

eDOCSNL

Information Management Framework

A Policy of the EMR Management Committee

Effective until November 1, 2023

TABLE OF CONTENTS

Executive Summary	5
1.0 INTRODUCTION	7
1.1 <i>eDOCSNL Information Management Framework Ownership</i>	<i>7</i>
1.2 <i>Document Purpose</i>	<i>7</i>
1.3 <i>Definitions</i>	<i>9</i>
2.0 RECIPIENT PARTIES	9
2.1 <i>Newfoundland and Labrador Centre for Health Information</i>	<i>9</i>
2.2 <i>Regional Health Authorities</i>	<i>10</i>
2.3 <i>Researchers</i>	<i>10</i>
2.4 <i>Canadian Institute for Health Information</i>	<i>10</i>
3.0 GOVERNANCE FRAMEWORK	10
3.1 <i>Legislation</i>	<i>10</i>
3.2 <i>Governance Committees</i>	<i>11</i>
3.2.1 <i>EMR Management Committee</i>	<i>11</i>
3.2.2 <i>EMR Executive Committee</i>	<i>11</i>
3.2.3 <i>EMR Data Governance Advisory Committee</i>	<i>11</i>
3.3 <i>EMR Participation Agreements</i>	<i>11</i>
3.4 <i>RHA EMR Committees</i>	<i>11</i>
3.5 <i>Policies and Procedures</i>	<i>11</i>
3.6 <i>Data Sharing Agreements</i>	<i>12</i>
4.0 EMR Data for Direct Patient Care.....	12
5.0 Secondary Use of EMR Data	12
5.1 <i>EMR Data Elements for Secondary Use</i>	<i>13</i>
5.2 <i>Preparing EMR Data for Secondary Use</i>	<i>13</i>
5.3 <i>Secondary Use Activities.....</i>	<i>13</i>
5.3.1 <i>Health System Planning, Management, and Health Policy Development</i>	<i>14</i>
5.3.2 <i>Public Health Surveillance.....</i>	<i>14</i>
5.3.3 <i>Quality Improvement.....</i>	<i>14</i>
5.3.4 <i>Research</i>	<i>14</i>
5.3.5 <i>Clinical Practice and Program Management.....</i>	<i>14</i>
5.3.6 <i>Required by Legislation.....</i>	<i>14</i>
5.4 <i>Restrictions on the use of EMR Data</i>	<i>15</i>
6.0 REPORTING OF SECONDARY USE OF EMR DATA	15

7.0	Approval Process	15
7.1	NLCHI Approval Process.....	17
7.2	HREB Approval Process.....	17
7.3	RHA Approval Process	17
7.4	EMR Management Committee Approval Process	17
7.5	EMR Management Committee Appearance.....	18
8.0	CONCLUSIONS	18
	Appendix A: NLCHI's Data De-identification and Re-identification Procedure	20
	Appendix B: Examples of Secondary Use Activities that do not require Separate Approval	22
	Appendix C: Examples of Secondary Use Activities that Require Separate Approval or Consent.....	24
	Appendix D: Template for Reporting Use and Disclosures of EMR Data	26
	Appendix E: NLCHI Approval Process	27

Version Control - Updates and Additions

Date of Approval by EMR Management Committee	Changes, Updates or Addition	Communicated to the following stakeholders
October 30, 2020		DHCS, NLMA, RHAs, NLCHI, Quality of Care (MUN)

Executive Summary

In October 2015, a Memorandum of Understanding (MOU) between the Department of Health and Community Services (DHCS), the Newfoundland and Labrador Medical Association (NLMA) and the Newfoundland and Labrador Centre for Health Information (NLCHI) was signed to jointly govern, implement and operate a sustainable Electronic Medical Record (EMR) Program in Newfoundland and Labrador referred to as eDOCSNL.

The EMR Management Committee, the governing committee created through the MOU, provides strategic advice, guidance and direction on the management of eDOCSNL, including approvals related to Secondary Use of EMR Data, and the EMR Data elements that can be used for Primary and Secondary Uses. This Information Management Framework, a policy of the EMR Management Committee, provides this direction and is agreed by the Parties to be the Data Sharing Agreement required by Clause 5.5(b) of the MOU. The EMR Management Committee has approved the framework for three years, from the date of approval, with a required annual review by the EMR Management Committee. At the conclusion of three years, the Information Management Framework expires and the EMR Management Committee must re-approve the existing framework or develop a new one.

