

# In Respect of CytoBase

Report to the Information and Privacy Commissioner of Ontario Three-Year Review as a Prescribed Person under *PHIPA* Year of Submission (2022)

INDICATORS

August 2, 2022

Inscyte Corporation

Dr. Allan Seidenfeld– President Jack Golabek – Privacy Officer



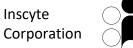
## Privacy, Security and Other Indicators

### Part 1 – Privacy Indicators

Categories	Privacy Indicators			
	that apply to Inspirata acts The "Privacy requirements <i>Approval of I</i> The privacy p September 20 reviewed at r	oration has a consolidated Inscyte Corporation, and as Agent for Inscyte in re- t & Security Policies and I in Appendix "B" of the I <i>Prescribed Persons and P</i> policies and procedures w 020, February 2021, and A egular annual privacy/sec se reviews were as follow	by extension, Inspir espect to CytoBase. Procedures Manual' PC Manual for the P Prescribed Entities. There reviewed in Feb August 2021 and con- urity review meetin	ata. since addresses the <i>Review and</i> oruary 2020, ntinue to be
	Review Date	Recommendations	Actions	Action Completed
	February 2020	No recommendations.	N/A	N/A
	September 2020	Review Privacy policy in light of Covid.	Adhere to current policy	Yes
General Privacy Policies, Procedures and Practices	February 2021	Review policy and procedures with respect to new office.	Review Privacy and Security document	Aug 2021
	August 2021	Review Training requirements during covid	Update Training	May 2022
	July 2022	Revised policy to require privacy/security training twice per year. Amended policy to permit secure cloud- based storage of backup media.	Changes to be reviewed at upcoming privacy and security policy review August 2022.	Pending
		Added policy to implement automated system monitoring and alerts.		
	Inscyte's Age	ed and/or new policy proc ent Inspirata on the date/ti en minutes and action iter	ime of each joint rev	view meeting



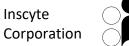
Categories	Privacy Indicators
	No changes were recommended or made to privacy policies as a result of the above reviews. Consequently, communication materials available to the public or other stakeholders were not amended as a result of these reviews.
	The next review or privacy/security procedures and practices is scheduled for August 2022
	Since the last review by the IPC in 2019 no data linkages with third parties were performed and no new data linkages were contemplated. As a result, CytoBase consist of one data holding, namely, cervical cancer screening reports performed by laboratories participating in the CytoBase program. These cervical cancer screening reports consist of:
Collection	CytoBase DatabaseThis is the main CytoBase database.CytoBase RFCManual change requests (data corrections).Archived HL7 LogsArchived report transmission logs on disk.
	These are held in accordance with the Statement of Purpose, Collection, Use, and Retention for CytoBase. CytoBase is the only data holding and no amendments have been made to the purpose of this holding since the last review by the IPC. This data holding has been reviewed by Inscyte since the last review by the IPC.
Use	Inscyte Corp. has no employees that work with CytoBase patient-level data. Inspirata acts as Agent for Inscyte with respect to the day-to-day operations and maintenance of CytoBase. Only designated members of Inspirata staff are permitted to work with the information in CytoBase and are limited to specific and restricted roles. These roles do not permit use of CytoBase PHI for research purposes. At the time of writing seven (7) staff members of Inspirata were authorized to work with CytoBase patient-level data.
	Aggregated statistics can be produced from CytoBase data. However, no statistical publications have been made since the last IPC review in 2019. Further, no requests for use of CytoBase PHI for research purposes were received or granted since the last review by the IPC in 2019.
Turneformul Dist	Inscyte Corporation discloses personal health for non-research purposes to the following entities under the terms and conditions of their respective data sharing agreements:
Transfer and Disclosure	<ol> <li>Patient test results are disclosed to Ontario Health on a daily basis for the purposes of the Ontario Cervical Cancer Screening Program.</li> </ol>



