complaint number from which the recommendation emanated.
- b) The personnel responsible for addressing each recommendation;
- c) The date each recommendation was or is expected to be addressed; and
- d) The manner in which each recommendation was or is expected to be addressed.

Inscyte's policy and procedures require that a perpetual *Log of Privacy Complaints* be maintained in Inscyte's privacy document archives and identifies the Privacy Officer as being responsible for maintaining the log and for tracking whether the recommendations arising from the investigation of privacy complaints are addressed within the identified timelines. The Log of Privacy Complaints identifies each complaint using a unique number and includes complete copies of documentation related to each complaint, including the *Privacy Compliance Challenge Form*, the *Complaint Investigation and Resolution Form*, and the *Letter of Complaint Resolution*.

Inscyte requires its agents to comply with its policies and procedures regarding privacy complaints and designates the Privacy Officer as being responsible for monitoring and ensuring compliance. The policy and procedures also set out the consequences of breach. Inscyte's policy and procedures in respect of privacy and security audits stipulate that compliance will be audited at minimum on an annual basis and that spot security audits will be conducted on a monthly basis. It is the responsibility of the Privacy Officer to initiate privacy audits and the responsibility of the Security Officer to initiate security audits at the prescribed intervals. The procedures outline the steps involved and the data and documentation holdings that are to be audited and how the results of the audits are to be documented.

Inscyte's policy and procedures with respect to privacy complaints further stipulate that in the event that a complaint reveals a breach or potential breach of privacy, then Inscyte's policies and procedures regarding privacy breach management shall also take effect.



# 32. Log of Privacy Complaints

Inscyte Corporation maintains a *Log of Privacy Complaints* that includes a summary of all received complaints. including:

- The date that the privacy complaint was received;
- A unique complaint number
- The nature of the complaint
- The date that the individual making the complaint was advised that the complaint will be investigated;
- The personnel assigned to conducting the investigation;
- The dates that the investigation was commenced and completed;
- The recommendations arising from the investigation
- The date that the individual making the privacy complaint was advised of the findings of the investigation and the measures taken, if any, in response to the privacy complaint.

In addition the privacy document archives contain the complete documentation related to each complaint, consisting of the *Privacy Compliance Challenge Form*, the *Complaint Investigation and Resolution Form*, and the *Letter of Complaint Resolution*.

The following information is also retained in Inscyte's *Consolidated Log of Recommendations* for each complaint:

- a) The recommendation description together with the reference to the Complaint number from which the recommendation emanated.
- b) The personnel responsible for addressing each recommendation;
- c) The date each recommendation was or is expected to be addressed; and
- d) The manner in which each recommendation was or is expected to be addressed.

## **33.** Policy and Procedures for Privacy Inquiries

Inscyte Corporation has developed and implemented policies and procedures to address the process to be followed in receiving, documenting, tracking and responding to privacy inquiries. The policies define a "privacy inquiry" as a question regarding Inscyte's privacy and security policies, procedures and practices and related to Inscyte Corporation's compliance with the Act and its regulation.

The policy states that Inscyte shall make its inquiry process and standard *Privacy Inquiry Form* freely available to the public on its website together with the contact information of the President of Inscyte and the Privacy Officer of Inscyte, designated as the individuals to whom all inquiries should be addressed. The policies also stipulate that Inscyte's Privacy Code and its



Privacy & Security Policies and Procedures shall be available to the public on its website together with frequently asked questions and answers.

The procedure for handling privacy inquiries state that Inscyte's standard *Privacy Inquiry Form* will be provided to the inquirer for submitting an inquiry and that the inquiry will be logged in Inscyte's *Log of Privacy Inquiries*, which includes at minimum, the following information:

- a) A unique inquiry identification number
- b) The date of the inquiry
- c) The name(s) of the person(s) making the inquiry
- d) A summary of the nature of the inquiry
- e) The status of the inquiry (posted, in progress, completed)
- f) The date of response
- g) The name of the person making the response
- h) A summary of the response
- i) A copy of the Privacy Inquiry Form
- j) A copy of the Response Letter

The policies state that it is the responsibility of the Privacy Officer to ensure that all inquiries are logged, documented and responded to in a timely manner and to delegate tasks to appropriate personnel in order to prepare a *Letter of Response*, including informing the inquirer about the anticipated date of response. The policies set out the format and minimum content of the *Letter of Response*. Further, the policies require the Privacy Officer to review and approve all *Letters of Response* prior to delivering the response to the inquirer.

In the event that activities related to a privacy inquiry lead to a complaint being filed then the provisions of Inscyte's policies and procedures regarding privacy complaints shall take effect.

In the event that activities related to a privacy inquiry reveal that a breach of privacy or potential breach of privacy has occurred then the provisions of Inscyte's policies and procedures regarding breach management shall take effect and the breach shall be contained, managed and remediated in accordance with those policies and procedures.

Inscyte requires its agents to comply with its policies and procedures regarding privacy inquiries and designates the Privacy Officer as being responsible for monitoring and ensuring compliance. The policies and procedures set out the consequences of breach. Inscyte's policy and procedures in respect of privacy and security audits stipulate that compliance will be audited at minimum on an annual basis and that spot security audits will be conducted on a monthly basis. It is the responsibility of the Privacy Officer to initiate privacy audits and the responsibility of the Security Officer to initiate security audits at the prescribed intervals. The procedures outline the steps involved and the data and documentation holdings that are to be audited and how the results of the audits are to be documented.

# Part 2 – Security Documentation

## **1.** Information Security Policy

Inscyte Corporation has a comprehensive and overarching information security policy place to protect personal health information received by Inscyte under the Act. The information security policy requires that reasonable and effective steps to ensure that the personal health information in the custody of Inscyte is protected against theft, loss and unauthorized use or disclosure and to ensure that the records of personal health information are protected against unauthorized copying, modification or disposal.

The information security policy states that Inscyte Corporation is required to undertake comprehensive and organization-wide threat and risk assessments of all information security assets, including personal health information, as well as appropriate project specific threat and risk assessments. The policies prescribe a methodology for identifying, assessing, documenting and remediating threats and risks and for prioritizing all threats and risks identified for remedial action.

The information security policy establishes a comprehensive information security program that implements administrative, technical and physical security controls that meet with established industry standards and practices. The information security program addresses the threats and risks identified, is open to independent verification, and is consistent with Inscyte's and its agent's security framework and control objectives. The security policies and procedures specify that responsibility for the development and implementation of the security program rests with the Security Officer of Inscyte, who is also the Security Officer of Inscyte's agent AIM Inc.

Inscyte's security policy requires the information security program to consist of the following control objectives and security policies, procedures and practices:

- A security governance framework for the implementation of the information security program, including security training and awareness;
- Policies and procedures for the ongoing review of the security policies, procedures and practices implemented;
- Policies and procedures for ensuring the physical security of the premises;
- Policies and procedures for the secure retention, transfer and disposal of records of personal health information, including policies and procedures related to mobile devices, remote access and security of data at rest;



- Policies and procedures to establish access control and authorization including business requirements, user access management, user responsibilities, network access control, operating system access control and application and information access control;
- Policies and procedures for information systems acquisition, development and maintenance including the security requirements of information systems, correct processing in applications, cryptographic controls, security of system files, security in development and support procedures and technical vulnerability management;
- Policies and procedures for monitoring, including policies and procedures for maintaining and reviewing system control and audit logs and security audits;
- Policies and procedures for network security management, including patch management and change management;
- Policies and procedures related to the acceptable use of information technology;
- Policies and procedures for back-up and recovery;
- Policies and procedures for information security breach management; and
- Policies and procedures to establish protection against malicious and mobile code.

Inscyte's information security policy are organized around the above objectives and are broken down into detailed policies and procedures to address the above-noted matters.

The information security policy requires that Inscyte maintain comprehensive documentation describing its computing infrastructure and security controls including the transmission of personal health information over authenticated, encrypted and secure connections; the establishment of secured servers, firewalls, demilitarized zones and other perimeter defenses; anti-virus, anti-spam and anti-spyware measures; intrusion detection and prevention systems; privacy and security enhancing technologies; and mandatory system-wide password-protected screen savers after a defined period of inactivity.

Inscyte's security policy also sets out the procedures for day-to-day monitoring of security controls to verify the effectiveness of the security program and to detect and deal with threats and risks to holdings of personal health information.

Inscyte requires its agents to comply with its security policies and procedures and designates the Security Officer as being responsible for monitoring and ensuring compliance. The policies and procedures set out the consequences of breach. Inscyte's policy and procedures in respect of security audits stipulate that compliance will be audited at minimum on an annual basis and that spot security audits will be conducted on a monthly basis. It is the responsibility of the Security Officer to initiate security audits at the prescribed intervals. The procedures outline the steps involved and the data and documentation holdings that are to be audited and how the results of the audits are to be documented.

Inscyte's policy further requires its agents to notify Inscyte at the first reasonable opportunity, in accordance with the Policies and Procedures for Security Breach Management, if an agent breaches or believes there may have been a breach of this policy or any of the security policies, procedures and practices.

# 2. Policy and Procedures for Ongoing Review of Security Policies, Procedures and Practices

Inscyte's Privacy & Security Policies and Procedures Manual includes policies and procedures governing the regular review of its security policies, procedures and practices. The policies state that Inscyte shall review its security program at minimum on an annual basis, or more frequently should there be changes in technology, best practices, or the Act and its regulation. The policies further state that a review of relevant policies and procedures shall be taken following a breach of privacy or security to determine if modifications to the policies and procedures are necessary to avert a similar breach in the future.

The policies state that it is the responsibility of the Privacy Officer to initiate a review process, that a committee shall be organized to carry out the review consisting of the Privacy Officer, the Security Officer and selected representatives from Inscyte's staff and associated health information custodians (e.g. member laboratories or prescribed persons/entities with whom Inscyte exchanges information). The policy and procedures identify the Security Officer as being responsible for amending and/or drafting new security policies, procedures and practices if deemed necessary as a result of the review. The policies state that in the event that proposed changes represent a material change to daily operations, the results and recommendations of the review will be reported to the President of Inscyte and CEO of AIM Inc. for review and approval before the changes are implemented.

The policies state that the review process shall take into account any orders, guidelines, fact sheets and best practices issued by the Information and Privacy Commissioner of Ontario under the Act and its regulation; evolving industry security standards and best practices; technological advancements; amendments to the Act and its regulation relevant to the prescribed person or prescribed entity; and recommendations arising from privacy and security audits, privacy impact assessments and investigations into privacy complaints, privacy breaches and information security breaches. The review process also takes into account whether the security policies, procedures and practices of Inscyte Corporation continue to be consistent with its



actual practices and whether there is consistency between and among the security and privacy policies, procedures and practices implemented.

The policies describe the procedure for amending and documenting policies and procedures and for communicating the amendments to agents and the public. Amended policies and procedures result in a revision of Inscyte's Privacy & Security Policies and Procedures Manual, which is made available through AIM's internal business network and to the public on Inscyte's website. The Privacy Officer is responsible for ensuring that emended policies and procedures are published and communicated to all affected parties and stakeholders.

Inscyte requires its agents to comply with its security policies and procedures and designates the Privacy Officer and the Security Officer as being responsible for monitoring and ensuring compliance. The policy also sets out the consequences of breach. Inscyte's policy and procedures in respect of security audits stipulate that compliance will be audited at minimum on an annual basis and that spot security audits will be conducted on a monthly basis. It is the responsibility of the Security Officer to initiate security audits at the prescribed intervals. The procedures outline the steps involved and the data and documentation holdings that are to be audited and how the results of the audits are to be documented.

# 3. Policy and Procedures for Ensuring Physical Security of Personal Health Information

Inscyte Corporation has policies and procedures in place addressing the physical safeguards that are required to protect personal health information against theft, loss and unauthorized use or disclosure and to protect records of personal health information against unauthorized copying, modification or disposal. Inscyte's agent AIM Inc. is responsible for implementing all necessary physical security safeguards at its premises to control access to locations where records of personal health information are retained, including zone-dependent individual-specific key card entry points, locked physical storage cabinets, intrusion detection and alarm systems.

AIM's premises are divided into zones and varying levels of security with each successive level being more secure and restricted to fewer individuals. Furthermore, to access locations where records of personal health information are retained or can be accessed via computer terminals requires individuals to pass through at least two audited security checkpoints.

Inscyte requires its agents to comply with its security policies and procedures and designates the Security Officer as being responsible for monitoring and ensuring compliance. The policy also sets out the consequences of breach. Inscyte's policy and procedures in respect of security audits stipulate that compliance will be audited at minimum on an annual basis and that spot security audits will be conducted on a monthly basis. It is the responsibility of the Security Officer to initiate security audits at the prescribed intervals. The procedures outline the steps involved and the data and documentation holdings that are to be audited and how the results of the audits are to be documented.

Inscyte's policy requires its agents to notify Inscyte at the first reasonable opportunity, in accordance with Inscyte's Policies and Procedures for Security Breach Management, if an agent breaches or believes there may have been a breach of this policy or any of Inscyte's security policies, procedures and practices.

## Policy, Procedures and Practices with Respect to Access by Agents

Inscyte Corporation's policies require that documentation be kept describing AIM's premises and the security control zones and access levels for various staff granted access to the premises. The security zones within AIM's premises are categorized as:

- 1) "General Offices" require keycard access but does not contain PHI
- 2) "Secured Offices" require at least two security checkpoints and may contain PHI
- 3) "Datacenter" requires at least two security checkpoints and contains PHI

The policy and procedures identify the Security Officer as being responsible for receiving, reviewing, granting and terminating access by an agent of Inscyte to the premises and to locations within the premises where records of personal health information are retained, including the levels of access that may be granted. The policy and procedures further indicate to whom this determination will be communicated. The process of granting physical access to premises requires an individual to submit a standard access request form to the Security Officer setting out the individuals name, the date of the request, the individual's job functions, the zones to which the individual requests access, the time of day during which access is requested, and the duration for which access is requested. The Security Officer is responsible for reviewing and approving or denying the requests for access. In making this determination, the Security Officer must take into account reasonable access requirements in order for the individual to fulfill his/her job functions, employment, contractual or other responsibilities.

In the event that an individual requests access to a security zone where personal health information is retained or can be accessed, the policy requires the request to be further reviewed and approved/denied by the Privacy Officer. In making the determination to grant access to security zones containing personal health information, the Privacy Officer takes into consideration the "need to know" principle to ensure that access is only provided to a limited number of persons who routinely require access to personal health information for their job functions, employment, contractual or other responsibilities.

Specifically, Inscyte's security policies state that as best practice, keys, pass cards, or access codes to physical security checkpoints should only be issued to employees of Inscyte or AIM Inc. and not to contracted individuals or third parties. Furthermore, the polices set out minimum criteria for granting access to different categories of security zones as follows.



An employee shall be issued keys, pass cards, or access codes to general offices provided that:

- a) The employee has completed his/her probationary period of employment.
- b) The employee has executed a signed and witnessed Personal Health Information Confidentiality and Non-Disclosure Agreement.
- c) The employee requires access to general offices.
- d) Approval has been given by the Security Officer.

An employee shall be issued keys, pass cards, or access codes to secured offices where personal health information is stored and used provided that:

- a) The employee has completed his/her probationary period of employment.
- b) The employee is required to work with personal health information.
- c) The employee has executed a signed and witnessed Personal Health Information Confidentiality and Non-Disclosure Agreement.
- d) The employee has received privacy & security awareness training.
- e) Approval has been given by the Privacy Officer.

An employee shall be issued keys, pass cards, or access codes to the datacenter where personal health information is stored provided that:

- a) The employee has completed his/her probationary period of employment.
- b) The employee is required to work in the datacenter.
- c) The employee has executed a signed and witnessed Personal Health Information Confidentiality and Non-Disclosure Agreement.
- d) The employee has received privacy & security awareness training.
- e) Approval has been given by the Privacy Officer.

Where physical access rights are granted to an individual for a limited period of time, it is the responsibility of the Security Officer to monitor and ensure that the access rights are terminated at the expiry of the stated time period.

In practice, employees of Inscyte or its agent AIM Inc. are only issued electronic access cards and not physical keys. The issuing, activation, and de-activation of electronic access cards is a strictly controlled process that can only be performed by individuals authorized to do so by the Security Officer. Access cards are stored in a combination-lock safe and the software for activating, de-activating and monitoring access card usage is account/password protected and available in the secure datacenter only. Access rights to administer the electronic access card system are limited to three individuals. Each access card is linked to a specific employee and the system records the use of the cards at each security checkpoint noting the date/time of use, the checkpoint name, the success/failure of the card and the corresponding name of the employee to whom the card was issued.



The electronic access card system is a software controlled security network. Inscyte's security policies state that when a card is created, the operator must specify the following properties for each card:

- a) The name of the employee to whom the card is issued
- b) The security checkpoint(s) that the card will open
- c) The times-of-day during which the card will open the specified checkpoints
- d) The timeout (idle) period after which the card will automatically expire
- e) Whether the card will be perpetual or expire upon a specified date

The policies and procedures further state that upon receipt of an access card the employee must sign a *Keycard Sign-out and Declaration* form that sets out the terms and conditions under which the card is issued to the employee and the responsibilities of the employee in that regard. The policies require that signed copies of all *Keycard Sign-out and Declaration* forms be retained in perpetuity in the privacy document archives.