The purpose of this document is to provide direction to Custodians of EMR Data which is collected, used, disclosed, stored, and retained for patient care and Secondary Uses. The Information Management Framework describes the uses and disclosures of EMR Data, the request and approval processes required, and establishes principles to be followed by any Custodian or entity in Newfoundland and Labrador using EMR Data for patient care and Secondary Uses.

The type of approval required for use and disclosure of EMR Data will depend on the type of EMR Data being used or disclosed. For most uses and disclosures, separate approval by the EMR Management Committee will not be required (e.g., patient care and Secondary Uses approved in this Information Management Framework). In addition, mandatory disclosures required under legislation (e.g., *Medical Act*, *Prescription Monitoring Act*, etc.) will not be subject to EMR Management Committee approval. Secondary Uses, where separate approval from the EMR Management Committee is required, include uses and disclosures of EMR Data for Research and/or commercial purposes, and uses and disclosures by NLCHI that require identifiable individual physician information not previously approved in this Information Management Framework. However, if a fee-for-service physician consents to, or requests that, NLCHI, an RHA, or the Minister of Health and Community Services use their identifiable data for a specific purpose, EMR Management Committee approval will not be required.

The guidelines to be followed by any Custodian or non-Custodian in Newfoundland and Labrador using EMR Data for patient care and Secondary Use include:

- **EMR Data disclosures may only be done with a data sharing agreement that details the use and disclosure requirements of the recipient and references the eDOCSNL Information Management Framework.**
- **Each person or organization who uses EMR Data for Secondary Use must have policies and procedures in place that are compliant with the *Personal Health Information Act* and consistent with this Information Management Framework.**

- **Any Custodian, including Fee for Service Physicians, who uses personal health information for direct patient care and Secondary Uses must have policies and practices that clearly delineate the two roles under taken by the Custodian.**
- **An up to date list of all data elements used for Secondary Use will be maintained and published on the eDOCSNL website www.edocsnl.ca.**
- **Best efforts will be made to notify the EMR Management Committee in advance of the use, or if prior notification is impossible at the time of the use, of EMR Data for mandatory legislative requirements that monitor or evaluate individual patients, physicians or other healthcare providers that has not previously been documented in this Information Management Framework or policy of the EMR Management Committee. Where prior or simultaneous disclosure is impossible, NLCHI or the RHA shall notify the EMR Management Committee within two business days.**
- **Each Custodian using EMR Data for Secondary Uses that was collected by another Custodian must have a documented process for approving all uses and disclosures.**
- **Uses and disclosures of EMR Data for commercial or Research purposes or activities that involve identifiable-physician requires individual EMR Management Committee approval, unless previously approved in this Information Management Framework.**

1.0 INTRODUCTION

In October 2015, a Memorandum of Understanding (MOU) between the Department of Health and Community Services (DHCS), the Newfoundland and Labrador Medical Association (NLMA) and the Newfoundland and Labrador Centre for Health Information (NLCHI) was signed to jointly govern, implement and operate a sustainable Electronic Medical Record (EMR) Program in Newfoundland and Labrador referred to as eDOCSNL. The EMR Management Committee is responsible for ensuring the protection of personal health information throughout all stages of the EMR Program.

The mandate of eDOCSNL is to improve collaboration and information sharing between physicians and other health care providers; improve the overall quality of care; enhance the overall capability for patient safety within healthcare; provide a means for physicians to improve clinical efficiencies; and provide health information to inform future health planning and policy development.

The eDOCSNL program is comprised of two streams: a fee-for-service (FFS) physician stream and a regional health authority (RHA) primary health care stream with some FFS physician participation. Each FFS physician and RHA participating in eDOCSNL has entered into an agreement with NLCHI to participate in the EMR program, which includes provisions for the Secondary Uses of EMR Data. These agreements are the **EMR Physician Participation Agreement**, the **Fee for Service Physician Participation Agreement for Joining eDOCSNL through a Regional Health Authority Electronic Medical Record**, and the **Regional Health Authority eDOCSNL Participation Agreement**, collectively referred to as the "Agreements". These Agreements include the general terms and conditions for the sharing of the data with NLCHI, and for the FFS physicians on an RHA instance, with the applicable RHA.