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Categories	Privacy Indicators
	<ol> <li>Patient test results are disclosed on an ad-hoc real-time basis to participating medical laboratories for the purpose of improving quality in the interpretation of new test specimens and for ensuring patients with abnormal screening results are followed-up appropriately.</li> <li>Patient test results are disclosed ad-hoc to registered authorized users of the "CytoBase for Clinicians" online service for the purpose of improving patient care.</li> </ol>
	Outside of the above modalities, no other requests for the disclosure of personal health information for non-research purposes were received by Inscyte since the last IPC review in 2019.
	No new third-party data sharing agreements have been executed since the IPC review in 2019.
	Inscyte did not receive requests for disclosure of personal health information for research purposes, and no disclosures of personal health information have been made for research purposes since the last IPC review in 2019.
	Inscyte did not receive requests for aggregate and/or de-identified information and has not disclosed aggregate or de-identified information for research since the last IPC review in 2019 and has not entered into any research agreements.
	As there were no disclosures of aggregate and/or de-identified information, Inscyte has had no acknowledgements or agreements from persons to whom such information was disclosed since the last review by IPC in 2019.
	Inscyte Corp. has the following data sharing agreements in place for the collection, use and disclosure of personal health information (there is only one agreement in effect per organization).
Data Sharing Agreements	<ul> <li>Laboratories (collection &amp; transfer)</li> <li>1. LifeLabs</li> <li>2. Dynacare Health</li> <li>3. Medical Laboratories of Windsor</li> </ul>
	These agreements have not changed since the IPC review of 2019 and remain in effect.
	Healthcare Service Providers (disclosure/use) 1. Ontario Health



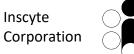
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Categories	Privacy Indicators
	The data sharing agreement with Ontario Health has not changed since the IPC review of 2019 and remains in effect. No new data sharing agreements have been executed between Inscyte and third parties since the last review by the IPC in 2019.
Agreements with Third Party Service Providers	Inscyte Corp. has a contractual agreement in place with <b>Inspirata</b> <b>Canada Inc.</b> for the on-going operations and maintenance of the CytoBase database and data collection network. This agreement has not changed since the last IPC review in 2019. This is the only third-party service agreement that Inscyte Corporation has in effect.
Data Linkage	No data linkages have been performed, requested or approved since the last review by the IPC in 2019.
	The most recent Privacy Impact Assessment (PIA) was conducted and completed October 31, 2013. This PIA focused on the CytoBase system and database. No recommendations for changes were made as the privacy and security controls, policies and procedures in place were deemed adequate and appropriate.
Privacy Impact Assessments	Review of the existing Privacy Impact Assessment was conducted at each annual privacy and security review meeting in February 2020, September 2020, February 2021, and August 2021. After each review a determination was made that further PIAs were not required as the operational infrastructure of CytoBase, and the collection, use and disclosure of CytoBase information had not changed and did not warrant a new or revised PIA. As such, since the last review by IPC in 2019:
	<ul> <li>No new PIAs were completed</li> <li>No PIAs were undertaken but not completed</li> <li>No new PIAs have been scheduled</li> </ul>