Inscyte's security policies require maintaining a *Log of Individuals Having Access to Premises* to document the activation and de-activation of access cards to individuals and designate the Security Officer as being responsible for maintaining the log up-to-date and accurate. The policies require that the *Log of Individuals Having Access to Premises* be updated every time a change in access rights for an individual occurs. The log contains the following information:

- a) The log entry date
- b) The name/title of the individual to whom the entry pertains
- c) The access card identification number
- d) The security zone(s) to which access has been granted or terminated
- e) The time-of-day restrictions on the access rights to each security zone
- f) The expiry date of access to each security zone (if applicable)
- g) The name/title of the person that granted or terminated access
- h) The name/title of the person approving the granting of access rights
- i) The date access rights were granted or terminated
- j) Description of the reasons for granting or terminating access rights

#### Theft, Loss and Misplacement of Identification Cards, Access Cards and Keys

Inscyte's policy and procedures require agents of Inscyte to notify the Security Officer at the first reasonable opportunity of the theft, loss or misplacement of identification cards, access cards and/or keys. This notification can be made verbally or by email and must indicate the time and circumstances under which the theft, loss or misplacement occurred. Upon receiving notification, it is the responsibility of the Security Officer to ensure that appropriate measures are taken to disable the access rights of the access cards or keys in question. It is also the responsibility of the Security Officer to log the event in the *Log of Individuals Having Access to* 



*Premises* and to re-issue new identification cards, access cards or keys as appropriate. In practice, only electronic access cards are issued to agents and not physical keys. One feature of the electronic access card system is that if a card is not used during a specified period of time (e.g. 3 days) the card will automatically expire and become useless.

Since the security system automatically expires (de-activates) cards depending on the properties specified at the time an access card is issued, there is no need for policies and procedures to issue and recover temporary or replacement cards. In the event of theft, loss or misplacement of a card, the policies and procedures state that the lost or stolen card be de-activated (if it has not automatically expired) and that a new card be produced in accordance with the policy and procedure regarding issuing of access cards.

#### Termination of the Employment, Contractual or Other Relationship

Inscyte's policies and procedures require all agents of Inscyte and an agent's supervisor to notify the Security Officer of the termination of their employment, contractual or other relationship with Inscyte or AIM, and to return their identification cards, access cards and/or keys to the Security Officer on or before the date of termination of their employment, contractual or other relationship in accordance with the Policy and Procedures for Recovery of Keys, Pass Cards and Access Codes at Termination of Employment and Inscyte's Policy and Procedure for Actions at Termination of Employment or Contract.

Inscyte Corporation's policies also require that access to the premises be terminated and that it is the responsibility of the Security Officer to ensure that access cards are de-activated upon the cessation of the employment, contractual or other relationship in accordance with its Policy and Procedures for Recovery of Keys, Pass Cards and Access Codes at Termination of Employment and its Policy and Procedure for Actions at Termination of Employment or Contract.

#### Notification When Access is No Longer Required

The policy and procedures require that agents of Inscyte granted approval to access location(s) where records of personal health information are retained, as well as the agent's supervisor, to notify Inscyte when the agent no longer requires such access.

The policies state that notification may be verbally or in writing to the Security Officer, as soon as is reasonably practical. It is the responsibility of the Security Officer to ensure that appropriate measures are taken to disable the access rights of the access cards or keys in question within three (3) business days of receiving the notification. It is also the responsibility of the Security Officer to log the event in the *Log of Individuals Having Access to Premises* indicating the date that access rights were terminated and the name of the individual who terminated the access rights.

#### Audits of Agents with Access to the Premises

Inscyte's policies and procedures with respect to conducting security audits require a review of all persons with access rights to premises where records of personal health information are stored to ensure that these individuals continue to require the same level of access in accordance with their job functions or contractual obligations. The policies state that Security Audits shall be conducted on an annual basis in conjunction with Inscyte's annual privacy and security policy review process.

The Security Officer is responsible for conducting security audits. In the event that a security audit reveals that an individual no longer requires access to premises where records of personal health information are stored, the policies require the Security Officer to ensure that appropriate measures are taken to disable the access rights of the access cards or keys in question within three (3) business days and to log the event in the *Log of Individuals Having Access to Premises* indicating the date that access rights were terminated and the name of the individual who terminated the access rights.

#### Tracking and Retention of Documentation Related to Access to the Premises

Inscyte's policies and procedures requires that employees sign a *Keycard Sign-out and Declaration* form upon receipt of access rights that sets out the terms and conditions under which the card is issued to the employee and the responsibilities of the employee in that regard. The policies require that signed copies of all *Keycard Sign-out and Declaration* forms be retained in perpetuity in the privacy document archives and that it is the responsibility of the Security Officer to maintain this documentation.

## Policy, Procedures and Practices with Respect to Access by Visitors

Inscyte's policies and procedures require that all visitors who may be required to enter secured premises where personal health information is stored, or could be accessed, must be registered in a *Visitor Log* prior to being admitted to the secured premises and must be escorted and supervised during the visit by an agent who has access rights to the secured premises. Under these circumstances each visitor is required to provide:

- a) His/her name
- b) Name of associated business or organization
- c) Reason for visit
- d) Name of the person with whom the visitor is meeting
- e) Name of the agent supervising the visit
- f) Arrival date & time + signature of visitor
- g) Departure time + signature of visitor

The policies and procedures require this information to be recorded in a perpetual *Visitor Log*, either in hardcopy or electronic format. All items are mandatory. It is the responsibility of the



Security Officer to ensure that *Visitor Logs* are transferred to electronic format and retained in the privacy document archives.

The policies and procedures also require that visitors be accompanied by an agent at all times and as such do not require visitors to wear identification tags. The policies and procedures require the supervising individual to ensure that visitors sign the *Visitors Log* upon arrival and departure. In the event that a visitor departs without signing the log, the supervising individual is required to sign-out on behalf of the visitor.

### 4. Log of Agents with Access to the Premises of the Prescribed Person or Prescribed Entity

Inscyte's security policies require maintaining a *Log of Individuals Having Access to Premises* to document the activation and de-activation of access cards to individuals and designate the Security Officer as being responsible for maintaining the log up-to-date and accurate. The policies require that the *Log of Individuals Having Access to Premises* be updated every time a change in access rights for an individual occurs. The policies require the log to contain the following information at minimum:

- a) The log entry date
- b) The name/title of the individual to whom the entry pertains
- c) The associated access card identification number
- d) The security zone(s) to which access applies
- e) The time-of-day restrictions on the access rights to each security zone
- f) The expiry date of access to each security zone (if applicable)
- g) The name/title of the person that granted, changed or terminated access
- h) The name/title of the person approving the action
- i) The date the access rights were granted, changed or terminated
- j) The date of the next audit of access
- k) Description of the reason for granting, changing or terminating access rights

The policies also require the *Log of Individuals Having Access to Premises* to be maintained in perpetuity in Inscyte's privacy document archives.

# 5. Policy and Procedures for Secure Retention of Records of Personal Health Information

Inscyte Corporation has developed and implemented policies and procedures with respect to the secure retention of records of personal health information in paper and electronic format.

The policies and procedures address the retention periods for each holding of personal health information in various formats and media and stipulate that records shall not be retained for



longer than the specified retention period. Inscyte's data sharing agreements with health information custodians also specify the retention period for the information in question.

With respect to the CytoBase database, the retention period is indefinite (i.e. perpetual) since CytoBase serves as a longitudinal electronic medical record of historical cervical cancer screening test result.

Inscyte does not use personal healthy information for research purposes, and does not enter research agreements with third parties. As such, there are no policies governing the retention of personal health information related to research projects.

The security policies and procedures require records of personal health information to be retained in a secure manner and designate the Security Officer as being responsible for ensuring the secure retention of these records. The policies and procedures specify the minimum technical security controls that must be applied to personal health information in paper and electronic formats to protect against theft, loss and unauthorized use or disclosure and to ensure that records of personal health information are protected against unauthorized copying, modification or disposal.

The policies set out the specific methods by which records of personal health information in paper and electronic format are to be secured. The policies require paper-based records to be stored behind at least two physical security checkpoints. The policies require that records stored on portable media (e.g. CDs or USB keys) to be password encrypted and physically stored behind at least two physical security checkpoints. The policies also specify the minimum encryption key strength and set out minimum password length and composition rules to ensure strong passwords are used.

Inscyte's security policies and procedures also require all agents of Inscyte to take steps that are reasonable in the circumstances to ensure that personal health information is protected against theft, loss and unauthorized use or disclosure and to ensure that records of personal health information are protected against unauthorized copying, modification or disposal. The policies require all personnel to be aware of what constitutes personal health information and to be vigilant of the potential for improper storage, use, disclosure, copying, modification, or disposal of such information, to confine records of personal health information to secure storage in the event that improper storage conditions are discovered, and to report potential breaches of security policies at the first available opportunity to the Security Officer and/or the Privacy Officer.

Inscyte Corporation has contracted AIM to manage the secure collection, retention, transfer and disposal of personal health information in the day-to-day operations of CytoBase. Since CytoBase is physically located at AIM's premises there are no transfers of records of personal health information between Inscyte and AIM. AIM is an agent of Inscyte with respect to the



daily operations and maintenance of CytoBase and is not considered to be a third party service provider for the storage of personal health information.

Inscyte requires its agents to comply with its security policies and procedures and designates the Security Officer as being responsible for monitoring and ensuring compliance. Inscyte's policy and procedures in respect of security audits stipulate that compliance will be audited at minimum on an annual basis and that spot security audits will be conducted on a monthly basis. It is the responsibility of the Security Officer to initiate security audits at the prescribed intervals.

Inscyte's security policies also require agents of Inscyte to notify Inscyte at the first reasonable opportunity, in accordance with the Policies and Procedures for Security Breach Management, if an agent breaches or believes there may have been a breach of this policy or any of Inscyte's security policies, procedures and practices.

### 6. Policy and Procedures for Secure Retention of Records of Personal Health Information on Mobile Devices

Inscyte Corporation has developed and implemented policies and procedures with respect to the storage, retention, or transfer of records of personal health information on mobile devices. In preparing these policies and procedures Inscyte Corporation has given regard to orders issued by the Information and Privacy Commissioner of Ontario under the Act and its regulation, including Order HO-004 and Order HO-007; and with guidelines, fact sheets and best practices issued by the Information and Privacy Commissioner of Ontario pursuant to the Act and its regulation, including Fact Sheet 12: Encrypting Personal Health Information on Mobile Devices, Fact Sheet 14: Wireless Communication Technologies: Safeguarding Privacy and Security and Safeguarding Privacy in a Mobile Workplace.

Inscyte's security policies define a "mobile device" as any portable device that can be used *alone* to store, retrieve, display and/or allow data to be manipulated or transferred to other devices. As such, "mobile devices" include laptops, notebooks, PDAs, smart phones, tablet computers etc. By contrast, the policies define "portable media" as portable storage media that can only be used in conjunction with another device to store and retrieve data. As such, "portable media" includes tapes, diskettes, CDs, DVDs, USB keys, flash memory devices etc.

Inscyte's policies and procedure prohibit the use of mobile devices for the storage, retention or transfer of personal health information.

Inscyte requires its agents to comply with its security policies and procedures and designates the Security Officer as being responsible for monitoring and ensuring compliance. The policy and procedures sets out the consequences of breach. Inscyte's policy and procedures in respect of security audits stipulate that compliance will be audited at minimum on an annual



basis and that spot security audits will be conducted on a monthly basis. It is the responsibility of the Security Officer to initiate security audits at the prescribed intervals.

Inscyte's security policies also require its agents to notify Inscyte at the first reasonable opportunity, in accordance with the Policies and Procedures for Security Breach Management, if an agent breaches or believes there may have been a breach of this policy or any of Inscyte's security policies, procedures and practices.

### Where Personal Health Information is Permitted to be Retained on a Mobile Device

Inscyte's security policies expressly prohibit the use of mobile devices for the storage, retention or transfer of personal health information under any circumstances. As such, Inscyte Corporation has not developed or implemented polices or procedures for the approval/denial of retaining personal health information on a mobile device, or restrictions or conditions on using mobile devices for the storage, retention or transfer of personal health information.

### Where Personal Health Information is not Permitted to be Retained on a Mobile Device

Inscyte's security policies expressly prohibit the use of mobile devices for the storage, retention or transfer of personal health information. However, the security policies permit remote access through a secure virtual private network to systems containing personal health information for the purpose of (a) system maintenance and troubleshooting by authorized staff, and (b) to allow authorized users to access the "CytoBase for Clinicians" online service.

Inscyte Corporation acknowledges that transfers of personal health information to authorized users having access to the "CytoBase for Clinicians" are disclosures under the Act and that the clinicians are not agents of Inscyte. These disclosures are discussed in Part I – Section 12 of this report, however, to provide a more complete picture of the remote access (in this case disclosures as opposed to the more typical uses) to personal health information, which is permitted by Inscyte, we have included a discussion of these transfers as well in the subsections that follow.

#### Approval Process

Inscyte's policies and procedures stipulate that remote access to systems containing personal information shall only be granted to individual identified persons who have a legitimate need to access the systems and that approval by the Privacy Officer is required, on a person by person basis prior to granting access. The approval process and the policies and procedures for approving/denying access distinguish between (a) technical support staff of AIM that require remote access for routine maintenance and troubleshooting activities, and (b) physicians and nurse practitioners in Ontario who wish to use the "CytoBase for Clinicians" online service in their practice.

In the case of technical support staff, the policies state that it is the responsibility of the Security Officer to approve remote access for a limited number of individuals to support the



CytoBase system and maintain its availability. The policies state that the minimum criteria for approving remote access for technical support staff are:

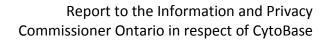
- a) The agent has completed his/her probationary period of employment.
- b) The agent is competent and required to support CytoBase
- c) The agent has executed a signed and witnessed Personal Health Information Confidentiality and Non-Disclosure Agreement.
- d) The agent has received privacy & security awareness training.

The policies and procedures also require that remote access accounts and passwords be issued in accordance with Inscyte's policies and procedures regarding account names and passwords. The policies further stipulate that all individuals having remote access shall be logged in Inscyte's *Log of Accounts Having Access to PHI* –a perpetual log of individuals' access accounts to computer networks, applications, databases and other secured resources that contain personal health information. The log is maintained in Inscyte's privacy document archives and contains:

- a) The full name of the individual to whom the account was granted
- b) The account name
- c) The resource to which the account applies (e.g. computer/network name, application name, database name or ID etc.)
- d) The access level restriction (if any)
- e) The reason the account was created
- f) The date the account was activated
- g) The name of the administrator who created the account
- h) The name of the person who authorized the account
- i) The status of the account (active, decommissioned, etc.)
- j) The date the account was decommissioned
- k) The name of the administrator who decommissioned the account
- I) The reason for decommissioning the account

In the case of physicians and/or nurse practitioners in Ontario who wish to use the "CytoBase for Clinicians" online service, Inscyte's policies and procedures require that a formal application, authentication, and approval process be followed, comprised of the following:

- 1. The applicant must fill out Inscyte's standard *CytoBase for Clinicians Account Application Form* (available on paper or downloadable from Inscyte's website) which captures:
  - a. Applicants name and job title
  - b. Professional designation
  - c. Associated healthcare institution or place of work
  - d. Address and telephone contact information
  - e. Email address



- f. Reason for requesting an account
- g. Agreement to Privacy and Confidentiality "terms of Use" restrictions
- 2. The form must be signed and dated and delivered to Inscyte's agent AIM Inc. together with the following supporting documentation:
  - a. The applicant's professional license number and licensing body (e.g. CPSO)
  - b. A copy of the applicant's current photo ID (e.g. driver's license or passport)
- 3. The application is reviewed by designated staff of Inscyte's agent AIM Inc. and the identity and professional standing of the applicant is verified by contacting the applicant's licensing body.
- 4. After review, it is the responsibility of the Privacy Officer of Inscyte to approve/deny the application and inform the applicant of the decision via email or mail.

The policies set out the requirements and criteria that must be satisfied in order to approve an application to use the "CytoBase for Clinicians" online service as follows:

- a) The applicant must be either a licensed physician, nurse-practitioner, or midwife in the province of Ontario.
- b) The applicant must be in good standing with his/her professional licensing body.
- c) The applicant must be currently in active practice in the province of Ontario.
- d) The applicant has demonstrated that in the course of practice he/she has a reasonable and legitimate need to access cervical cancer screening test results on his/her patients and that other information, namely de-identified and/or aggregate information, will not serve the identified purpose.
- e) The applicant has indicated that he/she shall comply with the Terms of Use of "CytoBase for Clinicians" and to protect the Privacy and Confidentiality of the information therein.

Inscyte's policies and procedures state that access accounts to "CytoBase for Clinicians" shall expire on an annual basis (from date of issue) and that applicants must re-apply each subsequent year using the process described above. Inscyte's policies and procedures require copies of all applications and approval/denial decisions to be retained in Inscyte's privacy document archives in perpetuity.

#### Conditions or Restrictions on the Remote Access to Personal Health Information

Inscyte's security policies restrict remote access to personal health information to a few selected technical support persons and approved users of CytoBase for Clinicians. The policies state that remote access to personal health information shall not be granted if other information, namely aggregate or de-identified information shall serve the purpose. Specifically, the policies require technical support staff not to access personal health information whilst performing troubleshooting or maintenance work unless such access is absolutely necessary.



The policy and procedures also set out the administrative, technical and physical safeguards that must be implemented in providing remote access to technical support staff and online access to "CytoBase for Clinicians". In the case of support staff, access is restricted by multiple sets of account ID and password under a "defense in depth" strategy that requires authentication on successive levels of system access, ranging from remote access to AIM's network, access to a specific workstation, access to a specific server, database and so on.

