Electronic Health Record Consent Directive & Consent Override Policy

Policy Level Approval:	Chief Privacy Officer, Ontario Health
Policy Category:	EHR Privacy Program
Cross Reference to Other policies/legislation/regulations/directives:	*Personal Health Information Protection Act, 2004* (PHIPA)*; Ontario Regulation, 329/04*
Original Date of Approval:	September 30, 2020

Policy Applies to:

☒ Employees of Ontario Health

☒ Health Information Custodians who collect Personal Health Information that is held within the Electronic Health Record

1. Purpose

This policy defines Ontario Health's policy and process for the intake, review, implementation, and confirmation of Consent Directive requests.

This policy also defines Ontario Health's policy and process related to the performance of Consent Overrides and associated notice.

2. Scope

This policy applies to the Electronic Health Record (EHR) that is developed and maintained by Ontario Health, under its authority as the Prescribed Organization pursuant to Ontario Regulation 329/04. For more information on the scope of the EHR, please see the Plain Language Description of the EHR.

This policy applies to Consent Directive requests made in relation to Personal Health Information (PHI) that is held within the EHR by Ontario Health, as well as the performance of Consent Overrides and associated notice.

3. Policy

Consent Directives

As the Prescribed Organization and in accordance with PHIPA, Ontario Health has processes in place to enable individuals, or a substitute decision-maker (SDM) on an individual's behalf, to make, modify, or withdraw a Consent Directive on the individual's PHI that is held within the EHR.

On its public website, Ontario Health communicates the process for an individual or SDM to: make, modify or withdraw a Consent Directive; the manner in which and where to send such requests; and how to obtain assistance in doing so.

A. Scope of a Consent Directive

PHIPA provides that an individual may, at any time, make a directive to withhold or withdraw, in whole or in part, the individual's consent to the collection, use and disclosure of their PHI, held within the EHR, by a Health Information Custodian (HIC) for the purposes of providing or assisting in the provision of health care to the individual (Consent Directive).

Where a HIC seeks to collect PHI that is held within the EHR that is subject to a Consent Directive, Ontario Health will notify the HIC that the individual has made a Consent Directive and ensures that no PHI that is subject to the Consent Directive is provided to the HIC unless a Consent Override is performed.

In accordance with PHIPA, Ontario Health may provide PHI that is held within the EHR to a coroner in relation to an investigation conducted under the *Coroners Act*, regardless of whether the PHI is subject to a Consent Directive.

In accordance with PHIPA, the Chief Medical Officer of Health (CMOH) or a medical officer of health within the meaning of the *Health Protection and Promotion Act* (HPPA) may collect PHI by means of the EHR for purposes related to their duties under the HPPA or the *Immunization of School Pupils Act*, regardless of whether the PHI is subject to a Consent Directive.

B. Requirements for a Consent Directive

An individual or SDM may make, modify, or withdraw a Consent Directive by submitting an EHR Consent Directive Request Form to Ontario Health.

The EHR Consent Directive Request Form must contain sufficient detail to enable Ontario Health to implement the directive. For example, it must contain: an Ontario health card number (HCN), medical record number (MRN) and name of the organization that issued the MRN, or a Client Health and Related Information System (CHRIS) client number to enable Ontario Health to locate the correct individual's records in the EHR.

If the EHR Consent Directive Request Form does not contain sufficient detail to enable Ontario Health to implement the directive with reasonable effort, Ontario Health will provide assistance to the individual or SDM in reformulating the request so that it is PHIPA compliant.

If the EHR Consent Directive Request Form contains sufficient detail to enable Ontario Health to implement the directive, and the Requestor has provided sufficient proof of authority, Ontario Health implements the directive in accordance with PHIPA, and sends a confirmation letter to the Requestor.

Where Ontario Health is unable to implement a directive due to the EHR Consent Directive Request Form containing insufficient detail or where the authority of the Requestor cannot reasonably be confirmed, Ontario Health will notify the requestor in writing.

Ontario Health takes reasonable steps to confirm that the individual who submitted the EHR Consent Directive Request Form is the individual to whom the PHI relates or is that individual's SDM.

C. Consent Directive Options

Where it is reasonably possible for Ontario Health to apply a Consent Directive only to the specific PHI identified by the Requestor on the EHR Consent Directive Request Form and the Requestor has provided sufficient detail to enable Ontario Health to implement the directive, Ontario Health implements the directive.

D. Application to PHI added to the EHR in the future

Where an individual has made a Consent Directive and additional PHI is subsequently added to the EHR in relation to that individual, Ontario Health implements the Consent Directive with respect to the additional information in accordance with PHIPA. For example, if a Consent Directive is in place blocking access to all of an individual's PHI in the Clinical Data Repository (CDR), the Consent Directive will apply to both the PHI related to that individual that exists in the CDR at the time the Consent Directive is made, and to any future PHI related to that individual that is added to the CDR after the Consent Directive is made, unless the individual's Consent Directive is modified or withdrawn.