<ol> <li>Data</li> <li>Staff</li> <li>Risk</li> <li>Busin</li> <li>Requi</li> <li>Requi</li> <li>Agree</li> </ol>	Register (review/ident ness Continuity Plan (I uirements for updates to uirements for updates to ements	ments ification/resolution Disaster Recovery) D TRA/PIA D Data Sharing and	n of risks) 1 Third-Party
iews of a ducted by tember 2( ewed at r ilts of the lits of Ag	gents granted approval V Inscyte and its agent 1 020, February 2021, an regular annual privacy/ se reviews were as foll ents Granted Approval	to access and use Inspirata in Februa Id August 2021 and security review me ows: to Access and Use	PHI were ry 2020, d continue to be eetings. The
ite			Completed
b 2020	No recommended changes	N/A	N/A
pt 2020	No recommended	N/A	N/A
b 2021	No recommended changes.	N/A	N/A
ig 2021	No recommended changes.	N/A	N/A
	<ul> <li>13. Staff</li> <li>14. Risk</li> <li>15. Busi</li> <li>16. Requ</li> <li>17. Requ</li> <li>17. Requ</li> <li>18. Consi</li> <li>iews of a</li> <li>ducted by</li> <li>tember 20</li> <li>tember 20</li></ul>	<ul> <li>13. Staff Confidentiality Agree</li> <li>14. Risk Register (review/ident)</li> <li>15. Business Continuity Plan (I</li> <li>16. Requirements for updates to Agreements for updates to Agreements</li> <li>18. Consolidated Log of Reconsidered by Inscyte and its agent I at the service and its agent I at the service and its agent I at the service and the service as foll the service and the service as foll the service and the service as foll the service and the service as foll the service as foll the service as foll to a service as following as a se</li></ul>	<ul> <li>13. Staff Confidentiality Agreements</li> <li>14. Risk Register (review/identification/resolution</li> <li>15. Business Continuity Plan (Disaster Recovery)</li> <li>16. Requirements for updates to TRA/PIA</li> <li>17. Requirements for updates to Data Sharing and Agreements</li> <li>18. Consolidated Log of Recommendations (actioniews of agents granted approval to access and use ducted by Inscyte and its agent Inspirata in Februatember 2020, February 2021, and August 2021 and ewed at regular annual privacy/security review method at regular annual privacy/security review method to these reviews were as follows:</li> <li>15. Staff Confidentiality Plan (Disaster Recommended N/A changes.</li> <li>16. On recommended N/A changes.</li> <li>17. Requirements for updates to Data Sharing and Agreements</li> <li>18. Consolidated Log of Recommended N/A changes.</li> <li>19. 2021 No recommended N/A changes.</li> </ul>



	Other than Inspirata, there are no other agents granted approval to access and use personal health information. Further, Inscyte's agent Inspirata is not granted approval to access and use personal health information; rather, certain designated staff of Inspirata are permitted to access PHI only as necessary for purposes of troubleshooting, quality control and system maintenance of CytoBase.
	Recommendations resulting in changes to policies and procedures are reflected in updates to Inscyte's "Privacy & Security Policies and Procedures Manual" and are communicated to its Agent Inspirata by the privacy officer and security officer via email notification and at the next scheduled privacy/security training and awareness session (held quarterly). The date of notification is noted in the policy description as the new or updated policy came into effect (the effective date).
	Inscyte's Agent Inspirata performs a privacy spot-audit every month to monitor and detect potential breaches of privacy within its operating environment. The audit program consists of scanning randomly selected workstations, laptops, and servers on a monthly basis to detect healthcare related data containing patient identifiers which may have been inadvertently stored in inappropriate locations. In addition to audits of workstation and server data files, Inspirata technicians also review server process logs and firewall activity logs on a weekly basis to detect intrusion attempts and potential breaches of security or privacy.
	A log is maintained of all computer scans, the date of the scan, the person performing the scan and the results of the scan.
	The results of the above privacy audits have revealed no significant vulnerabilities or breaches of privacy that would require specific recommendations or actions to be taken. The results are reviewed at annual privacy/security review meetings to decide on measures to be taken, if any, and are recorded in the recommendations and actions items of the minutes of the meeting.
Privacy Breaches	Inscyte Corp. has not received any notifications of privacy breaches or suspected privacy breaches since the last review by the IPC in 2019.
Privacy Complaints	Inscyte Corp. has not received any privacy complaints since the last review by the IPC in 2019.



