The purpose of this Consent Directive Procedure is to assist the hospitals (LHINs 1, 2, 3 & 4), Mohawk Shared Services (MSS), LHSC Regional Privacy Officer and Agents in implementing consent directive for patients involved in the SWO DI-r. To implement or remove lockbox, the organization must receive consent from the patient and this request must be submitted to LHSC Regional Privacy officer by the Privacy Officer or Agent of the Participating Hospital.
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Purpose

The purpose of this Consent Directive Procedure is to assist the hospitals (LHINs 1, 2, 3 & 4), Mohawk Shared Services (MSS), Diagnostic Imaging Repository’s Privacy Officer and/or Agents in implementing consent directives for patients involved in the SWO DI-r. To implement or remove lockbox, the organization must receive consent from the patient and this request must be submitted to the LHSC Regional Privacy Office. Participating sites in the DI-r and their agents should read this procedure in conjunction with the privacy provisions of the DI-r Services Agreement and other project documentation.

Important Note: This procedure does not address consent directives pertaining to the “use” of personal health information within their local Picture Archiving and Communications System (PACS) or any other paper or electronic information system, which will continue to be governed by health information custodians’ respective consent management or “lock box” processes in place.

As a best practice, this procedure should be appended to health information custodians’ existing documentation governing consent management or “lock box” processes.

This procedure outlines limitations to patient consent directives associated with the DI-r that Local Privacy Officers are responsible for disclosing to patients prior to implementing their directives. These risks are in addition to all clinical risks to the patient that relate to any consent directive when the patient presents at an organization outside the originating PACS organization (i.e. no access to an individual’s medical history may negatively impact clinicians ability to provide an accurate and timely diagnosis).

PHIPA Standard

The Ontario Personal Health Information Protection Act, 2004 (PHIPA) governs the collection, use, disclosure, retention and destruction of personal health information in Ontario, including the Diagnostic Imaging Repository (DI-r). PHIPA is a consent based statute that allows individuals to withhold or withdraw their consent for disclosures of their personal health information by health information custodians (e.g. hospitals, medical laboratories, primary care providers and long term care facilities). More specifically, individuals or their authorized substitute decision-makers (SDMs) have the legal right under PHIPA to restrict health information custodians from sharing their personal health information via the DI-r for the purpose of providing or assisting in the provision of health care. The express instruction of the individual to his/her health care provider not to use or disclose his/her personal health information by either expressly withdrawing or withholding consent is commonly referred to as the “lock box” for the purposes of PHIPA and is implicit in sections 20(2), 37(1) (a), 38(1) (a) and 50(1) (e) of this Act. For the purposes of this procedure, such an express instruction is referred to as a “consent directive.”
## Terminology

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Agent</td>
<td>Defined in section 2 of the Ontario Personal Health Information Protection Act, 2004 (PHIPA), an “agent” is a person who, with the authorization of a health information custodian, acts for, or on behalf of, a health information custodian in respect of personal health information for the purposes of the custodian, and not the agent’s own purposes, whether or not the agent has the authority to bind the custodian or is employed by or receives remuneration from the custodian. This includes employees, contract staff and volunteers.</td>
</tr>
<tr>
<td>Consent</td>
<td>“Consent” is an agreement, approval or permission as to some act or purpose given voluntarily by a competent person.¹ PHIPA requires consent for the collection, use or disclosure of personal health information, unless the collection, use or disclosure is required or permitted by this Act. Such consent may be expressed or implied as long as the consent obtained complies with the four elements established under PHIPA. Specifically, PHIPA deems consent to be valid if it: (1) is of the individual; (2) is knowledgeable; (3) relates to the information; and (4) is not obtained through deception or coercion. Knowledgeable consent means that the individual must: (1) know the purpose for the collection, use or disclosure; and (2) that he or she may provide or withhold consent as per section 18(4). It is reasonable to believe that an individual knows the purpose for the collection, use or disclosure of his/her personal health information if the custodian posts or makes readily available a notice describing the purposes as required under section 18(6) of PHIPA.</td>
</tr>
<tr>
<td>Consent Directive or Lockbox</td>
<td>The right of an individual to place restrictions on the use or disclosure of his/her personal health information by either expressly withdrawing or withholding consent is referred to as a “consent directive.” Consent directives are technically implemented through “blocking” mechanisms and approaches described within this procedure.</td>
</tr>
<tr>
<td>Diagnostic Imaging (DI) Information</td>
<td>For the purposes of this procedure, “diagnostic imaging information” refers to diagnostic images and related information, such as patient identifying and ...</td>
</tr>
</tbody>
</table>
### Term | Definition
--- | ---
Demographic information, diagnostic orders and reports. |  
**Disclose** | Defined in section 2 of PHIPA, “disclose” refers to making personal health information “available” or “to release it to another health information custodian or to another person.” For the purposes of the DI-r, a clinician accessing personal health information from the DI-r where the information was entered into the DI-r by a site other than the clinician’s is considered a disclosure.  
**Express Consent** | “Express consent” means asking a patient to expressly provide his/her permission (which may be provided either orally or in writing) to collect, use or disclose his/her personal health information. Express consent is required under PHIPA for any disclosures of personal health information made by a health information custodian to another custodian for a purpose unrelated to the provision of care and treatment or where the disclosure is made to a third party.  
**Health Information Custodian** | Defined in section 3(1) of PHIPA, “health information custodian” is a person or organization that has custody or control of personal health information as a result of, or in connection with, the person’s or organization’s powers or duties. Health information custodians listed under section 3(1) of PHIPA include, among others, public hospitals, medical laboratories, independent health care practitioners and community care access centres.  
**Implied Consent** | “Implied consent” is consent that can be reasonably determined through the actions or inactions of the patient when, for example, a patient presents himself/herself to a pharmacist, a laboratory, an emergency department, or a physician in private practice for health care and treatment.  
**Privacy Officer** | A Privacy Officer is an individual appointed by a custodian to facilitate the custodian’s compliance with PHIPA, ensure that agents of the custodian are appropriately informed of their duties under PHIPA, respond to inquiries and complaints from the public regarding the custodian’s privacy and information  