The sharing of personal health information for direct patient care is done through functionality within the EMR or the two-way flow of information between the EMR and HEALThe NL, the provincial electronic health record, of which NLCHI is the Custodian.

The sharing of personal health information for Secondary Uses is facilitated through a transfer of information from each eDOCSNL participant's EMR Data storage at TELUS Health Solution, who is the participant's Information Manager and Med Access vendor, to NLCHI's data warehouse on a daily basis.

1.1 eDOCSNL Information Management Framework Ownership

The Information Management Framework is a policy of the EMR Management Committee. The EMR Management Committee has approved the framework for three years, from the date of approval, with a required annual review by the EMR Management Committee. At the conclusion of three years, the Information Management Framework expires and the EMR Management Committee must re-approve the existing framework or develop a new one.

All updates approved by the EMR Management Committee are recorded in the version table following the table of contents of this Information Management Framework.

1.2 Document Purpose

The purpose of this document is to provide direction to Custodians of EMR Data which is collected, used, disclosed, stored, and retained for patient care and Secondary Uses, as part of eDOCSNL.

The RHAs will implement policies and procedures consistent with the Information Management Framework in conjunction with the RHA EMR Committee. These policies and procedures will be reviewed by the EMR Management Committee. If the RHA does not adopt its own policies for the Secondary Use of EMR Data they will follow NLCHI's EMR Data policies and procedures. Once the RHAs have these policies and procedures reviewed by the EMR Management Committee the Secondary Uses outlined in this Information Management Framework are exempt from the approval processes noted in section 7.0, except for the disclosures of EMR Data for Research or commercial purposes. The RHAs will be required to obtain approval from the EMR Management Committee for disclosures for Research or commercial purposes.

NLCHI shall implement policies and procedures on the collection, use and disclosure of EMR Data that have been approved by the EMR Management Committee. These policies will be available on www.eDOCSNL.ca. Once NLCHI has these policies and procedure reviewed by the EMR Management Committee the Secondary Uses outlined in this Information Management Framework are exempt from the approval processes noted in section 7.0, except for uses requiring identifiable physician EMR Data and for disclosures of EMR Data for Research or commercial purposes. NLCHI will be required to obtain approval from the EMR Management Committee for uses requiring identifiable physician EMR data and for disclosures for Research or commercial purposes.

The FFS physician using a RHA EMR provides consent to the RHA to use or disclose EMR Data the physician has disclosed to the RHA for primary purposes also for Secondary Uses. The Fee for Service Physician Agreement for Participation in eDOCSNL through a Regional Health Authority Electronic Medical Record includes this consent.

NLCHI, the RHAs, and the DHCS have agreed and reaffirm their intent and commitment to only use and disclose EMR Data in accordance with legislation and the processes and procedures noted in this document, and that EMR Data will be used for physician-identifying activities only when other data sources cannot provide the necessary information and in accordance with this Information Management Framework.

In the event that a request for EMR Data is received from any person or organization that is inconsistent with the processes and procedures in this document, NLCHI or the RHA will advise the requestor of this inconsistency and will not disclose the data. If NLCHI or a RHA receives such a request and believes it is legally compelled to disclose the EMR Data, it will make reasonable effort to provide notice to the physicians affected and the NLMA 30 days prior to the fulfilment of the request, or at the earliest possible opportunity.

If NLCHI or the RHA uses or discloses EMR Data in a manner that is inconsistent with the Information Management Framework, they will make best efforts to notify the NLMA and the affected physicians prior to or, if prior notification is impossible, at the time of such disclosure, including a description of the information disclosed. Where prior or simultaneous disclosure is impossible, NLCHI or the RHA shall notify the affected physician and the NLMA within two business days. Should the physicians affected by the disclosure decide to exit the eDOCSNL program or the RHA instance as a result of this disclosure, they will do so in accordance with the Agreements. NLCHI and/or the RHA will facilitate the transition at no cost to the affected physicians.