#### Part 2 – Security Indicators

Categories	Security Ind	licators		
	that apply to Inspirata act The "Privac requirement <i>Approval of</i> The security September 2 reviewed at following is	poration has a consolidated o Inscyte Corporation, and is as Agent for Inscyte in r y & Security Policies and s in Appendix "B" of the I <i>Prescribed Persons and F</i> policies and procedures v 2020, February 2021, and a regular annual privacy/sec a summary of recommend d actioned since the last IP	by extension, Inspir espect to CytoBase. Procedures Manual" PC Manual for the I Prescribed Entities. vere reviewed in Feb August 2021 and con- curity review meeting lations made, comm	ata since addresses the <i>Review and</i> oruary 2020, ntinue to be gs. The
	Review	Recommendations	Actions	Action
	Date Feb 2020	Add additional servers and desktops to quarterly scans	Review	Completed Completed
	Sept 2020	Keep BCP updated	Updated	Completed
	Feb 2021	No recommendations	N/A	N/A
General Security Policies	Aug 2021	No recommendations	N/A	N/A
and Procedures	July 2022	Amended policy to require privacy/security training twice per year. Amended policy to permit secure cloud- based storage of backup media.	Changes to be reviewed at upcoming privacy and security policy review August 2022.	Pending
		Added policy to implement automated system monitoring and alerts.		
	Each amended and/or new policy procedure was communicated to Inscyte's Agent Inspirata on the date/time of each joint review meeting through written minutes and action items recorded at each meeting.			
	Inscyte's Privacy & Security Policies and Procedures manual was last amended on July 25, 2022 for internal distribution to its Agent Inspirata. It was deemed that the changes to the security policies and procedures did not materially affect the public or other stakeholders. Consequently,			



Categories	Security Ind	icators		
	<ul><li>communication materials available to the public or other stakeholders were not amended as a result of these reviews.</li><li>The next review or privacy/security procedures and practices is scheduled for August 2022.</li></ul>			
	Inscyte's agent Inspirata monitors and reviews computerized logs of physical access to premises and locations within premises that contain personal health information. These logs are reviewed at minimum on a monthly basis, but in practice on a weekly basis. In the event that a breach of security is detected or suspected, Inscyte's policies require the breach to be contained and reported to the Security Officer and Privacy Officer at the first available opportunity.			
Physical Security	the premise are carried Since the la February 20	agents granted access to swhere records of perso out on an annual basis b ast review by IPC in 201 020, September 2020, Fo Agents Granted Access	onal health inform y Inscyte and its a 9, review meeting ebruary 2021, and	ation are retained gent Inspirata. s were held in
	Review	Recommendations	Actions	Action
	Date Feb 2020	No recommended changes.	N/A	Completed N/A
	Sept 2020	No recommended changes.	N/A	N/A
	Feb 2021	No recommended changes.	N/A	N/A
	Aug 2021	No recommended changes.	N/A	N/A
Security Audit Program	<ul> <li>While Inscyte's policies state that CytoBase system control logs and audit logs shall be reviewed on a monthly basis, we have since moved to automated processes for real-time monitoring of system controls, audit logs, and network activity to trigger alerts of unusual activity or degradation in performance.</li> <li>Inscyte's policies require that the security program be reviewed at least once per year. Since the last review by the IPC in 2019, formal privacy/security reviews have been implemented; scheduled annually, usually in August with recorded minutes, recommendations, and action items.</li> <li>The meeting agenda includes review of the following items:</li> </ul>			