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<table>
<thead>
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<tr>
<td>practices, and respond to requests from an individual for access to, or correction of, the individual’s personal health information.(^3)</td>
<td></td>
</tr>
<tr>
<td>SWO DIR</td>
<td>The Southwestern Ontario Diagnostic Imaging Repository is a service of London Health Sciences Centre that provides direction and support for implementing a shared IT solution at sites throughout Southwestern Ontario. PSA -</td>
</tr>
<tr>
<td>Substitute Decision Maker (SDM)</td>
<td>A substitute decision maker is an individual authorized under section 5 of PHIPA to consent on behalf of a patient to the collection, use or disclosure of personal health information about that patient. As such, all references to a “patient” made in this document are also inclusive of authorized SDMs.</td>
</tr>
<tr>
<td>Use</td>
<td>Defined in section 2 of PHIPA, “use” means “to handle or deal with personal health information.” The definition of use is distinct from, and should not be confused with, the term “disclose” (see above).</td>
</tr>
<tr>
<td>HIS</td>
<td>Hospital Information System</td>
</tr>
<tr>
<td>RIS</td>
<td>Radiology Information System</td>
</tr>
<tr>
<td>SDE</td>
<td>Service Desk Express also known as London Helpdesk</td>
</tr>
<tr>
<td>MRN/PIN</td>
<td>Medical Record Number/Personal Identifying Number</td>
</tr>
</tbody>
</table>

\(^3\) This definition is based on the functions of a “contact person” at section 15(3) of PHIPA.
**Participating Site Requirements**

Health information custodians that are participating in the SWO DI-r may assume they have an individual’s implied consent for the following purposes:

- To enter the individual’s DI information into the DI-r;
- To access and use the individual’s DI information stored in the DI-r; and
- To disclose the individual’s DI information to other health information custodians via the DI-r for the purpose of providing or assisting in the provision of patient care.

Patient’s information can only be removed from the SWO DI-r when participating sites;

- Completion of the Express Consent for Lockbox in OneView; including signature of patient and the document is received by the LHSC Regional Privacy Office or Agent.

Patient’s Information can only be reinstated when;

- Permission by the patient to reinstate images and reports has been delivered from the Organization to the LHSC Regional Privacy Office or Agent. Local Privacy Officer or Agent must fill in the Express Consent for Lockbox in OneView Form (Appendix Documentation) and have patient sign document.
- The participating site has the ability to retrigger an HL7 based report.
Consent Directive Procedure

An individual may request an health information custodian, participating in the SWO DI-r, to restrict disclosures of his/her personal health information in the DI-r by expressing consent and providing instructions (i.e. a consent directive) to, for example, block access to all of his/her DI information. Once individuals have placed a consent directive on their personal health information, they may reinstate clinician access to their personal health information for health care purposes through an express consent directive.

It is important to note, by applying patient consent directives in line with this procedure;

- The Patient’s information will not exist or be available via the DI-r. The images, orders, and/or reports (collectively referred to as “DI Information” hereafter) will not be available.
  - However, if with the patient’s consent, or a legally-permitted override of the consent directive ensues, the patient’s information can be reinstated (refer to Participating Site Requirements).

- There will be no functionality in the repository or One-View to comply with the PHIPA requirement to alert users that access to DI information has been restricted (day forward) at the request of the patient (at the time of this documentation).
  - This also implies that if the patient arrives at another participating hospital in Southwestern Ontario, the patient will need to request for a Consent Directive to inhibit their information from populating to the DI-r.

- There is no functionality in OneView to allow a patient’s reports to be viewed by the participating hospitals, when lockbox consent is received for the SWO DI-r.

- This does not impact access to this information via the local site HIS/RIS or PACS.

When health information custodians receive consent directives from the patient/SDM, these directives must be applied in the DI-r using an approach set out in the consent directive procedure. Consent directives can be made in accordance with health information custodians’ existing consent management practices.