In the case of "CytoBase for Clinicians" online application, a 1024 bit SSL server certificate is used to encrypt the connection between the server and the user's browser. The application server communicates with the CytoBase database server through a secondary firewall using an internal non-standard port and an encrypted database server account and password acting as a connection pool. The "CytoBase for Clinicians" application authenticates users via a unique application account ID and password combination for each user. These user accounts and passwords are application controlled aliases and cannot be used to access the CytoBase database or server directly. All accounts and passwords are required to comply with Inscyte's policies regarding account password composition rules and expiry, de-activation and renewal protocols.

## 7. Policy and Procedures for Secure Transfer of Records of Personal Health Information

Inscyte Corporation has developed and implemented policies and procedures with respect to the secure transfer of records of personal health information in paper and electronic format.

The policies and procedures require records of personal health information to be transferred in a secure manner and set out the methods of transferring records of personal health information and the precautions to be taken depending on whether the information is on paper, portable media, mobile devices (prohibited), email, or computer network transfer. Inscyte's policy and procedures require its agents to use the prescribed methods of transferring records of personal health information and prohibit the use of other methods.

In approving methods and security controls in the secure transfer of personal health information Inscyte Corporation takes into consideration :

- Orders issued by the Information and Privacy Commissioner of Ontario under the Act and its regulation, including but not limited to Order HO-004 (stolen laptop) and Order HO-007 (lost USB memory stick);
- Guidelines, fact sheets and best practices issued by the Information and Privacy Commissioner of Ontario, including Privacy Protection Principles for Electronic Mail Systems and Guidelines on Facsimile Transmission Security; and
- Evolving privacy and security standards and best practices.



In the case of paper-based records, Inscyte's policy requires that the following precautions be applied:

- (a) The paper-based records shall be enclosed in a sealed envelope or box (package).
- (b) The package(s) shall identify the individual recipient and sender of the information.
- (c) The package(s) shall identify the date when the records were sealed.
- (d) The package(s) should be labeled to clearly describe that it contains personal health information and the nature of the content.
- (e) The package(s) shall be stored in secure premises behind at least two physical security checkpoints before being handed over to couriers for transport.

Furthermore, the policies state that paper-based records of personal health information may not be transported by federal post. Paper-based records shall be transported via commercial bonded courier, by couriers of participating health information custodians (laboratories) of CytoBase, or by the designated staff of either the sender or recipient.

In the case of portable media (e.g. CD's, tapes, USB drives, Flash memory devices) the policies require the following precautions to be applied:

- (a) The files on the portable media that contain personal health information shall be encrypted and password protected in accordance with Inscyte's policies for file encryption and password formulation, and
- (b) The portable memory device itself shall be password protected (if possible).
- (c) The portable media should be labeled to clearly describe that it contains personal health information and the nature of the content.
- (d) The password(s) shall not be transferred together with the records in any manner. Passwords shall only be disclosed to the recipient via telephone after confirmation and verification of receipt of the portable media (which requires prior knowledge of the identity of the recipient).

Inscyte's policies state that transfers of personal health information on portable media must be approved by the Privacy Officer and governed by existing Data sharing Agreements executed between Inscyte and the recipient of the data, before the data transfers can take place.

Furthermore the policies state that personal health information on portable media may not be transported by federal post. Portable media shall be transported via commercial bonded courier, by couriers of participating health information custodians (laboratories) of CytoBase, or by the designated staff of either the sender or recipient.

In the case of mobile devices (e.g. laptops, PDAs, tablets, smart phones etc.) or the use of telephone facsimile, Inscyte's policies expressly prohibit the use of mobile devices or telephone facsimile for the transfer of personal health information.





In the case of email, Inscyte's policies state that email should only be used to transfer personal health information in exceptional circumstances where no reasonable alternative approved method is available (e.g. where time is of the essence). In this case, Inscyte's policies require the personal health information to be transferred as a file attachment to an email message and not in the body of the message. Further, the policies require that the attached file be encrypted and password protected in accordance with Inscyte's policies for file encryption and password formulation. Also, the polices state that the password to unlock an encrypted file attachment shall not be communicated to the recipient using email. Rather, it shall be communicated to the recipient personally by telephone allowing the sender to verify the recipient's identity.

In the event that Inscyte or its agent AIM receives personal health information via email the policies require that the personal health information received shall be saved to a secure server that is part of the secure PHI network and that the email message and attachment(s) be deleted from the email client and the email server forthwith. It is the responsibility of the Security Officer to monitor and ensure that email systems do not retain personal health information.

In the case of computer network transfer of personal health information, Inscyte's policies require the following safeguards to be applied:

- (a) The network connection between sending and receiving systems shall be encrypted and authenticated by implementing a self-managed or third-party public-private key infrastructure (PKI) mechanism with 1024 bit keys as a minimum strength.
- (b) Access to the secure network shall require authentication of a unique account ID and password combination (user login) in compliance with Inscyte's policies for issuing account IDs and passwords.

In addition, the policies state that, where possible, files/messages sent over secure networks should be further encrypted at the file/message level using a different encryption mechanism to provide dual layer encryption of personal health information.

The policies and procedures regarding transfer of personal health information also require that transfers of personal health information must be recorded in a *Log of PHI Transfers* containing at minimum:

- (a) The date of the transfer
- (b) The mode of transfer (paper, portable media, network)
- (c) The name of the sender and recipient
- (d) The nature of the information transferred
- (e) The quantum of personal health information involved (i.e. a count or estimate of the number of person-records involved).

(f) A confirmation of receipt or delivery (date and name of person confirming receipt)

The *Log of PHI transfers* is maintained in perpetuity in Inscyte's privacy document archives. The procedures for transfer of PHI stipulate that the individuals performing the transfers must make the appropriate entries in the log. It is the responsibility of the Security Officer to ensure that the *Log of PHI Transfers* is being maintained accurate and up-to-date.

Inscyte requires its agents to comply with its security policies and procedures regarding transfers of personal health information and designates the Security Officer as being responsible for monitoring and ensuring compliance. The policies and procedures also set out the consequences of breach. Inscyte's policy and procedures in respect of security audits stipulate that compliance will be audited at minimum on an annual basis and that spot security audits will be conducted on a monthly basis. It is the responsibility of the Security Officer to initiate security audits at the prescribed intervals.

Inscyte's security policies require its agents to notify Inscyte at the first reasonable opportunity, in accordance with the Policies and Procedures for Security Breach Management, if an agent breaches or believes there may have been a breach of this policy or any of Inscyte's security policies, procedures and practices.

### 8. Policy and Procedures for Secure Disposal of Records of Personal Health Information

Inscyte Corporation has developed and implemented policies and procedures with respect to the secure destruction and/or disposal of records of personal health information in paper and electronic format to ensure that such records cannot be reasonably recovered or reconstructed after destruction and disposal.

The policy and procedures require records of personal health information to be destroyed and disposed of in a secure manner and define secure destruction and disposal as the transmutation of the media on which personal health information is stored to a form that prevents, using reasonable and foreseeable methods, further access, interpretation, reconstruction or restoration of the information. As such, Inscyte's policies and procedure prescribe specific methods for the destruction and disposal of personal health information on paper, magnetic tapes, optical disks, magnetic disk drives, USB keys & Flash memory devices.

In the case of paper records the policies and procedures state that the personal health information shall be destroyed by cross-cut shredding, pulverization or incineration and further require that printed documents containing personal health information shall not be disposed of in waste baskets, re-cycling bins, or any other normal waste disposal methods.



In the case of personal health information stored on portable media (e.g. CDs, DVDs, tapes and USB keys or Flash memory devices), the policies state that in the event that the portable media are to be reused, the files containing personal health information shall be deleted from the media using a method the renders the files un-recoverable, such as commercial file shredding software or re-formatting the storage media. In the event that the policies require the media to be destroyed in a manner rendering it unusable and then discarded. To this end, the policies and procedures set out acceptable methods for destroying various type of media as follows.

For tapes, diskettes, DVDs or CDs an acceptable procedure is to de-gauss magnetic media, remove or black out any information printed on the tape, diskette, CD or DVD that describes the contents, author, owner, sender or recipient of the data. Make deep scratches into the optical surface of CDs or DVDs. Cut or tear the media into at least five random pieces and deform the pieces. Dispose of the pieces in at least two physically separate disposal locations.

For electronic memory devices such as USB keys or flash memory an acceptable procedures is to de-gauss the media if possible, then crush or pulverize the device using a hammer or other implement so that it is in at least five(5) pieces and to dispose of the pieces in at least two physically separate disposal locations.

For computer internal disk drives, an acceptable procedure is to remove the disk(s) from the computer housing. De-gauss the disks. Open the disk chassis and remove the platters, by force, if necessary. Then deform the platters to destroy alignment.

In addressing the precise method by which records of personal health information in paper and electronic format must be securely destroyed and disposed of, has given regard to the Act and its regulation; and orders issued by the Information and Privacy Commissioner of Ontario, including Order HO-001 and Order HO-006; and with guidelines, fact sheets and best practices issued by the Information and Privacy Commissioner of Ontario pursuant to the Act and its regulation, including Fact Sheet 10: Secure Destruction of Personal Information.

Inscyte's policies and procedures require that personal health information intended for destruction in paper or electronic formats to be stored in a secure clearly marked and locked physical location, behind at least two physical security checkpoints, in an area designated for the secure retention of records pending destruction and disposal and segregated from records intended for recycling. It is the responsibility of the Security Officer to ensuring the secure storage of records of personal health information pending their secure disposal.

Inscyte's policies and procedures state that in the event that records of personal health information are to be securely disposed of by a designated agent, who is not a third party service provider, Inscyte will provide to the agent a written instruction setting out the nature of



the information to be disposed of, stipulate acceptable methods of destruction/disposal, and set out the time frame in which the agent is to dispose of the information. It is the responsibility of the Privacy Officer to issue the instruction letter to the agent. Further, Inscyte's policies require the agent to return to Inscyte a written and signed confirmation letter within the prescribed time frame:

- Identifying the records of personal health information to be securely disposed of;
- Confirming the secure disposal of the records of personal health information;
- Setting out the date, time and method of secure disposal employed; and
- Bearing the name and signature of the agent(s) who performed the secure disposal.

In the event that records of personal health information on paper electronic media will be securely disposed of or destroyed by a third party service provider, Inscyte's policies require:

- a) Using a service provider that is accredited by an industrial trade association, such as the National Association for Information Destruction, or willing to commit to upholding its principles, including undergoing independent audits.
- b) The service provider issue a certificate of destruction (as described above) in each service instance.
- c) That a copy of the certificate of destruction be retained in Inscyte's privacy document archives in perpetuity.
- d) That transfer of paper or electronic media bearing personal health information and intended for destruction between Inscyte and the service provider shall be conducted in accordance with Inscyte's policies and procedures for the secure transfer of personal health information.

Inscyte's policies state that it is the responsibility of the Security Officer to ensure compliance with this policy when third-party service providers are engaged for the destruction and disposal of paper or electronic media containing personal health information.

Further, where a third party service provider is retained to securely dispose of records of personal health information, Inscyte's policy requires that a written agreement be executed with the third party service provider containing the relevant language from Inscyte's Template Agreement for Third Party Service Providers, and identifies the Security Officer as responsible for ensuring that the agreement has been executed prior to the transfer of records of personal health information for secure disposal.

The policy and procedures require that transfers of paper or electronic media containing personal health information slated for destruction and disposal be tracked in a *Log of PHI Destruction and Disposal,* which is to be retained in Inscyte's privacy document archives and contain the following information at minimum:



- a) The name of the service provider
- b) The nature of the media and information to be disposed of or destroyed
- c) The date the paper or electronic media was transferred for disposal
- d) The name of the individual who transferred the media to the service provider
- e) The date by which a certificate of destruction is expected
- f) The date the certificate of destruction was received

The policies state that it is the responsibility of the Security Officer to ensure the *Log of PHI Destruction and Disposal* is maintained up-to-date and accurate, to track the expected receipt of certificates of destruction.

In the event that a certificate of destruction is overdue, the policies and procedures require the Security Officer to inform the Privacy Officer that a certificate is overdue and to send a reminder notice to the service provider to obtain the certificate forthwith. If the service provider fails to provide the certificate of destruction after the reminder notice is sent, the policies require the issue shall to be referred to the President of Inscyte and brought before the Board of Directors to determine the actions to be taken in resolving the issue.

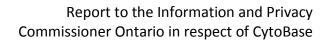
Inscyte requires its agents to comply with its security policies and procedures regarding the secure disposal of records personal health information and designates the Security Officer as being responsible for monitoring and ensuring compliance. The policy and procedures also set out the consequences of breach. Inscyte's policy and procedures in respect of security audits stipulate that compliance will be audited at minimum on an annual basis and that spot security audits will be conducted on a monthly basis. It is the responsibility of the Security Officer to initiate security audits at the prescribed intervals.

Inscyte's security policies require its agents to notify Inscyte at the first reasonable opportunity, in accordance with the Policies and Procedures for Security Breach Management, if an agent breaches or believes there may have been a breach of this policy or any of Inscyte's security policies, procedures and practices.

### 9. Policy and Procedures Relating to Passwords

Inscyte Corporation has developed and implemented policies and procedures with respect to passwords for authentication and passwords for access to information systems, technologies, equipment, resources, applications and programs regardless of whether they are owned, leased or operated by Inscyte Corporation.

The policies for issuing access accounts and passwords stipulate the following general requirements:



- a) Minimum length of passwords shall be eight (8) characters
- b) Passwords shall be composed of alphabetic, numeric, and non-alphanumeric characters
- c) Passwords shall be of mixed upper/lower case
- d) Passwords shall expire at maximum on a 90-day cycle
- e) A user's previous two passwords cannot be re-used when changing passwords
- f) Except when originally issued passwords cannot be the same as account names
- g) A user must change his/her password upon first use of an newly issued account
- h) Each combination of account name and password shall be unique
- i) Account names cannot be re-used for different individuals

The policies state that the above requirements shall be implemented to the maximum extent possible, recognizing that not all software, computer applications and equipment may support all of the above requirements.

The policies further state that whenever possible, three (3) successive failed attempts at authenticating a user's account ID and password combination should automatically disable the account, record the event in a failed login log, and alert system administrators about the event. Upon discovery of a failed login event, Inscyte's policies stipulate that an investigation shall be undertaken to determine if a breach of security or potential breach has occurred. The policies state that it is the responsibility of the Security Officer to ensure an investigation is carried out.

Inscyte's security policies require that all computer workstations that are able to access personal health information implement a maximum ten (10) minute idle timeout that locks the workstation and requires re-entry of a user's password to resume work.

Further, Inscyte's security policies in respect of passwords set out that each individual must keep his/her password secret and not share it with any other individual, that passwords should not be comprised of an individual's postal code, date of birth, vehicle license plate number or other publicly available information related to the individual, and that in the event that passwords are recorded on paper or electronic media, the information must be stored behind at least two physical security checkpoints and be secured such that only authorized personnel have access to the records. In the event that an individual suspects his/her account/password has or may have been compromised, the policies require the individual to report the incident to the Security Officer, and that the account/password be de-activated and a new account/password issued.

Inscyte's policies also set out the administrative procedures for requesting and issuing account names and passwords for access to systems containing personal health information. Inscyte's policies and procedures stipulate that access shall only be granted to agents of Inscyte and that approval by the Privacy Officer is required prior to granting access. The policies state that the minimum criteria for approving individual access accounts are:



- a) The agent has a legitimate need to access systems containing personal health information
- b) The agent has completed his/her probationary period of employment.
- c) The agent has executed a signed and witnessed Personal Health Information Confidentiality and Non-Disclosure Agreement.
- d) The agent has received privacy & security awareness training.

The policies further stipulate that all individuals having access accounts shall be logged in Inscyte's *Log of Accounts Having Access to PHI* –a perpetual log of individuals' access accounts to computer networks, applications, databases and other secured resources that contain personal health information.

In developing its policies and procedures regarding passwords and access accounts, Inscyte gives regard to orders issued by the Information and Privacy Commissioner of Ontario under the Act and its regulation; guidelines, fact sheets and best practices issued by the Information and Privacy Commissioner of Ontario; and with evolving privacy and security standards and best practices.

Inscyte requires its agents to comply with its security policies and procedures regarding passwords and access accounts and designates the Security Officer as being responsible for monitoring and ensuring compliance. The policies and procedures set out the consequences of breach. Inscyte's policy and procedures in respect of security audits stipulate that compliance will be audited at minimum on an annual basis and that spot security audits will be conducted on a monthly basis. It is the responsibility of the Security Officer to initiate security audits at the prescribed intervals.

Inscyte's security policy requires its agents to notify Inscyte at the first reasonable opportunity, in accordance with the Policies and Procedures for Security Breach Management, if an agent breaches or believes there may have been a breach of this policy or any of Inscyte's security policies, procedures and practices.

# 10. Policy and Procedure for Maintaining and Reviewing System Control and Audit Logs

Inscyte Corporation has developed and implemented policies and procedures for maintaining and reviewing system control and audit logs with respect to CytoBase. The policies require the that all information systems, technologies, applications and programs related to CytoBase and involving personal health information have the functionality to log access, use, modification and disclosure of personal health information. As such, the policies require the following logs to be maintained and specify AIM as agent of Inscyte responsible for ensuring that these logs are maintained and reviewed to monitor compliance with the policies.



- 1) Individual user connection log
- 2) Data modification audit log
- 3) Data disclosure audit log
- 4) Network transaction log

These logs are maintained by automated software processes built into the CytoBase system.