Categories	Security Ind	licators		
		of Data Holdings		
		of Authorized Personnel		
	3. Log	of Authorized Access to 1	PHI	
	4. Phys	sical Access Logs		
		5. Password Policies		
		6. Log of Privacy Complaints		
	U	7. Log of Privacy Breaches		
		of Security Breaches		
	Ű	of PHI Transfers		
	-	of Privacy Training		
		of System Configuration	Changes (Patch	Management)
		a Sharing Agreements		
		f Confidentiality Agreeme		<b>f i 1</b> - <b>v</b> )
		Register (review/identificities Continuity Plan (Dis		-
		iness Continuity Plan (Dis uirements for updates to T		)
		uirements for updates to I		1 Third-Party
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	and actioned Review	ng is a summary of recommendations		Action
	and actioned	l since the last IPC review	r in 2019.	
	and actioned Review Date	a since the last IPC review           Recommendations	r in 2019. Actions	Action Completed
	and actioned Review Date Feb 2020	Add additional servers and desktops to quarterly scans	r in 2019. Actions Review	Action Completed Completed
	and actioned Review Date Feb 2020 Sept 2020	Add additional servers and desktops to quarterly scans Keep BCP updated	r in 2019. Actions Review Updated	Action Completed Completed Completed
	and actioned Review Date Feb 2020 Sept 2020 Feb 2021	Add additional servers and desktops to quarterly scans Keep BCP updated No recommendations	r in 2019. Actions Review Updated N/A	Action Completed Completed Completed N/A
	and actioned Review Date Feb 2020 Feb 2021 Aug 2021	Add additional servers and desktops to quarterly scans Keep BCP updated No recommendations No recommendations	r in 2019. Actions Review Updated N/A N/A	Action         Completed         Completed         M/A         N/A
	and actionedReview DateFeb 2020Feb 2020Feb 2021Aug 2021The above re Inspirata and review. Rec procedures a Policies and Inspirata by and at the ne session. The new or updaSince the last	Add additional servers         Add additional servers         and desktops to quarterly         scans         Keep BCP updated         No recommendations         No recommendations         ecommendations were cord         d were scheduled for implecommendations resulting i         are reflected in updates to         Procedures Manual" and         the privacy officer and servers         ext scheduled privacy/secute         e date of notification is no         st review by the IPC in 20	Actions         Actions         Review         Updated         N/A         N/A         nmunicated to I         ementation beform         n changes to point         Inscyte's "Privation are communicated         curity officer visual         urity training and         ted in the policy         ted in the policy	Action Completed         Completed         Completed         N/A         N/A         nscyte's Agent         ore the next annual         licies and         acy & Security         ted to its Agent         a email notification         d awareness         d description as the         date).         e been applied to
	and actionedReview DateFeb 2020Feb 2021Aug 2021The above re Inspirata and review. Rec procedures a Policies and Inspirata by and at the ne session. The new or updaSince the lass the CytoBas	Add additional servers         Add additional servers         and desktops to quarterly         scans         Keep BCP updated         No recommendations         No recommendations         ecommendations were cord         d were scheduled for implecommendations resulting i         are reflected in updates to         Procedures Manual" and         the privacy officer and server         ext scheduled privacy/secute         e date of notification is no	r in 2019.         Actions         Review         Updated         N/A         N/A         nmunicated to I         ementation beform         n changes to point         Inscyte's "Privation are communicated         curity officer vision         urity training and         ted in the policy         et din the policy         et din the policy         ted in accordance	Action Completed         Completed         Completed         N/A         N/A         nscyte's Agent         ore the next annual         licies and         ncy & Security         ted to its Agent         a email notification         d awareness         / description as the         date).         e been applied to         with Inscyte's





Categories	Security Indicators
	(at the time of writing). All patches have been logged in the Log of Configuration Changes and Patches.
	In addition to annual privacy/security reviews, Inspirata performs security audits on a regular basis as follows:
	<ul> <li>Physical access logs are reviewed at minimum monthly but weekly in practice</li> <li>Internet facing firewall traffic patterns are monitored automatically</li> <li>CytoBase data transaction logs are monitored automatically</li> <li>CytoBase for Clinicians web server logs are monitored automatically</li> <li>CytoBase for Clinicians user activity logs are monitored automatically</li> <li>CytoBase for Clinicians user activity logs are monitored automatically</li> <li>Network activity is monitored automatically</li> <li>Network server vulnerability scans are run quarterly</li> </ul>
	The results of the above security audits have revealed no significant vulnerabilities or breaches of security that would require specific recommendations or actions to be taken. The results are reviewed at annual privacy/security review meetings to decide on measures to be taken, if any, and are recorded in the recommendations and actions items of the minutes of the meeting.
Information Security Breaches	Since the last review by the IPC in 2019, there have been no detected security breaches in respect of CytoBase.