As a best practice, the health information custodian must advise patients to provide the custodian with their consent directive in writing.
Lockbox Options

In order to implement a consent directive for DI information that has been sent to the SWO DI-r, one of the following lockbox options must be selected;

**Option A-Removing Image(s) Only**

Capability: Viewing Clinician can view the orders and reports associated to the patient

Limitations: NONE – Procedure is reversible

**Option B-Remove Reports and Image(s)**

Capability: Viewing Clinician will only be able to view the orders associated to the patient (no reports or images)

Limitations: YES – Image can be re-instated. The procedure for the report is reversible only for participating sites that have the ability to re-trigger the ORU HL7 message for that procedure. Otherwise this activity is irreversible.

**Option C-Remove Exam/Reports and Image(s)**

Capability: Viewing Clinician will be able to search and find patient and be aware that imaging has been performed but the description is replaced with “Patient Requests Lockbox-Consent Directive”. Report and Images will be removed.

Limitations: Yes – Image can be re-instated. The procedure for the report and order is reversible only for participating sites that have the ability to re-trigger the ORU HL7 message for that procedure. Otherwise this activity is irreversible
Responsibilities

Local Privacy Officer or Agent

Informing the Patient
- Outline the options to the patient/SDM with regards to the capabilities and limitations of a consent directive (Lockbox Options).
- Ensure the Request to Express Consent for Lockbox in OneView Form (Appendix Documentation) is completed in full.
- The Patient must sign the completed Request to Express Consent for Lockbox in OneView Form.
- Based on option selected (A, B or C) the report, images and order details will be unavailable to authorized SWO DI-r users once the consent directive has been implemented.
- This approach to consent directive implementation is image/investigation-specific and will not block access to images captured in the future or diagnostic visits to other participating hospitals.
- Once they visit another hospital, they will need to request for a lockbox on their radiology visit prior to registering in the radiology department.

Initiating Consent Directive
- Call the London Helpdesk SDE to open a ticket for the request – 1-877-465-7167
- Securely transfer (Secure File Transfer, Courier or Fax to 519-667-6706) the completed Request to Express Consent for Lockbox in OneView Form (Appendix-Documentation) with the Ticket # included to the Attention of: LHSC – Privacy Office for the Diagnostic Imaging Repository of Southwestern Ontario. Maintain a copy of the request.

LHSC SWO DI-r Privacy Office
The Regional Privacy Office will;
- Receive requests,
- Record the Lockbox Request for statistical reporting and
- Forward the request to the SWO DI-r Support Staff

SWO DI-r Support Staff
The SWO DI-r Support Staff will;

Planning Consent Directive
- Complete a one-time System Set up in OneView prior to applying an consent directive
- Maintain access to OneView RIS-IC mode and ConnectR and Enterprise Archive Module
- Complete a one-time build of Consent Directive Orders for each Organization and/or Modality.
Executing Consent Directive

- Review the notification entered via the London Helpdesk SDE ticket.
- Review the Request to Express Consent for Lockbox in OneView (Appendix-Documentation) and validate the requested exams, results and images exist in OneView.
- Report back to the Privacy Officer or individuals functioning on their behalf, any discrepancies for clarification.
- Proceed in implementing the request as outlined in the Request to Express Consent for Lockbox in OneView Form (Appendix-Documentation) in the presence of another SWO DI-r Support resource, for witnessing purposes.
- Ensure that the patient information detailed in the request is removed from the OneView application.
- Report back to the Regional Privacy Officer or individuals functioning on their behalf on completion of request for confirmation/verification.
- Maintain a copy of the request in the SWO DI-r shared drive.
Appendix-Workflow

<table>
<thead>
<tr>
<th>Implementing Consent</th>
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<tbody>
<tr>
<td>Patient places consent directive post DI-r migration</td>
</tr>
<tr>
<td>Local Privacy Officer notifies patient of implications and any technical limitations</td>
</tr>
<tr>
<td>Local Privacy Officer contacts London Helpdesk with request and receives Ticket # and completes request to express consent for Lockbox in OneView</td>
</tr>
<tr>
<td>Privacy Officer will forward request to the LHSC/SJHC Regional Privacy Office using a secure method of transmission</td>
</tr>
<tr>
<td>SWO DI-r Support Resource will remove information from OneView as per request</td>
</tr>
</tbody>
</table>

Appendix-Documentation

Appendix: Revision History

<table>
<thead>
<tr>
<th>Date</th>
<th>Version</th>
<th>Revision</th>
</tr>
</thead>
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<tr>
<td>July 1, 2010</td>
<td>D1.0</td>
<td>Draft</td>
</tr>
<tr>
<td>May 3, 2012</td>
<td>D2.3</td>
<td>Draft</td>
</tr>
<tr>
<td>May 9, 2012</td>
<td>D2.4</td>
<td>Draft</td>
</tr>
<tr>
<td>July 30, 2012</td>
<td>D2.5</td>
<td>Draft</td>
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