1.3 Definitions

“Circle of Care” has the meaning defined in PHIA;

“Custodian” has the meaning defined in PHIA;

“Collecting Party” means the party who collects personal health information directly from the patient or other authorized source;

“De-identified Data” is created when identifiers for individuals and health professionals are removed and replaced with a code. Depending on access to the code, it may be possible to re-identify specific individuals and health professionals (e.g., individuals are assigned a code and NLCHI retains a list that links the code with the particular individual’s actual name so data can be re-linked if necessary.) Secondary users who have access to the code and the data will be considered to have identifiable information;

“EMR Data” as defined in the EMR Physicians Participation Agreement;

“Fee-for-Service Physician” means a physician who submits accounts and receives payment of fees for insured medical services in accordance with the MCP Payment Schedule under the Medical Care Plan, pursuant to the *Medical Care and Hospital Insurance Act*, SNL 2016, c M-5.01. In relation to this Information Management Framework, a Fee for Service Physician refers to a physician who has signed one of the Agreements;

“HEALThe NL” has the meaning defined in the Fee for Service Physician Participation Agreement for Joining eDOCSNL through a Regional Health Authority Electronic Medical Record;

“Personal Health Information” has the meaning defined in PHIA;

“Primary Use” means the collection, use, and disclosure of personal health information for the care of the patient from, and about, whom the information is collected;

“Recipient Party” means the party who is receiving personal health information;

“Research” has the meaning defined in PHIA;

“RHA EMR Committee” has the meaning defined in the Fee for Service Physician Participation Agreement for Joining eDOCSNL through a Regional Health Authority Electronic Medical Record; and

“Secondary Use” has the meaning defined in the Memorandum of Understanding, October 2015.

2.0 RECIPIENT PARTIES

2.1 Newfoundland and Labrador Centre for Health Information

NLCHI is the Custodian of EMR Data disclosed to HEALThe NL for patient care and, also, of the EMR Data disclosed to NLCHI for Secondary Uses and stored in the NLCHI Data Warehouse. Its mandate includes the provision of information to inform decisions to enhance the health and well-being of persons in the province by providing a comprehensive province-wide information system.

NLCHI fulfils its mandate in part through the Secondary Use of data. The Data and Information Services Department is engaged in four main activities to support health system decision-makers: development and adoption of health information standards; analytics and evaluation; responding to requests for data and information; and data and information management. This department supports Research through the disclosure of data.

2.2 Regional Health Authorities

In addition to collecting personal health information directly from patients, the RHAs are also recipients of EMR Data from FFS physicians who have joined eDOCSNL through an RHA EMR. The RHAs provide information/data to organizational leaders, physicians, staff, and other health system stakeholders to inform clinical and operational performance and support informed decision-making.

2.3 Researchers

Researchers, academic or commercial, may receive EMR Data from NLCHI, RHAs, or FFS physicians. It is anticipated that most Research requests will be received by NLCHI. Researchers are not Custodians under PHIA but some are employees of a Custodian, particularly the RHAs and the designated facilities and schools at Memorial University, and therefore, must follow the policies and procedures of that Custodian.

2.4 Canadian Institute for Health Information

The Canadian Institute for Health Information (CIHI) is an independent, not-for-profit organization that provides essential information on Canada's health system and the health of Canadians. CIHI provides comparable and actionable data and information that are used to accelerate improvements in health care, health system performance and population health. Any disclosure to CIHI of personal health information is authorized by PHIA and is conducted in accordance with the agreement between the Department of Health and Community Services (DHCS) and CIHI. Prior to disclosing EMR Data to CIHI, the agreement between the DHCS and CIHI will be amended to ensure the appropriate restrictions on the use and disclosure of identifiable EMR Data.

3.0 GOVERNANCE FRAMEWORK

3.1 Legislation

Use and disclosure of EMR Data will occur in accordance with the MOU, the Agreements, NLCHI and RHA policies and procedures, the Information Management Framework, and the following legislation:

- a) *Personal Health Information Act (PHIA);*
- b) *Centre for Health Information Act, 2018;*
- c) *Health Research Ethics Authority Act;*
- d) *Medical Act, 2011;*
- e) *Transparency and Accountability Act;*
- f) *Medical Care Act and Hospital Insurance Act;*
- g) *Prescription Monitoring Act;*
- h) *Patient Safety Act;*
- i) *Public Health Protection and Promotion Act;* and
- j) Other legislation where appropriate.

3.2 Governance Committees

3.2.1 EMR Management Committee

The EMR Management Committee, the governing committee created through the MOU, provides strategic advice, guidance and direction on the management of eDOCSNL, including approvals related to Secondary Use of EMR Data, and the EMR Data elements that can be used for primary and Secondary Uses. This Information Management Framework, a policy of the EMR Management Committee, provides this direction and is agreed by the Parties to be the Data Sharing Agreement required by Clause 5.5(b) of the MOU.