The *Individual User Connection Log* is a CytoBase application log and contains the following information:

- A unique connection ID (system generated)
- The account ID name making the connection (corresponds to a user)
- The network/computer name from which the connection was made
- The date/time of connection start
- The date/time of disconnect
- The nature of the disconnect (normal, timeout, or dropped)

Entries are added to this log by whenever a user (or software process) connects to the CytoBase database, explicitly disconnects, or when an idle connection expires. The absence of a disconnect timestamp indicates a dropped connection. This log is retained in perpetuity. It is located on the CytoBase database server in AIM's secure datacenter and periodically archived to portable media, which are stored in secured premises behind at least two physical checkpoints.

The *Data Modification Log* is a CytoBase application log and contains the following information:

- The date/time of data modification
- The account ID making the modification (corresponds to a user)
- The affected patient ID (unique key to a patient record)
- The affected data entity ID (e.g. report ID, follow-up entry ID etc.)
- The type of modification action (insert, update or delete)
- The affected field names and new values (for insert and update actions)

Entries are added to this log whenever changes are made to data via the CytoBase data registration system or via administrative applications. This log is retained in perpetuity. It is located on the CytoBase database server in AIM's secure datacenter and periodically archived to portable media, which are stored in secured premises behind at least two physical checkpoints.

The *Data Disclosure Log* is a CytoBase application log that contains the following information:



- The date/time of disclosure
- The account ID triggering the disclosure
- The affected patient ID (unique key to a patient)
- The type of disclosure:
  - response to a network query from a laboratory
  - o placement on a follow-up letter package
  - o linkage to another data source
  - retrieval through an administrative application
- The nature of the information disclosed (e.g. test results, last screening date etc.)

Entries are added to this log whenever CytoBase processes data whether triggered by an automated process ob through administrative applications. This log is retained in perpetuity. It is located on the CytoBase database server in AIM's secure datacenter and periodically archived to portable media, which are stored in secured premises behind at least two physical checkpoints.

The *Network Transaction Log* records the on-going exchange of information (messages) between CytoBase and participating laboratories and contains the following information:

- The date/time of message receipt/transmission
- A unique message ID (system generated)
- The type of message (report submission, query request, query response etc.)
- The IDs of sending and receiving systems
- The success/failure of the transaction
- A copy of the raw message content

Entries are added to this log by the CytoBase network listener processes as messages are received and sent. This log is retained in perpetuity. It is located on the network communications server in AIM's secure datacenter and periodically archived to portable media, which are stored in secured premises behind at least two physical checkpoints.

Inscyte's policies also require restricting access to system control and audit logs to a limited number of individuals (system support personnel and authorized users of CytoBase administrative applications only) and prohibit these individuals from modifying, deleting audit log data or tampering with the automated audit logging processes.

Inscyte's policies and procedures stipulate that in order to render system control and audit logs immutable, the logs must be archived to read-only portable media on a regular schedule. The portable media must be treated as personal health information and stored in secured locations behind at least two physical security checkpoints. It is the responsibility of the Security Officer



to ensure that system control and audit logs are archived at appropriate intervals and stored in secured locations. The policies further prohibit the destruction of archived system control and audit logs.

Inscyte's policies require that CytoBase system control and audit logs be reviewed on a monthly basis to verify operational status, system performance, and unusual activity. It is the responsibility of the Security Officer to ensure that the logs are reviewed. Inscyte does not have a specific policy for documenting the results of these reviews, however, Inscyte's policies require that all agents of Inscyte be vigilant of circumstances that may indicate a breach or attempted breach of security. As such, if in the course of reviewing system control and audit logs evidence is found that a breach or attempted breach of security may have occurred, the policies require investigating the breach in accordance with Inscyte's policies and procedures in respect of security breach management that state if there is also cause to believe that a privacy breach management shall take effect as well.

Inscyte requires its agents to comply with its security policies and procedures regarding the maintenance and review of system control and audit logs and designates the Security Officer as being responsible for monitoring and ensuring compliance. The policy and procedures set out the consequences of breach. Inscyte's policy and procedures in respect of security audits stipulate that compliance will be audited at minimum on an annual basis and that spot security audits will be conducted on a monthly basis. It is the responsibility of the Security Officer to initiate security audits at the prescribed intervals.

Inscyte's security policies also require agents of Inscyte to notify Inscyte at the first reasonable opportunity, in accordance with the Policies and Procedures for Security Breach Management, if an agent breaches or believes there may have been a breach of this policy or any of Inscyte's security policies, procedures and practices.

### **11.** Policy and Procedures for Patch Management

Inscyte's policy for patch management designates its agent AIM Inc. as being responsible for monitoring the availability of software patches, evaluating the necessity for implementing patches, and performing routine patch updates to supporting software and systems as necessary to maintain CytoBase operational on a 7x24 basis and to keep pace with evolving operating system, database, network, security and other supporting technologies.

As AIM Inc. is the designer and developer of CytoBase, Inscyte's policy delegates authority to AIM to implement routine patches and software upgrades at its sole discretion provided that such changes do not degrade the performance of CytoBase, the strength of its security controls, availability, or its functionality, and that such changes do not require additional funding.





In all other cases, the policy requires AIM Inc. to submit a change request consisting of a work/cost breakdown and implementation schedule to Inscyte for prior approval. It is the responsibility of the CEO of AIM Inc. to communicate the change request to Inscyte. It is the responsibility of the President of Inscyte to approve/deny each change request.

Insofar as supporting technology is concerned, it is the responsibility of AIM's Operations Manager to monitor and evaluate new software patches, software upgrades and equipment/configuration upgrades on an on-going basis, as these become available, and to bring forward recommendations to AIM's CEO for approval to implement selected patches, software upgrades and equipment/configuration changes.

Insofar as the CytoBase database and application software are concerned it the responsibility of the Vice-President of Engineering of AIM Inc. to prepare and maintain version and release upgrade plans and bring these forward to AIM's CEO for approval and scheduling, and to recommend CytoBase database and application upgrades to Inscyte Corporation.

Inscyte's policy does not set out specific criteria on which patches, software upgrades or equipment/configuration changes are to be evaluated but require that recommendations be accompanied with a clear rationale describing the benefits of the changes.

Implementation of patches and software upgrades are performed in accordance with AIM's engineering practices and protocols, which require all patches and upgrades to be tested and verified on non-production systems before being rolled-out to production environments, with provisions for reverting to pervious good configurations. AIM's engineering practices and protocols require documentation to be maintained regarding all patches and upgrades.

Inscyte's policy requires AIM to maintain accurate and up-to-date Asset Inventory and Configuration Information documentation for all software and hardware components of the CytoBase System, describing each component, component type, its vendor and version, and date(s) of installation and/or upgrade. This documentation is maintained by AIM as part of Inscyte/AIM Risk Management and Business Continuity policies and procedures.

Inscyte requires its agents to comply with its security policies and procedures regarding patch management and designates the Security Officer as being responsible for monitoring and ensuring compliance. The policy and procedures set out the consequences of breach. Inscyte's policy and procedures in respect of security audits stipulate that compliance will be audited at minimum on an annual basis and that spot security audits will be conducted on a monthly basis. It is the responsibility of the Security Officer to initiate security audits at the prescribed intervals.

Inscyte's security policies also require agents of Inscyte to notify Inscyte at the first reasonable opportunity, in accordance with the Policies and Procedures for Security Breach Management,



if an agent breaches or believes there may have been a breach of this policy or any of Inscyte's security policies, procedures and practices.

### 12. Policy and Procedures Related to Change Management

Inscyte's policy for change management designates its agent AIM Inc. as being responsible for evaluating the necessity and implementing changes to the operational environment of CytoBase as necessary to maintain 7x24 operations and to keep pace with evolving operating system, database, network, security and other supporting technologies.

As AIM Inc. is the designer and developer of CytoBase, Inscyte's policy delegates authority to AIM to implement changes at its sole discretion provided that such changes do not degrade the performance of CytoBase, the strength of its security controls, availability, or its functionality, and that such changes do not require securing additional funding.

In all other cases, the policy requires AIM Inc. to submit a change request consisting of a description of the change and its rationale, the impact of executing or not executing the change, and a work/cost breakdown and implementation schedule to Inscyte for prior approval. It is the responsibility of the CEO of AIM Inc. to communicate the change request to Inscyte in writing. It is the responsibility of the President of Inscyte to approve/deny each change request, based on the criteria indentified in the policy. The President of Inscyte approves or denies each change request, in writing, and provides reasons for his decision to the CEO of AIM Inc.

With respect to the computing infrastructure of CytoBase, it is the responsibility of AIM's Operations Manager to evaluate existing infrastructure and plan for upgrades on an on-going basis taking into account obsolescence, maintainability, technological improvements, emerging technologies, and recommendations resulting from privacy and security audits or breach investigations, among other factors.

It is the responsibility of the Operations Manager to bring forward recommendations for changes to the computing infrastructure to AIM's Management, and to the President of Inscyte if the changes require Inscyte's approval.

Inscyte's policy does not set out specific criteria on which changes to infrastructure are to be evaluated but require that recommendations be accompanied with a clear rationale describing the benefits of the changes.

Implementation of infrastructure changes are performed in accordance with AIM's engineering practices and protocols, which require changes to be tested and verified on non-production systems before being rolled-out to production environments, with provisions for reverting to previous good configurations if required. It is the responsibility of the Operations Manager to



monitor and ensure that changes are implemented in accordance with specifications and set schedules. AIM's engineering practices and protocols require documentation to be maintained regarding all infrastructure changes, which include the minimum information required by the IPC Manual.

Inscyte's policy requires AIM to maintain accurate and up-to-date Asset Inventory and Configuration Information documentation for all components of the CytoBase infrastructure, describing each component, component type, its vendor, configuration, and date(s) of installation and/or upgrades, which include the minimum information required by the IPC Manual. This documentation is maintained by AIM as part of Inscyte/AIM Risk Management and Business Continuity policies and procedures.

Inscyte requires its agents to comply with its security policies and procedures regarding change management and designates the Security Officer as being responsible for monitoring and ensuring compliance. The policy and procedures set out the consequences of breach. Inscyte's policy and procedures in respect of security audits stipulate that compliance will be audited at minimum on an annual basis and that spot security audits will be conducted on a monthly basis. It is the responsibility of the Security Officer to initiate security audits at the prescribed intervals.

Inscyte's security policies also require agents of Inscyte to notify Inscyte at the first reasonable opportunity, in accordance with the Policies and Procedures for Security Breach Management, if an agent breaches or believes there may have been a breach of this policy or any of Inscyte's security policies, procedures and practices.

# 13. Policy and Procedures for Back-Up and Recovery of Records of Personal Health Information

Inscyte has developed and implemented a policy for the back-up and recovery of personal health information contained in CytoBase. The back-up/recovery policy designates Inscyte's agent AIM Inc. as being responsible for all back-up and recovery services. Inscyte Corporation does not use a third-party service provider for back-up and recovery services.

The policy requires that back-ups be performed in such a manner that the complete CytoBase database can be restored with a maximum loss of one week's data. The policy states that back-up media shall be made available to restore the CytoBase system to a good state in the event that an upgrade or change to the computing infrastructure requires reverting to a previous state, the a system failure occurs which requires restoring CytoBase to a last known good state, and in support of Inscyte's disaster recovery strategy.

It should be noted that CytoBase is a copy of information emanating from participating laboratories and the loss of up to several weeks of data can be restored by re-playing



transmissions from participating laboratories using the Network Transaction Logs residing at the laboratories.

Inscyte's policy requires that a complete back-up be performed on a daily basis to portable media (tapes) labeled with the date and time of the backup. The policy further requires that a log of back-ups be maintained with the date and sign-off by the individual making each day's backup tapes. The policy requires that two sets of tapes are to be maintained: one on-site and one off-site, and that the tapes must be stored in a secure location behind at least two physical security checkpoints. The policy designate AIM's Operations Manager as being responsible for ensuring that daily back-ups are performed in accordance with the policy.

In support of the policy, AIM performs full daily backups of CytoBase to tape on a two-week rotation. The back-up is performed by an automated system that incorporates a tape-loader. The daily tapes for the current week are store on-site in a fireproof safe in AIM's datacenter. The previous weeks set of daily back-ups are stored off-site in a secure location. The weekly tape sets are rotated from week to week.

The policy and procedures also require that restoration tests be performed on a quarterly basis (at minimum) to verify that the back-up tapes are useable. The test requires selecting a backup tape at random and performing a restore on selected files. It is the responsibility of AIM's Operations Manager to ensure that restoration tests are performed and that in the event of a failure, to report the failure to AIM's management for resolution and remediation.

Inscyte requires its agents to comply with its security policies and procedures regarding change management and designates the Security Officer as being responsible for monitoring and ensuring compliance. Inscyte's policy and procedures in respect of security audits stipulate that compliance will be audited at minimum on an annual basis and that spot security audits will be conducted on a monthly basis. It is the responsibility of the Security Officer to initiate security audits at the prescribed intervals.

Inscyte's security policies also require agents of Inscyte to notify Inscyte at the first reasonable opportunity, in accordance with the Policies and Procedures for Security Breach Management, if an agent breaches or believes there may have been a breach of this policy or any of Inscyte's security policies, procedures and practices.

### 14. Policy and Procedures on the Acceptable Use of Technology

Inscyte Corporation has developed and implemented a policy regarding the acceptable use of information systems, technologies, equipment, resources, applications and programs insofar as the handling of personal health information is concerned. The policy addresses prohibited uses of technologies only. All other uses are permitted and no policy exists for uses that are permitted only with prior approval.



The policy expressly prohibits the following:

- 1. Wireless access points to computer networks containing PHI are prohibited
- 2. Sending PHI in open text email messages is prohibited
- 3. Printing of material containing PHI in unsecured premises is prohibited
- 4. Storing PHI on portable computing devices is prohibited
- 5. Sending PHI via facsimile is prohibited

Inscyte requires its agents to comply with its security policies and procedures regarding acceptable use of technology and designates the Security Officer as being responsible for monitoring and ensuring compliance. The policy and procedures set out the consequences of breach. Inscyte's policy and procedures in respect of security audits stipulate that compliance will be audited at minimum on an annual basis and that spot security audits will be conducted on a monthly basis. It is the responsibility of the Security Officer to initiate security audits at the prescribed intervals.

Inscyte's security policies also require agents of Inscyte to notify Inscyte at the first reasonable opportunity, in accordance with the Policies and Procedures for Security Breach Management, if an agent breaches or believes there may have been a breach of this policy or any of Inscyte's security policies, procedures and practices.

### **15.** Policy and Procedures In Respect of Security Audits

Inscyte Corporation's policies require that a security audit be performed on an annual basis to assess security risks and whether current security policies and controls are adequate to mitigate the identified risks.

Inscyte's policy states that the purposes of the security audit is to ensure that its information security program adequately addresses the preservation of confidentiality (ensuring that information is accessible only to those authorized to have access), integrity (safeguarding the accuracy and completeness of information and processing methods) and availability (ensuring that authorized users have access to information and associated assets when required) of personal health information and business critical information; and to ensure that the information security program complies with all applicable legislation and keeps pace with emerging best practices.

Inscyte's policies state that it is the responsibility of the Privacy Officer to initiate an annual security audit and that it is the responsibility of the Security Officer to conduct and report on the findings of the audit.



Inscyte's annual security audits are conducted in conformance with ISO/IEC 27002 Information Security Standards. Accordingly, the policy identifies the following subject matter areas to be reviewed and sets out general instructions for doing so as follows:

- 1. Threat Risk assessments (TRAs)
  - a. Review *Threat Risk Assessments* to assess completeness and accuracy
  - b. Assess adequacy of response to previous TRA recommendations (if any)
  - c. Assess if new TRAs are required to align with changing assets and/or processes
- 2. Security policy management direction
  - a. Review current strategic objectives regarding information security
  - b. Assess adequacy/alignment of strategic objectives
- 3. Organization of information security governance of information security
  - a. Review governance structure
  - b. Assess adequacy and effectiveness of governance structure
- 4. Asset management inventory and classification of information assets
  - a. Review Asset Inventory and Configuration Information to ascertain accuracy and completeness
- 5. Human resources security access rights of agents joining, moving and leaving the organization
  - a. Review the Log of Individuals Having Access to Premises to ascertain accuracy and completeness
  - b. Assess adequacy of access rights and roles for each individual
- 6. Physical and environmental security protection of the computer facilities and premises where personal health information is stored
  - a. Inspect physical security checkpoints and entry logs to ascertain functionality and completeness
  - b. Assess adequacy of physical security controls
  - c. Inspect environmental controls to ascertain functionality
  - d. Assess adequacy of environmental controls
- 7. Communications and operations management management of technical security controls in systems and networks
  - a. Review technical security controls in servers, networks, workstations etc.
  - b. Review system access and control logs to determine completeness and functionality
  - c. Review emerging trends, technologies and best practices
  - d. Assess adequacy of technical security controls
- 8. Access control restriction of access rights to networks, systems, applications, functions and data
  - a. Review the Log of Individuals Accounts Having Access to PHI to ascertain accuracy and completeness
  - b. Assess adequacy of access rights and roles for each individual
  - c. Assess adequacy of application security controls



- 9. Information systems acquisition, development and maintenance building security into applications
  - a. Review all technical security controls in the computing infrastructure
  - b. Identify differences in technical security controls from one checkpoint to another
  - c. Assess adequacy and consistency of checkpoint security controls
  - d. Assess potential weaknesses or obsolescence of technical security controls
  - e. Review all back-up/restore and system availability controls
  - f. Review outages (planned or unplanned) and assess adequacy of response
  - g. Assess adequacy of system availability controls
- 10. Information security incident management anticipating and responding appropriately to information security breaches
  - a. Review Log of Security Breaches to assess completeness and accuracy
  - b. Assess adequacy of response to security breaches
  - c. Analyze security breaches and recommend solutions to prevent recurrence
- 11. Business continuity management protecting, maintaining and recovering businesscritical processes and systems
  - a. Review the current Disaster Recovery Plan for accuracy and completeness
  - b. Assess adequacy of the disaster recovery plan with respect to current assets and operations
- 12. Compliance ensuring conformance with security policies and procedures, standards, laws and regulations
  - a. Review security policies and procedures; emerging standards and best practices; laws and regulations
  - b. Assess compliance with above

With respect to technical security controls in systems and networks, and access controls to networks, systems, applications, functions and data, the policy and procedures provide guidelines for performing penetration testing and ethical hacks to assess the strength and adequacy of these security controls.