#### Part 3 – Human Resources Indicators

Categories	Human Resource Indicators
Privacy Training and Awareness	All agents of Inscyte have received at least two privacy awareness training session since the last review by the IPC in 2019.
	Training sessions are conducted at Inspirata's all-staff meetings, which are scheduled on a nominally quarterly basis and cover both privacy and security matters. Communications to agents related to privacy are delivered on the dates of these meetings. Since the last review by the IPC in 2019, training sessions have been held in the following months:
	February 202019 Employees (HIPAA Awareness)May 202221 Employees (HIPAA Awareness)
	Communications to agents by Inscyte in relation to privacy matters are made at the privacy training sessions.
	There are no employees of Inspirata or Agents of Inscyte that have not received privacy and security awareness training. Seven (7) employees of Inspirata are authorized to work with CytoBase.
	There have been no new hires authorized to work with CytoBase since the last review by the IPC in 2019.
Security Training and Awareness	All agents of Inscyte have received at least two security awareness training session since the prior review by the IPC in 2019.
	Training sessions are conducted at Inspirata's all-staff meetings, which are scheduled on a nominally quarterly basis, and cover both privacy and security matters. Communications to agents related to security are delivered on the dates of these meetings. Since the last review by the IPC in 2019, training sessions were held on the following dates:
	February 202019 Employees (HIPAA Awareness)May 202221 Employees (HIPAA Awareness)
	Communications to agents by Inscyte in relation to security matters are made at the security training sessions.
	There are no employees of Inspirata or Agents of Inscyte that have not received privacy and security awareness training. Seven (7) employees of Inspirata are authorized to work with CytoBase. There have been no new hires authorized to work with CytoBase since the last review by the IPC in 2019.



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Categories	Human Resource Indicators
Confidentiality Agreements	All agents of Inscyte (including all employees of Inspirata) as a condition of employment or contract, execute a signed and witnessed "Personal Health Information Confidentiality and Non-Disclosure Agreement" with respect to the handling of personal health information. There are no Agents of Inscyte who have not executed a confidentiality agreement. These agreements refer to the Act as the prevailing legislation, the privacy & security policies and procedures, and stipulate the consequences of breach. At present all employees of Inscyte's Agent Inspirata 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.
Termination or Cessation	Since the last review by the IPC in 2019, Inscyte Corp. was notified by its agent Inspirata of the termination of two individuals that had been authorized to work with CytoBase. One in November 2019 and the other in November 2020. Inspirata has not replaced these individuals and no additional staff have been hired to work with CytoBase.

## Part 4 – Organizational Indicators

Categories	Organizational Indicators
Risk Management	<ul> <li>Inscyte Corporation's policy states that the risk register will be reviewed at least once per year. Since the last review by the IPC in 2019, annual privacy/security review meetings have been established at which the risk register is reviewed.</li> <li>In addition, Inscyte's Agent Inspirata, reviews risk to CytoBase on an on-going basis at weekly technical support departmental meetings. The corporate risk register was reviewed at each annual privacy/security review meeting in February 2020, September 2020, February 2021, and August 2021. The risk register is updated as required.</li> <li>Since the last review by the IPC in 2019, the risk register was updated in Dec 2021 as follows:</li> <li>Security Risk: Log4j Vulnerability: No action was needed as Tomcat and Oracle Database do not use log4j libraries.</li> </ul>
Business Continuity and	Inspirata's business continuity plan incorporates the recovery of Inscyte
Disaster Recovery	Corporation's CytoBase system since it is hosted on Inspirata's



Categories	Organizational Indicators
	computing infrastructure. Inspirata's business continuity plan is updated on an on-going basis in conjunction with infrastructure modifications, upgrades, or expansions.
	Inscyte does not have a policy stipulating a specific frequency at which the disaster recovery plan is to be tested. However, Inscyte requires that a backup and restore procedure is to be carried out to verify disaster recovery on a component level each time a significant hardware and/or software change is made to the CytoBase computing infrastructure. It is the responsibility of the Operations Manager of Inspirata to ensure that tests of the disaster recovery plan, in whole or in part, are performed at the earliest opportunity whenever the computing infrastructure is significantly changed.
	Updated versions of Inspirata's business continuity plan were published internally in May 2021. Changes to the plan consisted of updated technical specifications and configurations of hardware and software for the CytoBase system, as well as backup images of virtual severs. A test of the disaster recovery plan was conducted in April 2021 with successful results.