3.2.2 EMR Executive Committee

The EMR Executive Committee, comprised of the DHCS Deputy Minister, the Executive Director of the NLMA, the CEO of Eastern Health and the CEO of NLCHI, adjudicates matters referred to it by the EMR Management Committee and monitors the effectiveness of the eDOCSNL program.

3.2.3 EMR Data Governance Advisory Committee

The Data Governance Advisory Committee reports to the EMR Management Committee with a mandate to advise the EMR Management Committee on matters related to the collection, use, disclosure, storage, retention, and disposal of EMR Data. The specific responsibilities of the advisory committee are to make recommendations to the EMR Management Committee regarding:

- the Secondary Uses of EMR Data;
- the EMR Data elements to be disclosed to NLCHI for Secondary Uses; and
- the EMR Data elements to be disclosed to HEALTHe NL for patient care.

3.3 EMR Participation Agreements

Each FFS physician and RHA participating in eDOCSNL has signed one of the Agreements with NLCHI which provides them with a subscription to Med Access, an interface with HEALTHe NL and other systems authorized by NLCHI, and the support of the eDOCSNL program staff. These agreements also establish the general terms and conditions for the disclosure of EMR Data to NLCHI for Secondary Uses and to support patient care.

3.4 RHA EMR Committees

Each RHA has a RHA EMR Committee comprised of FFS physicians, RHA employees and agents, and NLCHI staff, which advises on issues related to the Custodianship of EMR Data, and for discussion on issues related to the use and management of the EMR instance, including the implementation, training, policies, performance and operation of the RHA EMR. These committees will provide advice to the RHAs on the Secondary Use of EMR Data consistent with this Framework.

3.5 Policies and Procedures

NLCHI and the RHAs who collect EMR Data from another Custodian shall have policies and procedures to ensure EMR Data is managed and used appropriately, effectively, and efficiently. Policies and procedures regarding the manner of collection, use, disclosure, storage, retention, transfer, copying, modification, and disposition of EMR Data is required in accordance with PHIA.

3.6 Data Sharing Agreements

All disclosures of EMR Data for Secondary Uses must involve the execution of a data sharing agreement between the disclosing and Collecting Parties. The Agreements and this Information Management Framework meet this requirement for Custodians participating in eDOCSNL and as required in the MOU.

4.0 EMR Data for Direct Patient Care

Each FFS physician and RHA joined eDOCSNL to improve direct patient care through collaboration and information sharing within the Circle of Care. PHIA establishes the rules for the collection, use and disclosure of this information. The eDOCSNL program has made available privacy and security resources for collecting Custodians, and in particular FFS physicians, that provides advice on the sharing of personal health information within a single EMR instance and between EMR instances.

Collecting Parties will collect personal health information from HEALThe NL and store it in their EMR. This indirect collection for patient care is authorized by PHIA. Similarly, personal health information will be disclosed from the EMR to HEALThe NL, pursuant to PHIA for the purposes of providing patient care.

One of the objectives of the eDOCSNL Program is to enhance the overall capability for patient safety. TELUS may be required to access EMR Data and provide to NLCHI, in accordance with the terms and conditions of the eDOCSNL participation agreements and Professional Service Agreement, when issues involving patient safety or other support services arise.

5.0 Secondary Use of EMR Data

The Secondary Use of EMR Data is an integral part of the eDOCSNL Program. This EMR Information Management Framework establishes the terms and conditions for disclosure of EMR Data by eDOCSNL participants to NLCHI to inform health planning and policy development and other Secondary Uses as noted in section 5.3. NLCHI will also link EMR Data with other data they are the Custodians of for Secondary Uses.

As noted in section 1.2, NLCHI shall implement policies and procedures on the collection, use and disclosure of EMR Data that have been approved by the EMR Management Committee. These policies will be available on www.eDOCSNL.ca. Once NLCHI has these policies and procedures reviewed by the EMR Management Committee the Secondary Uses outlined in this Information Management Framework are exempt from the approval processes noted in section 7.0, except for uses requiring identifiable physician EMR Data and for disclosures of EMR Data for Research or commercial purposes. In these instances, NLCHI will be required to obtain approval from the EMR Management Committee (See Table 1 in section 7.0 for details on approvals required for disclosure and use of EMR Data).