All of the above subject matter areas are addressed in annual security audits, however the policies permit specific areas to be addressed at any time if there is reason to believe a deficiency exists in the security program or in the event of a breach or suspected breach of security has occurred. It is the responsibility of the Privacy Officer to determine if an audit of a specific subject matter area is required under such circumstances.

The policies require that a *Security Audit Report* to be prepared for each subject matter area identifying the subject matter, the date the audit was started and completed, the activities preformed, the names of the individuals carrying out the audit, the findings and resulting recommendations for changes (if any) and the proposed manner in which the recommendations shall be addressed. The policies require that these reports are to be retained in perpetuity in the *Log of Security Audits* in Inscyte's privacy document archives.

The policies further require that each *Security Audit Report* must be reviewed and approved by the Security Officer and a copy provide to the Privacy Officer and the President of Inscyte. It is the responsibility of the Security Officer to track any recommendations for changes resulting from security audits; to ensure that the recommendations are summarized in the *Consolidated Log of Recommendations*, and to determine the schedule upon which recommendations shall be acted upon giving regard to the nature and urgency of the recommended changes. The policies require that recommended changes resulting from security audits are to be implemented in accordance with Inscyte's policies and procedures for change management and/or its policies regarding patch management.

The policy further requires that a *Log of Security Audits* be maintained in perpetuity within Inscyte's privacy document archives and designates the Security Officer as being responsible for maintaining the log and for tracking that the recommendations arising from security audits are addressed within the specified time frame.

Inscyte's policy and procedures regarding security audits also require agents responsible for conducting security audits to notify Inscyte, at the first reasonable opportunity, of an information security breach or suspected security breach in accordance with the Policy and Procedures for Information Security Breach Management and of a privacy breach or suspected privacy breach in accordance with the Policy and Procedures for Privacy Breach Management.

# 16. Log of Security Audits

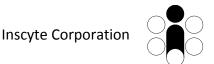
Inscyte Corporation maintains a *Log of Security Audits* that have been completed. The log contains a summary of each *Security Audit Report* identifying the subject matter are that was audited, the date the audit was started and completed, the activities performed, the names of the individuals carrying out the audit, the findings and resulting recommendations for changes (if any) and the proposed manner in which the recommendations shall be addressed.

Inscyte's policies also require that recommendations from security audits be recorded in its *Consolidated Log of Recommendations* for tracking and work scheduling purposes.

### **17.** Policy and Procedures for Information Security Breach Management

Inscyte Corporation has developed and implemented policies and procedures to address the identification, reporting, containment, notification, investigation and remediation of security breaches. The policies define a "breach of security" as:

- a) An unauthorized person gaining access to, or attempting to gain access to, secured premises or secured information, by any means whatsoever.
- b) An act that compromises the confidentiality, integrity (accuracy and completeness), or availability of secured information.



c) A contravention of Inscyte's security policies and procedures.

Inscyte's policy does not differentiate between a "security breach" and "information security breach". Rather, the policies state that a breach of security occurs in the above circumstances regardless of the consequences of the breach, and in the event that there is reasonable cause to believe that personal health information has been disclosed to unauthorized parties, or is likely to be disclosed as a consequence of the security breach, Inscyte's policies and procedures for privacy breach management shall also come into effect.

In addition to providing a definition of a breach of security, Inscyte's policies further state that a breach of security occurs whenever a person has gained, or attempts to gain, unauthorized access to secured premises or secured information; that a breach of security may be reported via a complaint or challenge to Inscyte's or its agent's compliance with these policies and procedures filed by a third party; and that a breach of security may be self-identified by an agent of Inscyte through the course of everyday work signaled by the discovery that (without limitation):

- a) A physical security control has been damaged, disabled or tampered with
- b) A key or pass card is found in a suspicious location
- c) A security log (computer network access logs, application access logs, internet activity logs etc.) contains information indicative that unauthorized access has been attempted.
- d) A computer security control behaves erratically or is disabled
- e) A computer system is disabled or behaves erratically
- f) Computer files are missing or corrupted
- g) A database system is corrupted
- h) Unexpected loss of availability of a computer system or data

The policies state that upon discovery of a breach or suspected breach of security, the party discovering the breach shall immediately report the incident to the Privacy Officer and Security Officer of Inscyte either verbally or by email. The policies include the contact information for the Privacy and Security Officers.

Inscyte's policies and procedures for security breach management further set out the actions to be taken after discovery of a breach or suspected breach of security.

The policies require that the reported incident be immediately assessed to determine if a breach of security has in fact occurred and to further determine if a breach of privacy has also occurred, or is likely to occur as a result of the security breach. It is the responsibility of the Security Officer to ensure that this assessment is performed. The policies state that if there is reasonable cause to believe that personal health information has been disclosed to unauthorized parties, or is likely to be disclosed as a consequence of the security breach, then it is the responsibility of the Security Officer to immediately notify the Privacy Officer about the



breach, at which time Inscyte's policies and procedures for privacy breach management also take effect.

The policies then require that a confirmed breach of security be contained by taking all necessary actions to secure the premises and/or information systems affected by the breach, including suspending access to authorized individuals, recovering access keys, pass cards, resetting access codes and accounts, taking affected computer systems off-line and so forth. It is the responsibility of the Security Officer to ensure that these actions are taken as quickly as possible and to determine whether the security breach has been effectively contained or whether further containment measures are necessary.

The policies also require that each incident of security breach be documented using Inscyte's standard *Security Breach Report* which contains the following information at minimum:

- a) Incident report number (unique for each incident)
- b) The incident report date
- c) The name/title of the person(s) who discovered/reported the breach security
- d) The name/title of the person(s) who investigated the breach of security
- e) The date/time of the breach (or estimate thereof)
- f) The evidence that lead to the discovery of the breach of security
- g) likelihood and/or evidence that a breach of privacy also occurred (if any)
- h) Containment procedures (what was done to contain the breach, when and by whom)
- i) Suspected perpetrator the breach (if known)
- j) The motivation/cause for the breach (or suspected motivation/cause)
- k) Description of security controls that were compromised
- I) Description of how the security controls were compromised
- m) Recommendations for changes and mitigating strategies
- n) The agent(s) responsible for implementing the recommendations
- o) The date each recommendation is expected to be addressed
- p) The manner in which each recommendation is expected to be addressed
- q) Sign-off/approval name, title and date

It is the responsibility of the Security Officer to delegate work to appropriate staff and ensure that an investigation is carried out and report is completed as quickly as possible and no later than 30 days following a breach of security. The policies require that the *Security Breach Report* by provided to the Privacy Officer and the President of Inscyte for review and final approval. The policies further require that all Security Breach Reports be retained in perpetuity in Inscyte's privacy document archives.

In the event that a breach of security includes a breach of privacy, Inscyte's policies and procedures for privacy breach management come into effect and require the Privacy Officer to immediately notify the President of Inscyte about the breach, either verbally or by email. The





policies state that is subsequently the responsibility of the President of Inscyte to notify, at the first reasonable opportunity, the health information custodians or other organizations that disclosed the personal health information to Inscyte Corporation and advise them of the extent of the breach; the nature of the personal health information at issue; the measures taken to contain the breach; and any further actions that will be undertaken with respect to the breach.

Inscyte's policies and procedures require that recommendations for changes and mitigating strategies emanating from investigations of security breaches also be recorded in the *Consolidated Log of Recommendations* citing the Security Breach Report number as the source of the recommendations and specifying the actions to be taken to implement the recommendations, the personnel responsible for carrying out the actions, and the target date(s) of completion. The policies designate the Security Officer as responsible for logging the recommendations; delegating work to address the recommendations; establishing timelines to address the recommendations; and for monitoring and ensuring that the recommendations are implemented within the stated timelines.

The policy and procedures require that upon completion of recommended changes, all affected documents, such as the Asset Inventory and Configuration Information, Log of Individuals Having Access to PHI, Log of Individuals Having Access to Premises, and so forth are updated to reflect the implemented changes and that the Consolidated Log of Recommendations is updated to reflect the completion of the changes, the date of completion and the name/title of the person confirming the completion. The policies designate the Security Officer as being responsible to ensure that the related documentation is up-to-date and accurate.

Further, Inscyte's policies and procedures require that a *Log of Security Breaches* be maintained and identify the Security Officer as responsible for maintaining the log and for tracking that the recommendations arising from the investigation of security breaches are addressed within the identified timelines. The policies require that *Security Breach Reports* in the *Log of Security Breaches* be maintained in perpetuity in Inscyte's privacy document archives.

Inscyte requires its agents to comply with its security policies and procedures regarding security breach management and designates the Security Officer as being responsible for monitoring and ensuring compliance. The policies and procedures also set out the consequences of breach. Inscyte's policy and procedures in respect of security audits stipulate that compliance will be audited at minimum on an annual basis and that spot security audits will be conducted on a monthly basis. It is the responsibility of the Security Officer to initiate security audits at the prescribed intervals.

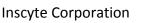
# **18. Log of Security Breaches**

Inscyte Corporation maintains a *Log of Security Breaches* as a perpetual archive of *Security Breach Reports* setting out:



- Incident report number (unique for each incident)
- The incident report date
- The name/title of the person(s) who discovered/reported the breach security
- The name/title of the person(s) who investigated the breach of security
- The date/time of the breach (or estimate thereof)
- The evidence that lead to the discovery of the breach of security
- Likelihood and/or evidence that a breach of privacy also occurred (if any)
- Containment procedures (what was done to contain the breach, when and by whom)
- Suspected perpetrator the breach (if known)
- The motivation/cause for the breach (or suspected motivation/cause)
- Description of security controls that were compromised
- Description of how the security controls were compromised
- Recommendations for changes and mitigating strategies
- The agent(s) responsible for implementing the recommendations
- The date each recommendation is expected to be addressed
- The manner in which each recommendation is expected to be addressed
- Sign-off/approval name, title and date

In the event that a breach of privacy occurs within the context of a breach of security, the *Log* of *Privacy Breaches* contains additional information such as the nature of the personal health information that was or may have been compromised, the containment measures taken, and the health information custodians or other organizations that were notified about the breach.





# Part 3 - Human Resources Documentation

### **1.** Policy and Procedures for Privacy Training and Awareness

Inscyte has developed and implemented a policy requiring its agents to attend initial privacy awareness training upon hiring as well as ongoing privacy awareness training.

The policy specifies that Privacy Awareness Training shall be provided to agents before an individual is granted access to secured premises or information systems containing personal health information. The policy further requires that quarterly privacy awareness training sessions ne conducted and that all agents are required to attend these sessions (unless away due to illness or vacation) and that each agent attend at minimum two of the quarterly training sessions each fiscal year. In the event that an individual misses three consecutive training sessions, it is the responsibility of the Privacy Officer to notify the individual and schedule a "special" training session at the earliest opportunity.

The policy designates the Privacy Officer as being responsible for ensuring that agents obtain privacy awareness training and for scheduling and preparing quarterly privacy awareness training sessions.

The policy sets out the content of the initial privacy awareness training as follows:

- 1. Definition of "personal health information".
- 2. Explanation for the need for privacy regarding health information
- 3. A description of the Office of the Information and Privacy Commissioner of Ontario
- 4. Description of the Act, its purpose and the roles of health information custodians, prescribed persons and prescribed entities.
- 5. Description of the status of Inscyte Corporation under the Act and the duties and responsibilities that arise as a result of this status.
- 6. Description of the personal health information held by Inscyte and the health information custodians from whom the information is collected.
- 7. Explanation of the purposes for which the personal health information is collected.
- 8. Description of the limitations on the uses of the personal health information.
- 9. Description of the users of CytoBase.
- 10. Explanation of how the collection and use is permitted by the Act and its regulation.
- 11. Description of the status of AIM Inc. as agent of Inscyte and the privacy governance and accountability framework.
- 12. Explanation of the privacy program, including the key activities of the program and the persons that have been delegated day-to-day authority to manage the privacy program.
- 13. Limitations placed on access to and use of the personal health information by AIM.
- 14. An overview of Inscyte's *Privacy Policies and Procedures* that have been implemented and the obligations arising from these policies and procedures.



- 15. Description of the administrative, technical and physical safeguards implemented to protect personal health information against theft, loss and unauthorized use or disclosure and to protect records of personal health information against unauthorized copying, modification or disposal.
- 16. A description of the policies and procedures that must be followed in the event that an agent is requested to disclose personal health information.
- 17. The duties and responsibilities of all agents in adhering to the administrative, technical and physical safeguards put in place.
- 18. Discussion of the purpose and content of the standard *Personal Health Information Confidentiality and Non-Disclosure Agreement* that each agent is required to execute.
- 19. Definition of "breach of privacy"
- 20. Consequences of a breach of the privacy policies and procedures
- 21. An overview of the Policy and Procedures for Privacy Breach Management and the duties and responsibilities imposed on agents in identifying, reporting, containing and participating in the investigation and remediation of privacy breaches.

The policy and procedures also require that quarterly privacy training sessions be formalized and standardized and to address the following topics at minimum:

- 1. Reminder of the status of Inscyte Corporation under the Act and the duties and responsibilities that arise as a result of this status.
- 2. Reminder of the status of agents of Inscyte and review of the privacy governance and accountability framework.
- 3. Review of what is and what is not "personal health information"
- 4. Review of recent breaches of privacy with respect to CytoBase (if any).
- 5. Review and discussion of recent breaches of privacy in the industry (case studies) as reported through the Office of the Information and Privacy Commissioner, Ontario, or other authorities in Canada or the U.S.
- 6. Review and discussion of specific policies and procedures applying to specific agent roles.
- 7. Review and discussion of new or amended policies and procedures since the last training session, if any.
- 8. Discussion regarding specific privacy policies or procedures arising from questions, or recommendations resulting from privacy audits, privacy impact assessments, threat risk analyses, privacy complaints or privacy breach reports.
- 9. Discussion regarding any changes to the Act and its regulations or recent orders issued by the Office of the Information and Privacy Commissioner, Ontario that may impact on the privacy program.

The policy and procedures regarding privacy awareness training require that each individual sign an attendance sheet at each training session (initial, quarterly, or special) and that the attendance sheets be retained in perpetuity in Inscyte's privacy document archives. The policy



designates the Privacy officer as being responsible for tracking attendance and maintaining the training attendance log accurate and up-to-date.

The process of tracking attendance consists of printing an attendance sheet for each training session. The attendance sheet consist of the date of the training session, the type of session (initial, routine quarterly, or special) and, in the case of initial or special training, the names of the designated attendees; otherwise for routine quarterly training sessions a complete list of all agents of Inscyte.

At the conclusion of the training session each attendee is required to sign beside their name on the attendance sheet. After all attendees have signed, the sheet is verified and signed-off by the Privacy Officer or Security Officer. The attendance sheet is then scanned into a computer image file and placed in the privacy document archives. In addition the cumulative number of sessions attended by each agent since the start of his/her engagement is maintained. Further, the content (slide show & any handouts) of each training session is retained. The policies designate the Privacy Officer as being responsible for maintain this documentation in Inscyte's privacy document archives.

Beyond the requirements of Inscyte's policy and procedures regarding privacy awareness training, AIM Inc., as a software engineering firm working in the healthcare domain, with many customers who are health information custodians across Canada and the U.S., promotes a culture of sensitivity to privacy issues on a daily basis by encouraging all staff to be vigilant of hazards and practices that may endanger patient privacy and to report these openly for discussion and remediation. AIM communicates this culture of sensitivity by sending email updates with news of recent privacy/security breaches in the healthcare industry and changes to legislation and/or practices as these occur. In addition, privacy matters are discussed at weekly management meetings as part of operations reports.

Inscyte requires its agents to comply with its policies and procedures regarding privacy awareness training and designates the Privacy Officer as being responsible for monitoring and ensuring compliance. The policy and procedures set out the consequences of breach. Inscyte's policy and procedures in respect of privacy audits stipulate that compliance will be audited at minimum on an annual basis and that it is the responsibility of the Privacy Officer to initiate audits at the prescribed intervals.

Inscyte's privacy policies also require its agents to notify Inscyte at the first reasonable opportunity, in accordance with the Policies and Procedures for Privacy Breach Management, if an agent breaches or believes there may have been a breach of this policy or its procedures.

# 2. Log of Attendance at Initial Privacy Orientation and Ongoing Privacy Training

Inscyte Corporation maintains a log of the attendance of agents at initial privacy awareness training, ongoing quarterly privacy training and special training sessions. The log includes the name of the individual, the date that the individual attended privacy training and the type of training session (initial, quarterly, or special).

### 3. Policy and Procedures for Security Training and Awareness

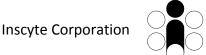
Inscyte has developed and implemented a policy requiring its agents to attend initial security awareness training upon hiring as well as ongoing security awareness training. In practice, privacy awareness and security awareness training are combined into concurrent sessions.

The policy specifies that security awareness training shall be provided to agents before the individual completes his/her three-month probationary period and before the individual is granted access to secured premises or information systems containing personal health information. The policy further requires that quarterly security awareness training sessions be held and that all agents are required to attend these sessions (unless away due to illness or vacation) and that each agent attend at minimum two of the quarterly training sessions each fiscal year. In the event that an agent misses three consecutive training sessions, it is the responsibility of the Privacy Officer to notify the individual and schedule a "special" training session at the earliest opportunity.