E. Consent Directives made prior to Part V.1. of PHIPA coming into force

If prior to the enactment of section 55.6 of PHIPA an individual made a directive withholding or withdrawing, in whole or in part, the individual's consent to the collection, use or disclosure of PHI held within the EHR and that PHI was created and maintained by Ontario Health under the authority of section 6.2 of Ontario Regulation 329/04, then Ontario Health will continue to implement the individual's directive as it existed prior to section 55.6 coming into effect.

Consent Overrides

Ontario Health has processes and technology in place to enable HICs to perform Consent Overrides in accordance with PHIPA, applicable agreements, and this policy.

A HIC that is seeking to collect an individual's PHI that is held within the EHR and subject to a Consent Directive may only perform a Consent Override in accordance with PHIPA, applicable agreements, this policy, and the supporting technology.

As the Prescribed Organization, Ontario Health logs, monitors, and audits Consent Overrides. As soon as possible after a Consent Override occurs, Ontario Health provides written notice to the HIC that collected the PHI in question.

Upon receiving notice from Ontario Health of a Consent Override, the HIC that collected the PHI is responsible for confirming the reason for the Consent Override, notifying the individual to whom the PHI relates, and giving written notice to the IPC where required by PHIPA.

Upon request and subject to availability, Ontario Health provides further relevant information to the HIC that collected the PHI as result of a Consent Override to support the HIC in fulfilling its notice obligations to the individual to whom the PHI relates, and the IPC where applicable.

Enforcement

Ontario Health requires its employees to comply with this policy and associated processes, and enforces compliance.

4. Process for Consent Directive Requests

4.1 Intake & Review

a. As soon as possible after receiving an EHR Consent Directive Request Form, Ontario Health logs the request and saves the EHR Consent Directive Request Form.

b. Ontario Health reviews the EHR Consent Directive Request Form to determine whether sufficient information has been provided to enable implementation of the request, including, where applicable, whether sufficient proof of authority has been provided:

i. If the EHR Consent Directive Request Form does not contain sufficient information to enable Ontario Health to implement the request, or if the Requestor is an SDM and has not provided sufficient proof of authority, Ontario Health contacts the Requestor to offer assistance to obtain the missing information, using the preferred method of contact and information provided by the Requestor on the EHR Consent Directive Request Form.

4.2 Implementation

a. Once the Requestor has provided sufficient detail and proof of authority, Ontario Health uses the information provided on the EHR Consent Directive Request Form to implement the Consent Directive in the EHR in accordance with the Requestor's instructions.

b. Once the Consent Directive is implemented in the EHR, Ontario Health ensures the following details are recorded and maintained in accordance with applicable law:

i. The first and last name of the individual or SDM who made, modified, or withdrew the Consent Directive (Requestor);
ii. The name of the individual to whom the PHI relates;
iii. The instructions the Requestor provided regarding the Consent Directive;
iv. The HIC, agent or other person to whom the directive is made, withdrawn or modified; and,
v. The date and time the Consent Directive was implemented in the EHR.

4.3 Confirmation

a. To confirm implementation of the Consent Directive, Ontario Health prepares a letter to the Requestor, which includes the following information:

i. The first and last name of the Requestor;
ii. The name of the individual to whom the PHI relates;
iii. The details of the Consent Directive implemented, including the type of data subject to the directive (i.e. clinical data in the Clinical Data Repository (CDR) or diagnostic imaging results in the Diagnostic Imaging Common Service repository (DI-CS)), and the level of consent applied to each type of data (i.e. block all users from accessing, block only specific users from accessing, etc.); and,
iv. The date the Consent Directive was implemented in the EHR.

b. As soon as possible after the Consent Directive is implemented, Ontario Health mails the confirmation letter to the Requestor, using the mailing address provided on the EHR Consent Directive Request Form.

5. Consent Overrides

5.1 Process for Performing Consent Overrides

a. A HIC that is seeking to collect an individual's PHI that is held within the EHR and subject to a Consent Directive may only perform a Consent Override to collect the individual's PHI where:

i. The HIC that is seeking to collect the individual's PHI obtains the express consent of the individual to whom the PHI relates, which may be provided by the individual themselves or their SDM;
ii. The HIC that is seeking to collect the individual's PHI believes on reasonable grounds that the collection is necessary for the purpose of eliminating or reducing a significant risk of serious bodily harm to the individual to whom the PHI relates and it is not reasonably possible for the HIC to obtain the individual's consent in a timely manner; or
iii. The HIC that is seeking to collect the individual's PHI believes on reasonable grounds that the collection is necessary for the purpose of eliminating or reducing a significant risk of serious bodily harm to a person other than the individual to whom the PHI relates or to a group of persons.

b. Further to 5.1a, a Consent Override may only be performed where the reason for the Consent Override as described in 5.1a above is permitted by the HIC with custody and control of the PHI in question, and as supported by the technology.

c. At the time of the Consent Override, the HIC uses available means to record the reason for the Consent Override as described in 5.1a above.

d. A HIC that collects PHI by means of a Consent Override may only use or disclose that PHI for the purpose for which it was collected.