The policy designates the Privacy Officer as being responsible for ensuring that agents obtain security awareness training and for scheduling and preparing quarterly security awareness training sessions, which are combined in practice with privacy awareness training as described in the section above.

The policy sets out the content of the initial security awareness training as follows:

- 1. An overview of Inscyte's *Security Policies and Procedures* that have been implemented and the obligations arising from these policies and procedures.
- 2. An explanation of the security program, including the key activities of the program and the persons that have been delegated day-to-day authority to manage the security program.
- 3. Description of the security governance and accountability framework.
- 4. The administrative, technical and physical safeguards implemented to protect personal health information against theft, loss and unauthorized use or disclosure and to protect records of personal health information against unauthorized copying, modification or disposal.
- 5. The duties and responsibilities of agents in implementing the administrative, technical and physical safeguards put in place.



- 6. A definition of "breach of security" and its relationship to a breach of privacy.
- 7. The consequences of breach of the security policies and procedures.
- 8. An overview of the Policy and Procedures for Security Breach Management and the duties and responsibilities imposed on agents in identifying, reporting, containing and participating in the investigation and remediation of security breaches.

The policy and procedures also require that quarterly security training sessions be formalized and standardized and address the following topics at minimum:

- 1. Review of the security governance and accountability framework.
- 2. Review of the nature of physical and technical security controls implemented.
- 3. Discussion of continued adequacy of security controls with regard to emerging technologies and best practices.
- 4. Review of recent breaches of security with respect to CytoBase (if any).
- 5. Review and discussion of recent breaches of security in the industry (case studies) as reported through the Office of the Information and Privacy Commissioner, Ontario, or other authorities in Canada or the U.S.
- 6. Discussion regarding specific security policies or procedures arising from questions, or recommendations resulting from privacy impact assessments, security audits, threat risk analyses, security complaints or security breach reports.
- 7. Discussion regarding any changes to the Act and its regulations or recent orders issued by the Office of the Information and Privacy Commissioner, Ontario that may impact on the security program.
- 8. Review and discussion of specific policies and procedures applying to specific agent roles.
- 9. Review and discussion of new or amended policies and procedures since the last training session, if any.

The policy and procedures regarding security awareness training require that each individual sign an attendance sheet at each training session (initial, quarterly, or special) and that the attendance sheets be retained in perpetuity in Inscyte's privacy document archives. The policy designates the Privacy officer as being responsible for tracking attendance and maintaining the training attendance log accurate and up-to-date.

The process of tracking attendance consists of printing an attendance sheet for each training session. The attendance sheet consists of the date of the training session, the type of session (initial, routine quarterly, or special) and, in the case of initial or special training, the names of the designated attendees; otherwise for routine quarterly training sessions a complete list of all agents of Inscyte.

At the conclusion of the training session each attendee is required to sign beside their name on the attendance sheet. After all attendees have signed, the sheet is verified and sign-off by the



Privacy Officer or Security Officer. The attendance sheet is then scanned into a computer image file and placed in the privacy document archives. In addition the cumulative number of sessions attended by each agent since the start of his/her engagement is maintained. Further, the content (slide show & any handouts) of each training session is retained. The policies designate the Privacy Officer as being responsible for maintain this documentation in Inscyte's privacy document archives.

Beyond the requirements of Inscyte's policy and procedures regarding security awareness training, AIM Inc., as a software engineering firm working in the healthcare domain, with many customers who are health information custodians across Canada and the U.S., promotes a culture of sensitivity to security issues on a daily basis by encouraging all staff to be vigilant of hazards and practices that may place secured assets at risk and to report these openly for discussion and remediation. AIM communicates this culture of sensitivity by sending email updates with news of recent privacy/security breaches in the healthcare industry and changes to legislation and/or practices as these occur. In addition, privacy matters are discussed at weekly management meetings as part of operations reports.

Inscyte requires its agents to comply with its policies and procedures regarding security awareness training and designates the Privacy Officer as being responsible for monitoring and ensuring compliance. The policy and procedures set out the consequences of breach. Inscyte's policy and procedures in respect of security audits stipulate that compliance will be audited at minimum on an annual basis and through random spot checks, and that it is the responsibility of the Security Officer to initiate security audits at the prescribed intervals.

Inscyte's privacy policies require agents of Inscyte to notify Inscyte at the first reasonable opportunity, in accordance with the Policies and Procedures for Security Breach Management, if an agent breaches or believes there may have been a breach of this policy or its procedures.

### 4. Log of Attendance at Initial Security Orientation and Ongoing Security Training

Inscyte Corporation maintains a log of the attendance of agents at initial security awareness training, ongoing quarterly security training and special training sessions. The log includes the name of the individual, the date that the individual attended security training and the type of training session (initial, quarterly, or special).

# 5. Policy and Procedures for the Execution of Confidentiality Agreements by Agents

Inscyte's policy states that its agents shall be required to execute a signed and witnessed *Personal Health Information Confidentiality and Non-Disclosure Agreement* in accordance with the minimum content standard of the template confidentiality agreement.



The policy further requires that *Personal Health Information Confidentiality and Non-Disclosure Agreements* are to be executed before the start of employment or contract, prior to giving the individual access, if any, to personal health information, and that the agreements survive the duration of employment or contract.

The policy states that is the responsibility of the Privacy Officer to ensure that all agents of Inscyte who may reasonably be expected to work with personal health information have a signed and witnessed *Personal Health Information Confidentiality and Non-Disclosure Agreement* in effect.

The policy does not require *Personal Health Information Confidentiality and Non-Disclosure Agreements* to be re-executed on an annual basis but states that should the standard template agreement be amended, all current agents shall be required to re-execute the new amended agreement.

The process of obtaining signed and witnessed *Personal Health Information Confidentiality and Non-Disclosure Agreements* consists of presenting each agent with an engagement package that includes the pre-printed standard confidentiality agreement. The individual is given time to read and understand the agreement. Any questions or concerns are addressed, including an explanation of the privacy and security program as required. The individual must execute the agreement as a condition of engagement. After the individual signs the agreement it must be dated and witnessed. One copy of the agreement is given to the individual and another copy is retained in the privacy document archives.

The policy and procedures also require a log of executed *Personal Health Information Confidentiality and Non-Disclosure Agreements* to be maintained and designate the Privacy Officer as being responsible for maintaining this log. The policies require that documentation related to the execution of confidentiality agreements be retained in Inscyte's privacy document archives and designate the Privacy Officer as being responsible for ensuring the documents are retained.

Inscyte requires its agents to comply with its policies and procedures regarding execution of confidentiality agreements and designates the Privacy Officer as being responsible for monitoring and ensuring compliance. The policy and procedures set out the consequences of breach. Inscyte's policy and procedures in respect of privacy audits stipulate that compliance will be audited at minimum on an annual basis and that it is the responsibility of the Privacy Officer to initiate privacy audits at the prescribed intervals.

Inscyte's security policies require agents of Inscyte to notify Inscyte at the first reasonable opportunity, in accordance with the Policies and Procedures for Security Breach Management, if an agent breaches or believes there may have been a breach of this policy or its procedures.



### 6. Template Confidentiality Agreement with Agents

Inscyte's policy states that its agents who may reasonably be expected to work with personal health information to execute a signed and witnessed *Personal Health Information Confidentiality and Non-Disclosure Agreement* (the agreement) addressing Inscyte's minimum content standard as set out below.

#### **General Provisions**

The agreement provides a definition of personal health information in accordance with the Act and its regulations.

The agreement identifies Inscyte Corporation as a prescribed person under the Act and describes the duties and responsibilities arising from this status.

The agreement states that the individuals executing the agreement are agents of Inscyte in respect of personal health information and describes the duties and responsibilities associated with this status.

The agreement requires agents to comply with the provisions of the Act and its regulation relating to prescribed persons or prescribed entities, as the case may be, and with the terms of the agreement as may be amended from time to time.

The agreement requires the agent to acknowledge that he/she has read, understood and agrees to comply with the Inscyte's Privacy & Security Policies and Procedures as implemented and as may be amended from time to time following the execution of the agreement.

#### *Obligations with Respect to Collection, Use and Disclosure of Personal Health Information*

The agreement stipulates that any and all collection, use, disclosure, transfer and/or disposal of personal health information by agents on behalf of Inscyte shall be in compliance with Inscyte's *Privacy Code* and its *Privacy & Security Policies and Procedures* and the limitations, conditions and/or restrictions imposed therein.

The agreement prohibits agents from collecting, using or disclosing personal health information if other information will serve the purpose and from collecting, using or disclosing more personal health information than is reasonably necessary to meet the purpose.

#### Termination of the Contractual, Employment or Other Relationship

In accordance with policies for actions to be taken at the termination of employment, contract, or other relationship, the agreement requires agents to surrender any and all records of personal health information in their possession, in printed format or on portable media, prior to termination, and to return all identification cards, access cards and/or keys, on or before the



date of termination. The agreement further permits inspection of an agent's place(s) of work and any personal mobile devices to ensure that no personal health information remains in the individual's possession.

#### Notification

The agreement requires the agent to notify the Privacy Officer at the first reasonable opportunity if the agent breaches or believes that there may have been a breach of the agreement or if the agent breaches or believes that there may have been a breach of Inscyte's Privacy & Security Policies and Procedures.

#### *Consequences of Breach and Monitoring Compliance*

The agreement states that compliance with the agreement and the Privacy & Security Policies and Procedures is monitored and audited by the Privacy Officer and Security Officer and that a breach of the agreement, a breach of privacy or a breach of security may result in the termination of employment or contract. The agreement also stipulates that unauthorized disclosure or inappropriate use of personal health information may also result in legal action taken by affected parties against the agent.

#### 7. Log of Executed Confidentiality Agreements with Agents

Inscyte Corporation policies and procedures require maintaining a log of confidentiality agreements that have been executed by agents of Inscyte. The log includes the name of the individual, the date of commencement of employment or contract, and the dates that *Personal Health Information Confidentiality and Non-Disclosure Agreements* were executed by each individual.

### 8. Job Description for the Position(s) Delegated Day-to-Day Authority to Manage the Privacy Program

Inscyte's privacy policy designates the position of "Privacy Officer" as having day-to-day authority to manage the privacy program. The Privacy Officer of Inscyte's agent AIM Inc. is the acting Privacy Officer of Inscyte Corporation.

The job description specifies that the Privacy Officer of Inscyte reports to the President of Inscyte. The job description specifies that Privacy Officer is responsible for the following:

- Developing, implementing, reviewing and amending privacy policies, procedures and practices;
- Ensuring compliance with the privacy policies, procedures and practices implemented;
- Ensuring transparency of the privacy policies, procedures and practices implemented;
- Facilitating compliance with the Act and its regulation;
- Ensuring agents are aware of the Act and its regulation and their duties thereunder;



- Ensuring agents are aware of the privacy policies, procedures and practices implemented by Inscyte Corporation and are appropriately informed of their duties and obligations thereunder;
- Directing, delivering or ensuring the delivery of the initial privacy orientation and the ongoing privacy training and fostering a culture of privacy;
- Conducting, reviewing and approving privacy impact assessments;
- Receiving, documenting, tracking, investigating, remediating and responding to privacy complaints pursuant to the Policy and Procedures for Privacy Complaints;
- Receiving and responding to privacy inquiries pursuant to the Policy and Procedures for Privacy Inquiries;
- Receiving, documenting, tracking, investigating and remediating privacy breaches or suspected privacy breaches pursuant to the Policy and Procedures for Privacy Breach Management; and
- Conducting privacy audits pursuant to the Policy and Procedures In Respect of Privacy Audits.
- Monitoring privacy industry standards and developments, including orders and recommendations of the Office of the Information and Privacy Commissioner, Ontario, and bringing forth recommendations to ensure Inscyte's privacy program keeps pace with evolving best practices.

# 9. Job Description for the Position(s) Delegated Day-to-Day Authority to Manage the Security Program

Inscyte's privacy policy designates the position of "Security Officer" as having day-to-day authority to manage the security program. The Security Officer of Inscyte's agent AIM Inc. is the acting Security Officer of Inscyte Corporation.

The job description specifies that the Security Officer of Inscyte reports to the President of Inscyte. The job description specifies that Security Officer is responsible for the following:

- Developing, implementing, reviewing and amending security policies, procedures and practices;
- Ensuring compliance with the security policies, procedures and practices implemented;
- Ensuring agents are aware of the security policies, procedures and practices implemented by Inscyte Corporation and are appropriately informed of their duties and obligations thereunder;
- Directing, delivering or ensuring the delivery of the initial security orientation and the ongoing security training and fostering a culture of information security awareness;
- Receiving, documenting, tracking, investigating and remediating information security breaches or suspected information security breaches pursuant to the Policy and Procedures for Information Security Breach Management; and



- Conducting security audits pursuant to the Policy and Procedures In Respect of Security Audits.
- Monitoring industry standards and best practices with respect to technical, physical and environmental security controls, orders and recommendations of the Office of the Information and Privacy Commissioner, Ontario, and bringing forth recommendations to ensure Inscyte's security program keeps pace with evolving technology and best practices.

## 10. Policy and Procedures for Termination or Cessation of Employment or Contractual Relationship

Inscyte's policies and procedures require its agents to notify Inscyte of the termination of employment, contract or other relationship. The policy requires that the Privacy Officer be notified in writing identifying the agent who ceased to be employed or contracted, the date of the termination, and acknowledgment that the individual has surrendered all personal health information in his/her possession, on portable media or on paper, that the individual's personal mobile devices (if any) do not contain any personal health information, that the individual has returned all identification cards, access cards and/or keys, and that the individual has been advised that the terms and conditions of his/her *Personal Health Information Confidentiality and Non-Disclosure Agreement remain* in force following termination. Inscyte's policies specify that such notification will be provided within ten (10) business days following the termination. In the event that the termination concerns an agent who had been granted access to personal health information in CytoBase, the policies require that the President of Inscyte be notified in the same manner and designate the Privacy Officer are being responsible to provide this notification.

The policies require the following actions to be taken upon cessation of employment, contract, or other relationship to supervise and ensure that all personal health information, identification cards, access cards and/or keys are surrendered and returned, and that all information system access accounts are deactivated:

- (a) Obtain all keys issued to the individual.
- (b) Obtain all pass cards issued to the individual.
- (c) De-activate the individual's numeric lock passwords.
- (d) De-activate the individual's computer network access account(s).
- (e) De-activate the individual's application access account(s).
- (f) Check the individual's computer workstation(s) and mobile devices (if any) for the presence of personal health information.
- (g) Archive or destroy any PHI found on the individual's computer(s) or mobile devices.
- (h) Check the individual's physical workspace for any portable media or printed information that may contain personal health information and either archive these in a secure location or dispose of (destroy) the personal health information.



The policy designates the Security Officer as being responsible for ensuring the above actions are carried out and as the agent to whom personal health on portable media or paper records, identification cards, access cards and/or keys should be returned.

The policy further requires that upon termination all related privacy and security documentation, such as the *Log of Individuals Having Access to Premises*, the *Log of Accounts Having Access to PHI*, and the *Log of Authorized Personnel* who have been granted access to CytoBase information, to be updated to reflect the termination and de-activation of access rights. The policies specify that it is the responsibility of the Security Officer to ensure that the documentation is updated within ten (10) business days following the termination and to advise the Privacy Officer of same so that notification can be forwarded to the President of Inscyte.

Inscyte Corporation requires its agents to comply with its policy and procedures regarding cessation of employment or contractual relationships and designates the Privacy Officer as being responsible for monitoring and ensuring compliance. The policies and procedures set out the consequences of breach. Inscyte's policy and procedures in respect of privacy audits stipulate that compliance will be audited at minimum on an annual basis and that it is the responsibility of the Privacy Officer to initiate privacy audits stipulate that compliance will be audited at minimum on an annual basis and that it is the audited at minimum on an annual basis and that it is the responsibility of the Privacy Officer to fecurity audits stipulate that compliance will be audited at minimum on an annual basis and through random spot checks, and that it is the responsibility of the Security Officer to initiate security audits at the prescribed intervals.

Inscyte's policies and procedures require its agents to notify Inscyte at the first reasonable opportunity, in accordance with the Policy and Procedures for Privacy Breach Management and/or the Policy and Procedures for Information Security Breach Management, if an agent breaches or believes there may have been a breach of this policy or its procedures.

### **11.** Policy and Procedures for Discipline and Corrective Action

Inscyte's policy for discipline and corrective action in respect of personal health information requires its agents to take corrective actions in accordance with its policies and procedures to remedy non-compliance with Privacy & Security Policies and Procedures.

The policy states that in the event of an incident of non-compliance, it is the responsibility of the Privacy Officer to investigate the incident by:

 Interviewing the individual(s) involved to ascertain the circumstances and reasons surrounding the non-compliance. In particular, to determine whether the noncompliance was intentional or accidental and whether or not the individual(s) had been aware of the policies and procedures that were breached.



- 2. Assessing the severity and consequences of the non-compliance. In particular, determining if the non-compliance had or could have resulted in an unauthorized disclosure or use of personal health information.
- 3. Assessing if the incident is an individual(s) first incident of non-compliance or a repeat incident.

The policy provides general guidelines for corrective actions depending on the results of the investigation as follows:

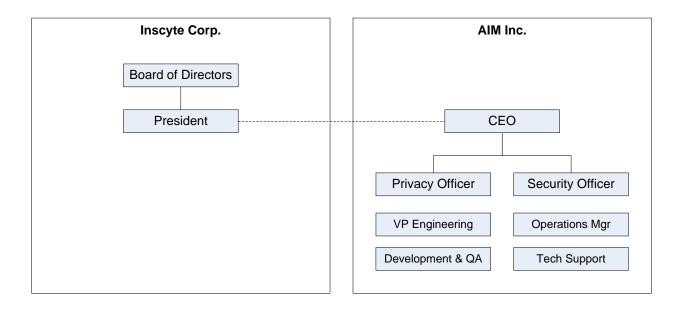
- a) If the non-compliance is a first incident, is accidental or due to a lack of awareness of policies and procedures, and unauthorized disclosure or use of personal health information did not occur, then a warning to the individual(s) and review of applicable policies and procedures is sufficient. It is the responsibility of the Privacy Officer to deliver the warning either verbally or by email and to ensure the individuals involved understand the importance of adhering to the policies and procedures and the consequences of failing to do so.
- b) If the non-compliance is a repeat incident, is accidental or due to a lack of awareness of policies and procedures, then a written warning letter to the individual(s) describing the incident, the policies and procedures that were breached, and a warning that further non-compliance may result in disciplinary action is to be prepared for each individual involved. It is the responsibility of the Privacy Officer to prepare the letter, serve the letter to the individual(s) and notify the President of Inscyte that such a warning was served. The policies require a copy of the letter to be retained in the privacy document archives.
- c) If the non-compliance was determined to be intentional, or a repeat incident following a previous written warning letter, or has resulted in the unauthorized disclosure or use of personal health information, the matter is to be immediately referred to the President of Inscyte and to agents of Inscyte for determination of appropriate disciplinary actions, which may include termination of employment, contract or other relationship.

## Part 4 – Organizational and Other Documentation

#### 1. Privacy Governance and Accountability Framework

Inscyte Corporation's Privacy and Security Program is implemented and managed by its agent AIM Inc., under contract to Inscyte Corporation for the day-to-day operations of CytoBase. AIM is responsible for ensuring compliance with the Act and its regulation in this regard and for implementing and ensuring compliance with Inscyte's privacy policies and procedures.

The privacy governance and accountability framework is depicted in the diagram below.



The privacy governance and accountability framework stipulates that the President of Inscyte Corporation is ultimately accountable for ensuring that Inscyte and its agents comply with the Act and its regulation and comply with its Privacy Code and its Privacy Policies and Procedures. The President of Inscyte is accountable to the Board of Directors of Inscyte Corporation, which is comprised of representatives from the member laboratories (health information custodians) that provide personal health information to CytoBase.

The Privacy Officer of Inscyte's agent AIM Inc. has been delegated day-to-day authority to manage the privacy program and as such is the acting Privacy Officer of Inscyte. The Privacy Officer reports directly to the CEO of AIM Inc. The CEO of AIM is accountable to the President of Inscyte Corporation in regards to fulfilling AIM's obligations with respect to implementing and managing Inscyte's privacy program.

The Privacy Officer is supported by AIM's Vice-President of Engineering and Operations Manager, who are authorized to delegate work to software development, quality assurance, technical support, and human resource departments.



The role of Inscyte's Board of Directors in respect of the privacy program is to review and approve of changes brought before the Board by the President of Inscyte. The Board may also request an update on the privacy program from the President on a regular or ad hoc basis, but at the minimum, the Board is updated on an annual basis. The update addresses the initiatives undertaken by the privacy program including privacy training and the development and implementation of privacy policies, procedures and practices. It also includes a discussion of privacy audits and privacy impact assessments conducted, including the results of and recommendations arising from the privacy audits and privacy impact assessments and the status of implementation of the recommendations. The Board of Directors is also advised of any privacy breaches and privacy complaints which were investigated, including the results of and any recommendations. The privacy program is not currently overseen by a committee of the Board of Directors.

The privacy governance and accountability framework is documented in Inscyte's privacy document archives and is communicated to agents of Inscyte by the Privacy Officer as part of initial privacy training and on-going privacy awareness training.

### 2. Security Governance and Accountability Framework

Inscyte Corporation's Privacy and Security Program is implemented and managed by its agent AIM Inc., under contract to Inscyte Corporation for the day-to-day operations of CytoBase. AIM is responsible for ensuring compliance with the Act and its regulation in this regard and for implementing and ensuring compliance with Inscyte's security policies and procedures.

The security governance and accountability framework stipulates that the President of Inscyte Corporation is ultimately accountable for ensuring that Inscyte and its agents comply with the Act and its regulation and comply with its Security Policies and Procedures. The President of Inscyte is accountable to the Board of Directors of Inscyte Corporation, which is comprised of representatives from the member laboratories (health information custodians) that provide personal health information to CytoBase.

The Security Officer of Inscyte's agent AIM Inc. has been delegated day-to-day authority to manage the security program and as such is the acting Security Officer of Inscyte. The Security Officer reports directly to the CEO of AIM Inc. The CEO of AIM is accountable to the President of Inscyte Corporation in regards to fulfilling AIM's obligations with respect to implementing and managing Inscyte's security program.

The Security Officer is supported by AIM's Vice-President of Engineering and its Operations Manager, who are authorized to delegate work to software development, quality assurance, technical support, and human resource departments.

The role of Inscyte's Board of Directors in respect of the security program is to review and approve of changes brought before the Board by the President of Inscyte. The Board may also request an update on the security program from the President on a regular or ad hoc basis, but

at the minimum, the Board is updated on an annual basis. The update addresses the initiatives undertaken by the privacy program including privacy training and the development and implementation of privacy policies, procedures and practices. It also includes a discussion of privacy audits and privacy impact assessments conducted, including the results of and recommendations arising from the privacy audits and privacy impact assessments and the status of implementation of the recommendations. The Board of Directors is also advised of any privacy breaches and privacy complaints which were investigated, including the results of and any recommendations arising from these investigations and the status of implementation of the recommendations. The security program is not currently overseen by a committee of the Board of Directors.

The security governance and accountability framework is documented in Inscyte's privacy document archives and is communicated to agents of Inscyte by the Security Officer as part of initial security training and on-going security training.

### 3. Terms of Reference for Committees with Roles with Respect to the Privacy Program and/or Security Program

Inscyte does not currently have committees overseeing or having roles in the privacy or security program. In the event that such committees should be convened in the future, Inscyte shall ensure that appropriate terms of reference shall be specified for these committees identifying the membership of the committee, the chair of the committee, the mandate and responsibilities of the committee in respect of the privacy and/or the security program and the frequency with which the committee meets. The terms of reference shall also set out to whom the committee reports; the types of reports produced by the committee, if any; the format of the reports; to whom these reports are presented; and the frequency of these reports.

### 4. Corporate Risk Management Framework

Inscyte Corporation's policy requires that its agent AIM Inc. implement a risk management framework to identify, assess, mitigate and monitor risks, including risks that may negatively affect Inscyte's ability to protect the privacy of individuals whose personal health information is received, to maintain the confidentiality of that information, and to maintain the availability of the information.

Inscyte's policy requires its agent AIM to have processes in place to identify and manage risks with respect to the safeguarding of personal health information and its availability; to ensure that identified risks are communicated to the Privacy Officer and Security Officer; and to ensure that risks are recorded in a *Corporate Risk Register*, and acted upon to monitor, mitigate or obviate risks in a timely manner.

Inscyte's policies state that it is the responsibility of every agent to be vigilant of and identify circumstances that may put patient privacy and/or the safeguarding of personal health information or its availability at risk. The policies require that each identified risk is to be



reported as soon a possible to the Privacy Officer, either verbally or by email. The policies specify that it is the responsibility of the Privacy Officer to ensure that each reported risk is recorded in the *Corporate Risk Register* and that each risk is quantified in terms of the likelihood of occurrence and severity of impact (consequence) should the risk materialize. The combination of likelihood and severity are used to compute an overall threat ranking for each risk.

The risk management policy requires review of *the Corporate Risk Register* at minimum on a quarterly basis and requires acting on risks in order of ranking (from highest to lowest) for risks exceeding a specified threat rank threshold. It is the responsibility of the Privacy Officer to ensure that the *Corporate Risk Register* is reviewed and to track and ensure that risks are monitored and mitigated in accordance with this policy.

Acting on risks involves a review of each risk by AIM's Vice-President of Engineering and AIM's Operations Manager to formulate recommendations and strategies to mitigate or obviate an indentified risk. This may include recommendations to engage third-party service providers and/or outside experts. Recommendations for mitigating risks that will incur substantial expense to implement require the prior approval of the CEO of AIM and may be subject to Inscyte's policy and procedures in respect of change management.

It is the responsibility of the Privacy Officer to ensure that recommendations are recorded in the *Corporate Risk Register* including the names of agent(s) responsible for implementing the recommendations and the target date for the implementation.

The policy states that when mitigating strategies/changes are implemented, the *Corporate Risk Register* is to be updated to include a description of the mitigating strategy/change, the date of completion, and a re-assessment of the risk ranking.

### 5. Corporate Risk Register

Inscyte Corporation requires its agent AIM Inc. to maintain an on-going and perpetual *Corporate Risk Register* that records and identifies each risk identified that may negatively affect the ability of Inscyte to protect the privacy of individuals whose personal health information is received, to maintain the confidentiality of that information, and to ensure the availability of the information to authorized parties. The minimum content of the *Corporate Risk Register* is as follows:

- (a) Risk number (unique to each risk)
- (b) Date of entry
- (c) Name of person making the entry
- (d) Description of the risk
- (e) The likelihood of occurrence



- (f) The impact of occurrence
- (g) Threat rank (original)
- (h) Risk status
- (i) Recommendations for monitoring and/or mitigating the risk
- (j) The agent(s) responsible for implementing the recommendations
- (k) The target date for implementing the recommendations
- (I) The date the recommendations were implemented/completed
- (m) Threat rank after mitigation

# 6. Policy and Procedures for Maintaining a Consolidated Log of Recommendations

Inscyte Corporation policy requires its agent AIM Inc. to maintain a centralized, on-going and perpetual *Consolidated Log of Recommendations* of all recommendations arising from privacy impact assessments, threat risk assessments, privacy audits, security audits and the investigation of privacy breaches, privacy complaints and security breaches. The policy states that the *Consolidated Log of Recommendations* shall also include recommendations made by the Information and Privacy Commissioner of Ontario that must be addressed by Inscyte Corporation prior to the next review of its practices and procedures.

The policy stipulates that it is the responsibility of the Privacy Officer to ensure that the *Consolidated Log of Recommendations* is maintained accurate, complete, an and up-to-date and that the log shall be updated as required when any of the following events occur:

- (a) A Privacy Impact Assessment (PIA) is conducted
- (b) A Threat Risk Analysis (TRA) is conducted
- (c) The Corporate Risk Register is updated
- (d) A privacy/security audit is conducted
- (e) A privacy/security breach is documented
- (f) A privacy complaint is resolved
- (g) A review by the Information and Privacy Commissioner, Ontario is conducted
- (h) A logged recommendation has been addressed

The policy further states that the *Consolidated Log of Recommendations* be reviewed at minimum on a quarterly basis to ensure that the recommendations are addressed in a timely manner and designates the Privacy Officer as being responsible to initiate a review of the log.

Inscyte Corporation requires its agents to comply with its policy and procedures regarding maintaining and acting upon the *Consolidated Log of Recommendations* and designates the Privacy Officer as being responsible for monitoring and ensuring compliance. The policy and procedures set out the consequence of breach. Inscyte's policy and procedures in respect of



privacy audits stipulate that compliance will be audited at minimum on an annual basis and that it is the responsibility of the Privacy Officer to initiate privacy audits at the prescribed intervals. Inscyte's policy and procedures in respect of security audits stipulate that compliance will be audited at minimum on an annual basis and through random spot checks, and that it is the responsibility of the Security Officer to initiate security audits at the prescribed intervals.

Inscyte's policies and procedures require its agents to notify Inscyte at the first reasonable opportunity, in accordance with the Policy and Procedures for Privacy Breach Management and/or the Policy and Procedures for Information Security Breach Management, if an agent breaches or believes there may have been a breach of this policy or its procedures.

### 7. Consolidated Log of Recommendations

Inscyte Corporation's policy requires its agent AIM Inc. to maintain an on-going and perpetual *Consolidated Log of Recommendations* of all recommendations arising from privacy impact assessments, threat risk assessments, privacy audits, security audits, the investigation of privacy breaches, the investigation of privacy complaints, the investigation of information security breaches and reviews by the Information and Privacy Commissioner of Ontario. The policy requires the log to contain the following information at minimum:

- (a) Recommendation number (unique to each recommendation)
- (b) Date of entry
- (c) The name of the person making the entry
- (d) Recommendation status
- (e) Type of action giving rise to the recommendation (e.g. audit, breach, TRA etc.)
- (f) Date of the action giving rise to the recommendation
- (g) References to supporting documents
- (h) Summary of the recommendation
- (i) The actions to be taken to address the recommendation
- (j) The agents responsible for carrying out these actions
- (k) The target date these actions are to be completed
- (I) The actual date the actions were completed

## 8. Business Continuity and Disaster Recovery Plan

Inscyte Corporation's policy requires that its agent AIM Inc. develop and implement policies and procedures to protect and ensure the continued availability of CytoBase in the event of short and long-term business interruptions, and in the event of threats to the operating capabilities of CytoBase arising from natural, human, environmental and technical disruptions. Since CytoBase is hosted, operated and maintained by AIM within its computing environment, it is covered by AIM's business continuity and disaster recovery plan.

AIM's policies and procedures in respect of operating and maintaining its datacenter specify the measures required to detect and warn against threats, outages, or potential outages, arising



from power failures, equipment failures, environmental threats (fire, water or excessive heat), network intrusions and physical break-ins. It is the responsibility of AIM's Operations Manager to ensure that such alarms and warning systems are in place and functional at all times except for scheduled maintenance.

AIM's policies require specific personnel to be contacted, by telephone, at the first available opportunity, whenever an alarm or warning system is activated. To this end, AIM maintains hierarchical lists of AIM personnel to be contacted for each type of alarm or warning system and designates the Operations Manager as being responsible for maintaining these lists accurate and up-to-date.

Upon warning or discovery of a threat, outage, or a potential outage, the policy states that it is the responsibility of AIM's Operations Manager to assess the extent and severity of the incident and to notify the CEO, Privacy Officer and Security Officer of AIM about the incident at the first available opportunity either verbally or by email. The policy specifies that the criteria for assessing the severity of a threat or outage must include estimating the likelihood that an interruption to normal operations will occur, the duration of such an interruption, the potential for loss/damage to assets or security controls, and the potential for a security or privacy breach occurring as a result of the threat or outage.

The policies further require an assessment to be made to determine if a breach of privacy has occurred, or is likely to occur, as a result of the threat, outage, or a potential outage. The policies set out the assets to be examined in making this determination and designate the Operations Manager as being responsible for inspecting the assets and reporting the findings to the Privacy Officer for a final determination. In the event that a breach of privacy has, or is suspected to have occurred, then the policy requires that Inscyte Corporation's procedures in respect of Privacy Breach Management shall also take effect.

The policies also require that an assessment be made to determine if a breach of security has occurred in relation to the threat or outage. The policies set out the assets to be examined in making this determination and designate the Operations Manager as being responsible for inspecting the assets and reporting the findings to the Security Officer for a final determination. In the event that a breach of security has, or is suspected to have occurred, then the policy requires that Inscyte Corporation's procedures in respect of Security Breach Management shall also take effect.

In the event that an unplanned outage occurs, AIM's policy requires the Manager of Operations to investigate the outage in detail and prepare a written *Outage Report* containing:

- a) The date of the outage
- b) Description of the outage
- c) Identification of affected assets



- d) Indication if a breach of privacy or security has occurred
- e) Assessment of the cause of the outage
- f) Recommended actions to restore operations
- g) Estimated time and cost to restore operations
- h) The agent(s) responsible for carrying out the actions to restore operations

AIM's policies require that this report be provided to the CEO and Vice-President of Engineering of AIM as soon as possible following an outage, and that in the event that the costs of repairs shall exceed a prescribed threshold, the CEO of AIM is required to provide approval to proceed.

In respect of CytoBase, the business continuity and disaster recovery plan requires that the President of Inscyte and all affected stakeholders of Inscyte shall be notified of an outage in the event that the estimated time to remedy the outage and restore operations exceeds or is likely to exceed twelve (12) hours. In this case, it is the responsibility of the Operations Manager of AIM to ensure that notification is sent via email to designated contacts of each stakeholder describing the outage, actions being taken to remedy the outage and the estimated date (and time if applicable) of restoration. In support of this requirement AIM maintains a list of stakeholders and contact information. It is the responsibility of the Operations Manager to ensure that this list is maintained accurate and up-to-date.

AIM's business continuity and disaster recovery plan designates AIM's Operations Manager as being responsible for conducting an impact assessment of an interruption or threat, including its impact on the technical and physical infrastructure and the operational processes of CytoBase. The plan requires the impact assessment to take into consideration the duration of an interruption, the potential for loss/damage to assets or security controls, and the potential for a security or privacy breach occurring. The plan prescribes that the Operations Manager may engage AIM's engineering and technical resources and/or third-party service providers or vendors as may be required to complete the impact assessment. The plan requires the Operations Manager to report the results of the impact assessment in writing to the CEO of AIM Inc.

AIM's business continuity and disaster recovery plan designates AIM's Operations Manager as being responsible for conducting and preparing a detailed damage assessment in order to evaluate the extent of the damage caused by a threat or interruption and the expected effort required to resume, recover and restore infrastructure elements, information systems and/or services related to CytoBase. The plan requires the damage assessment to take into consideration all assets affected by the interruption or threat. The plan prescribes that the Operations Manager may engage AIM's engineering and technical resources and/or third-party service providers or vendors as may be required to complete the damage assessment. The plan requires the Operations Manager to report the results of the damage assessment in writing to the CEO and the Vice-President of Engineering of AIM Inc.