5.2 Process for Notification of Consent Overrides

a. Each business day, Ontario Health generates Consent Override reports, which include all Consent Overrides performed since the period of the last such report, and clearly states the following in relation to each Consent Override:

i. The name of the individual to whom the PHI relates;

ii. The name of the HIC that collected the PHI;
iii. The name of the agent of the HIC who collected the PHI, if available;
iv. A description of the type of PHI that was collected (i.e. CDR, DI-CS, OLIS, DHDR);
v. The reason for the Consent Override, as provided by the HIC at the time of the Consent Override; and,
vi. The date and time of the Consent Override.

b. For each Consent Override in the report described in 5.2a, Ontario Health provides written notice of the Consent Override as soon as possible to the HIC who collected the PHI as a result of the Consent Override (Collecting HIC), which includes:

i. The name of the individual to whom the PHI relates;
ii. The name of the HIC that collected the PHI;
iii. The name of the agent of the HIC who collected the PHI, if available;
iv. A description of the type of PHI that was collected (i.e. CDR, DI-CS, OLIS, DHDR);
v. The reason for the Consent Override, as provided by the HIC at the time of the Consent Override; and,
vi. The date and time of the Consent Override.

5.3 HIC Requests for Further Information

a. If the Collecting HIC requests further information from Ontario Health for the purposes of providing notice of a Consent Override to the individual to whom the PHI relates or to the IPC, Ontario Health takes reasonable steps to retrieve the requested information and, where available, promptly provides the requested information to the Collecting HIC in accordance with PHIPA and applicable EHR policies and processes.

6. Definitions

Consent Directive: means a directive, made in accordance with section 55.6 of PHIPA, that withholds or withdraws, in whole or in part, an individual's consent to the collection, use and disclosure of their personal health information by means of the electronic health record by a health information custodian for the purposes of providing or assisting in the provision of health care to the individual.

Consent Override: has the meaning set out in section 55.7 of PHIPA.

Electronic Health Record (EHR): has the meaning set out in section 55.1 of PHIPA, and further detailed in the Plain Language Description of the EHR available on Ontario Health's website.

Health Information Custodian (HIC): has the meaning set out in section 3 of PHIPA.

Individual: has the meaning set out in section 2 of PHIPA.

IPC: means the Information and Privacy Commissioner of Ontario.

Ontario Health: a corporation under the *Connecting Care Act, 2019*, and a Crown agent, which, among other things, is charged with managing health service needs across Ontario in a manner consistent with the health system strategies of the Ministry of Health (as further detailed in section 6 of the Act) and has assumed the operations, activities and affairs of eHealth Ontario.

Personal Health Information (PHI): has the meaning set out in section 4 of PHIPA.

PHIPA: means the *Personal Health Information Protection Act*, 2004, and supporting regulations as may be amended from time to time.

Prescribed Organization: means the organization prescribed by Ontario Regulation 329/04 as the organization for the purposes of Part V.1 of PHIPA.

Requestor: means the individual or substitute decision-maker who signed the EHR Consent Directive Request Form submitted to Ontario Health.

Substitute decision-maker: has the meaning set out in section 5 of PHIPA.

7. Roles and Responsibilities

ROLE	RESPONSIBILITY
Ontario Health Chief Privacy Officer:	Responsible for approving this policy and its associated processes

Ontario Health (Digital Services) Privacy Office:	Responsible for authoring and maintaining this policy and its associated processes
Ontario Health (Digital Services) Legal Counsel:	Responsible for reviewing and providing input into this policy and its associated processes
Ontario Health Employees:	Responsible for complying with this policy and its associated processes
Health Information Custodians who contribute to or access the EHR:	Responsible for complying with this policy and its associated processes in relation to PHI that is accessible by means of the EHR

7. Review

Ontario Health's policies related to the EHR are reviewed as required in accordance with applicable law.

8. Appendices

N/A

9. Policy Change History

Revision Number:	1
Date of Approval:	September 30, 2020
Replaces Policy:	Consent Management Policy, Electronic Health Record v. 1.3
Description of Change:	N/A