Inscyte Corporation designates AIM Inc. as being responsible for recovery from a threat or outage of CytoBase. AIM's business continuity and disaster recovery plan designates AIM's Operations Manager as being responsible for taking all appropriate actions to recover from a threat or outage and resume normal operations of CytoBase. The plan includes the priority in which business functions should be restored, instructions and procedures for recovery of each hardware and software asset, and the order in which these assets must be restored in accordance with asset dependencies. The plan prescribes that the Operations Manager may engage AIM's engineering and technical resources and/or third-party service providers or vendors as may be required to complete the recovery. The plan requires that the Operations Manager submit a recovery plan to the CEO of AIM Inc. for approval before taking actions to recover from a threat or outage. Inscyte Corporation is not required to provide prior approval for actions taken by AIM Inc. to restore normal operations of CytoBase following a threat or outage unless such actions qualify as a change requiring Inscyte's prior approval in accordance with Inscyte's Policy and Procedures in respect of Change Management.

In support of actions to be taken to recover from a threat or outage AIM Inc. maintains comprehensive and detailed *Asset Inventory and Configuration Documentation* that includes all critical applications and business functions, hardware and software components, software licenses, vendor information, recovery media, ancillary equipment, system network diagrams, hardware configurations, software configurations, configuration settings for database systems and network settings for firewalls, routers, domain name servers, email servers and the like.

AIM's policies in respect of business continuity and disaster recovery designate the Operations Manager as being responsible for developing and maintaining the *Asset Inventory and Configuration Documentation* complete and up-to-date. The policy defines "critical assets" to mean without limitation software applications, supporting software, hardware, ancillary equipment, data holdings, and all third-party services that are required to enable or support AIM's core business functions and those of its customers.

AIM's business continuity and disaster recovery plan also address the testing, maintenance and assessment of the business continuity and disaster recovery measures. AIM Inc. validates the restoration procedures and asset configuration information whenever it performs a component upgrade within its computing infrastructure. This occurs on a regular basis as servers are upgraded or replaced, databases are migrated to newer versions, or other equipment, such as firewalls and routers are replaced and updated. It is the responsibility of the Operations Manager of AIM Inc. to ensure that on-going verifications of the disaster recovery plan are performed whenever the opportunity arises. If verification tests fail, the Operations Manager is required to ensure that all necessary amendments are made to the plan and its supporting documentation to resolve the deficiency. It is the responsibility of AIM's Operations Manager to approve AIM's business continuity and disaster recovery plan and any amendments thereto.



It is the responsibility of the Operations Manager of AIM to document and publish the most recent edition of AIM's Business Continuity and Disaster Recovery Plan in electronic format on AIM's business network (for internal use) and on portable media to be retained off-site. AIM's policy states that its Business Continuity and Disaster Recovery Plan will be made available to customers of AIM Inc. that are impacted by the plan, upon written request and prior approval by the CEO of AIM Inc.

# **Privacy, Security and Other Indicators**

## Part 1 – Privacy Indicators

Categories	Privacy Indicators		
	The existing policies and procedures, which had been previously divided into two sets of documents (one for Inscyte, the other for AIM Inc.) have been consolidated into one set of policies and procedures that apply to Inscyte Corporation, and by extension, AIM Inc. since AIM acts as Agent for Inscyte in respect to CytoBase.		
General Privacy Policies, Procedures and Practices	The new "Privacy & Security Policies and Procedures Manual" addresses the requirements in Appendix "B" of the IPC <i>Manual for the Review and</i> <i>Approval of Prescribed Persons and Prescribed Entities</i> as well as the recommendations made by the IPC following its review of Inscyte in 2008.		
	At this time, it is anticipated that modifications to Inscyte's public and stakeholder documents will be in place by October 31, 2011.		
	The number and type of data holdings have not changed since the last IPC review in 2008. The data holdings consist of:		
Collection	Retention Policy. As th	This is the main CytoBase database. Manual change requests (corrections). Data for linkage received from P-Prompt Data for linkage received from Healthlink Archived transmission logs CDs. Daily Backups Weekly Backups weekly Backups ord by Statement of Purpose, Permitted Use, and ne objectives of the CytoBase system have not tents have not been modified.	



ata. AIM Inc. acts as A perations and mainter ermitted to work with pecific and restricted r mployee poke, Elaine avey, Claire ito, Rudy an, Kevin	ployees that work with CytoBase patient-level agent for Inscyte with respect to the day-to-day nance of CytoBase. Only designated AIM staff are the information in CytoBase and are limited to oles. These individuals are: <b>Role</b> Follow-up letter production & distribution Cytology data QC/QA and statistics Oracle database administrator	
ooke, Elaine avey, Claire ito, Rudy an, Kevin	Follow-up letter production & distribution Cytology data QC/QA and statistics	
olabek (VP Engineerin ccess list as these indiv outine tasks and have in ytoBase is not used to bes not entertain requ ata. There have been eview in 2008. ggregated statistics ca nd Inscyte has previou	Data transmission & registration Network & server systems support Network & server systems support Application programming & troubleshooting v in 2008, Dr. Peter Brueckner (CEO) and Jack g) have been removed from the authorized viduals are not responsible for carrying out no need of access to CytoBase patient-level data. support specific research projects and Inscyte tests from principal investigators for patient-level no such research requests since the last IPC n be produced from the CytoBase information sly published statistical reports. However, no e been made since the last IPC review in 2008.	
Inscyte Corporation transfers personal health information to <b>participating laboratories</b> using encrypted electronic network data transfers. <sup>2</sup> These are automated transactions whereby a request for a patient history is sent by a laboratory to the CytoBase system (usually when a new test is requisitioned) and the patient's historical data are sent back to the laboratory in response to the request. The CytoBase system maintains an audit of all transactions. The latest available transaction counts are as follows:		
	<b>participating laboratories</b> using encrypted electronic network data transfers. <sup>2</sup> These are automated transactions whereby a request for a patient history is sent by a laboratory to the CytoBase system (usually when a new test is requisitioned) and the patient's historical data are sent back to the laboratory in response to the request. The CytoBase system maintains an audit of all transactions. The latest available	

<sup>&</sup>lt;sup>2</sup> Inscyte recognizes that transfers of personal health information to laboratories are actually "uses" of personal health information as per in the Act, and not disclosures. However, for the purpose of openness and clarity, these transfers are discussed here.

Categories	Privacy Indicators			
		4 004 1=0		
	Total Reports Processed	1,381,159		
	Total New Reports Registered	1,376,501	99.7%	
	Total New Reports Rejected	4,658	0.3%	
	Total Patient Inquiries Processed	1,418,244		
	Total Patient Histories Returned	1,183,042	83.4%	
	Total Patients not Found	235,202	16.6%	
	3,000-4,000 patient histories daily	<ul> <li>CytoBase receives about 4,000-5,000 patient inquiries daily and returns 3,000-4,000 patient histories daily (accounting for a match rate of about 80% since not all women being screened in Ontario are in CytoBase).</li> <li>Inscyte Corporation also discloses patients' most recent screening date to P-Prompt and Healthscreen upon formal request from these parties, and provides complete CytoBase data exports to CancerCare Ontario (CCO) on an on-going basis. Since the last IPC review in 2008, the following disclosures have been made:</li> </ul>		
	to <b>P-Prompt</b> and <b>Healthscreen</b> up and provides complete CytoBase of (CCO) on an on-going basis. Since			
	P-Prompt Healthscr	een C	<u>co</u>	
	May 6, 2008 Feb 8, 200		ep 2008	
	Nov 14, 2008 Mar 14, 20		ec 2008	
	May 12, 2009		lar 2009	
	Oct 29, 2009		lay 2009	
	May 10, 2010		il 2009	
	Oct 28, 2010		ct 2009	
	Apr 15, 2011		in 2010	
	Apr 13, 2011		il 2010	
			ov 2010	
			eb 2011 ın 2011	
	physicians of when to recall patier information for planning and decis	<b>P-Prompt</b> and <b>Healthscreen</b> use the disclosed information to advise physicians of when to recall patients for testing. <b>CCO</b> uses CytoBase information for planning and decision support with respect to the Ontario Cervical Cancer Screening Program.		
	Inscyte Corporation discloses pers users of the " <b>CytoBase for Clinicia</b> there were 66 registered physician total of 98 user accounts.	<b>ns</b> " online servi	ce. As at Dec 24, 2010	
	No disclosures of personal health i research purposes since the last IP			



Categories	Privacy Indicators		
	disclosed aggregate or de-identified information for research and has had no requests for such information since the last review.		
Data Sharing Agreements	Inscyte Corp. has the following data sharing agreements in place for the collection and transfer of personal health information: Laboratories (collection & transfer) 1. Canadian Medical Laboratories (CML Healthcare Inc.) 2. Lifelabs (formerly MDS Inc.) 3. Gamma-Dynacare Medical Laboratories 4. Medical Laboratories of Windsor The above entities have executed new data sharing agreements with Inscyte Corp. since the IPC review in 2008, incorporating terms and language recommended by the IPC at that time. Healthcare Service Providers (disclosure) 1. CancerCare Ontario 2. P-Prompt (Fig.P Software/Clinforma) 3. Healthscreen Solutions Inc. The above data sharing agreements have not changed since the last IPC review in 2008. Inscyte plans to update these agreements by June 30, 2012, incorporating the requirements of the new privacy policies and procedures.		
Agreements with Third Party Service Providers	Inscyte Corp. has a contractual agreement in place with <b>Artificial</b> <b>Intelligence In Medicine Inc.</b> for the on-going operations and maintenance of the CytoBase database and data collection network. This agreement has been amended since the last IPC review in 2008 to incorporate terms and language recommended by the IPC at that time.		

Categories	Privacy Indicators		
Data Linkage	Data linkages are performed for <b>P-Prompt</b> and <b>Healthscreen</b> in accordance with data sharing agreements executed with these parties. In these linkages, P-Prompt and Healthscreen provide Inscyte with lists of patients identified by Ontario health insurance number, surname, and date of birth. Inscyte performs a linkage with CytoBase and returns a matched patient's most recent screening date (see "Disclosure" above).		
	<ul> <li>P-Prompt and Healthscreen use the disclosed information to advise physicians of when to recall patients for testing. This is a patient-care related service of these organizations.</li> <li>No new data linkages have been approved since the last review by the IPC in 2008.</li> </ul>		
Privacy Impact Assessments	<ul> <li>Since the last review by the IPC in 2008:</li> <li>No new Privacy Impact Assessments have been conducted.</li> <li>No privacy impact assessments are underway and not completed.</li> <li>No new privacy impact assessments have been recommended since there have been no changes in the operational nature or infrastructure of CytoBase.</li> <li>No determinations have been made by the IPC in respect of privacy impact assessments have been reviewed.</li> </ul>		



Categories	Privacy Indicat	ors	
Categories Privacy Audit Program	Regular audits         detect potentia         For example, A         basis to find he         program was in         following audit         Audit Date         Oct 16, 2009         Nov 20, 2009         Dec 18, 2009         Jan 15, 2010         Feb 19, 2010         Mar 19, 2010         May 21, 2010         Jun 18, 2010         Jul 23, 2010         Aug 27, 2010         Sep 24, 2010         Nov 26, 2010         Jan 20, 2011         Feb 24, 2011         Mar 31, 2011	of privacy are c al breaches of p AIM scans rando ealthcare relate mplemented afi ts have been pe <b>Computer</b> MM YZ SJ BPC IS JC VB KH TPC 401 BPC NM JX SP SJ MS	Result Pass -No PHI found Pass -No PHI found Fail (HL7 files containing PHI) Pass-No PHI found Fail (HL7 files containing PHI)
	Feb 24, 2011	SJ	Pass-No PHI found
	Apr 28, 2011	MB	Pass-No PHI found
	May 26, 2011	DG	Failed (HL7 files containing PHI)
	Jun 30, 2011	RG	Pass-No PHI found
	Aug 25, 2011	OB	Pass-No PHI found
	The failures detected <u>are not related to CytoBase</u> but to work performed by AIM for U.S. clients. In all failed instances the personal health information was deleted from the computer and the employee was reminded and instructed not to retain personal health information on his/her workstation unless it is de-identified.		
Privacy Breaches	Inscyte Corp. has not received any notifications of privacy breaches or suspected privacy breaches since the last review by the IPC in 2008.		
Privacy Complaints	Inscyte Corp. h review by the I		any privacy complaints since the last

# Part 2 – Security Indicators

Categories	Security Indicators
	The existing policies and procedures, which had been previously divided into two sets of documents (one for Inscyte, the other for AIM Inc.) have been consolidated into one set of policies and procedures that apply to Inscyte Corporation, and by extension, AIM Inc. since AIM acts as Agent for Inscyte in respect to CytoBase.
General Security Policies and Procedures	The new "Privacy & Security Policies and Procedures Manual" addresses the requirements in Appendix "B" of the IPC <i>Manual for the Review and</i> <i>Approval of Prescribed Persons and Prescribed Entities</i> as well as the recommendations made by the IPC following its review of Inscyte in 2008.
	At this time, it is anticipated that modifications to Inscyte's public and stakeholder documents will be in place by October 31, 2011.
Physical Security	Audits of physical security measures have not been performed since the last review by the IPC in 2008. In 2011, a new electronic physical security access system was installed and implemented. In 2011, upgrades to network routers, firewalls and network security were implemented.
Security Audit Program	CytoBase system control and audit logs are monitored on a daily basis by technical staff assigned to system maintenance to ascertain the state of operations and respond to possible problems. Breaches or attempted breaches of security may be detected as part of this process.
Information Security Breaches	There have been no notifications/detections of security breaches or potential security breaches since the last review by the IPC in 2008.



## Part 3 – Human Resources Indicators

Categories	Human Resource Indicators	
Categories Privacy Training and Awareness	All agents of Inscyte (ir & Security Awareness t sessions have been hel with the number of pe Oct 21, 2008 Feb 6, 2009 June 12, 2009 Oct 30, 2009 Jan 29, 2010 Oct 22, 2010 Feb 25, 2011 Jun 17, 2011 Inscyte Corporation's s session, as is the overs Inscyte. Each training s interactive quiz, which sheets are hand-signed document archives.	ncluding all employees of AIM Inc.) obtain Privacy training on a regular basis. The following training d since the last review by the IPC in 2008 together rsons in attendance at each: attendance record unavailable attendance record unavailable 23 attendees 26 attendees 26 attendees 26 attendees 26 attendees 30 attendees 30 attendees tatus under the PHIPA is re-iterated at each ight of the IPC, and AIM's staff status as agents of session is comprised of a slide show and usually takes about 30-45 minutes. Attendance d at each session and retained in the privacy
	training session, regard CytoBase or not. Desig CytoBase have received	ive received at least one privacy awareness dless of whether or not an individual has access to gnated employees of AIM Inc. who have access to d at least three training sessions.
Security Training and Awareness	Security training and awareness is conducted simultaneously with privacy training and awareness as described above.	
Confidentiality Agreements	All agents of Inscyte (including all employees of AIM Inc.) as a condition of employment, execute a signed and witnessed "Personal Health Information Confidentiality and Non-Disclosure Agreement" with respect to the handling of personal health information. These agreements refer to the Act as the prevailing legislation, the privacy & security policies and procedures, and stipulate the consequences of breach. As at September 29, 2001 thirty-two (32) agents of Inscyte (i.e. all employees of AIM Inc.) have executed agreements. These agreements are not currently re- executed on an annual basis, however, all agents are reminded of their signed agreements and obligations at Privacy & Security Awareness training sessions, which are held on a quarterly basis with all agents.	



Categories	Human Resource Indicators
Termination or Cessation	No notifications of termination have been received by Inscyte Corporation from its Agent AIM Inc. with respect to the termination of employment of an individual assigned to work with CytoBase as such terminations have not occurred since the last review by the IPC in 2008.

# Part 4 - Organizational Indicators

Categories	Organizational Indicators
Risk Management	To date, Inscyte Corporation and its agent, AIM Inc. have not implemented a corporate risk register. As this is now a requirement of the IPC, AIM will undertake to implement and maintain a risk register on behalf of Inscyte Corporation in respect to the CytoBase system in accordance with Inscyte policies. It is expected that the risk register will be in place by October 31, 2011



Categories	Organizational Indicators
Categories Business Continuity and Disaster Recovery	Organizational IndicatorsAIM's corporate disaster recovery plan incorporates the recovery ofInscyte Corporation's CytoBase system since it is hosted on AIM'scomputing infrastructure. AIM's disaster recovery plan is updated on anon-going basis in conjunction with infrastructure modifications,upgrades, or expansions.While a full scale test of the recovery plan has not been undertaken, AIMperformed an upgrade to the CytoBase computing infrastructure in late2008, moving the system to new servers, storage devices, networkrouters etc.The protocols of AIM's Disaster Recovery Plan werefollowed including the appropriation of new equipment, re-installationof all supporting software from original installation media, and a fullrestoration of the production data from backup media.The success of this process indicates that AIM's disaster recoveryprotocols are suitable to effect a restoration of the CytoBase system.
	In the event of an actual catastrophic failure, business continuity would be interrupted insofar as providing information to member laboratories and clinicians would not be possible until system restoration was complete. However, the operational requirements of the parties to whom Inscyte discloses personal health information allow for an outage of 2-4 weeks without significant impairment of services. Within the parameters and protocols of the current disaster recovery plan this provides a sufficient time frame to restore the system.