The RHAs may use EMR Data from the RHA's EMR instance for similar Secondary Uses consistent with this Information Management Framework and the approval process in section 7.0, where required. As noted in section 1.2, the RHAs will implement policies and procedures consistent with the Information Management Framework in conjunction with the RHA EMR Committee. These policies and procedures will be reviewed by the EMR Management Committee. If the RHA does not adopt its own policies for the Secondary Use of EMR Data they will follow NLCHI's EMR Data policies and procedures. Once the RHAs

have these policies and procedures reviewed by the EMR Management Committee the Secondary Uses outlined in this Information Management Framework are exempt from the approval processes noted in section 7.0, except for the disclosures of EMR Data for Research or commercial purposes. The RHAs will be required to obtain approval from the EMR Management Committee (See Table 1 in section 7.0 for details on approvals required for disclosure and use of EMR Data).

5.1 EMR Data Elements for Secondary Use

EMR Data elements that are used or disclosed for Secondary Uses by NLCHI must be approved by the EMR Management Committee, following recommendations from the Data Governance Advisory Committee. The EMR Data elements that will be considered by the EMR Management Committee include select data elements from the Pan-Canadian Primary Health Care Electronic Medical Record Content Standards developed by CIHI as well as other data elements identified by the Data Governance Advisory Committee, DHCS, NLCHI, and the RHAs. The list of data elements may change over time.

An up to date list of all data elements used for Secondary Uses will be maintained and published on the eDOCSNL website www.edocsnl.ca.

5.2 Preparing EMR Data for Secondary Use

EMR Data is transferred from TELUS's secure data centre to NLCHI's secure data environment. This secure environment allows for controls on role-based access, and the restricted access can be set at the data field level. Once received by NLCHI, EMR Data used for Secondary Use will be de-identified prior to use or disclosure in accordance with NLCHI's Data De-Identification and Re-Identification Procedure, attached in Appendix A). Identifiable data will only be used and disclosed in accordance with the uses approved under this Information Management Framework and in accordance with legislation.

The RHAs, physicians and others may access EMR Data extracts held by NLCHI provided such access is consistent with the uses approved under this Information Management Framework.

5.3 Secondary Use Activities

Secondary Use refers to the use of data for a purpose other than patient care. Health system planning and management; health policy development; public health surveillance; quality improvement; Research; and clinical practice and program management are considered Secondary Uses. In addition to PHIA, Secondary Use of EMR Data will occur in accordance the *Centre for Health Information Act, 2018* and other legislation, the MOU, the Agreements, NLCHI and RHA policies and procedures, and the Information Management Framework parameters established in section 7.0.

The examples in Appendix B which do not require specific approval from the Management Committee are not exhaustive; however, the Secondary Uses must be consistent with the nature and scope of this Information Management Framework, or they require specific approval by the EMR Management Committee.

The examples in Appendix C that require separate approval from the Management Committee are not exhaustive.

5.3.1 Health System Planning, Management, and Health Policy Development

EMR Data will be used to inform health system planning, management, and health policy development initiatives. These types of initiatives assess the health needs of a geographic area or population in an effort to determine how these needs can be met.

5.3.2 Public Health Surveillance

The EMR has the potential to improve the accuracy, completeness, and timeliness of public health surveillance and reporting. Information produced from EMR Data can assist in understanding disease transmission and determining disease-related risk factors. As a result, EMR Data will be used to inform public health surveillance initiatives.

5.3.3 Quality Improvement

EMR Data will be used to support quality improvement initiatives. These initiatives require information on patient populations, their health care needs, what services are available, and how patients are utilizing these services to measure and report on quality of care and patient outcomes.

5.3.4 Research

EMR Data represent a rich data source for Researchers. Requests to access EMR Data for Research purposes will be processed through NLCHI and RHA approval processes and will require approval from the EMR Management Committee.

5.3.5 Clinical Practice and Program Management

EMR Data will be used to inform clinical practice and program management.

5.3.6 Required by Legislation

EMR Data may be used to meet legislative requirements. Mandatory disclosures required under legislation (e.g., *Medical Act*, *Prescription Monitoring Act*, etc.) will not be subject to EMR Management Committee approval. Other mandatory disclosures, such as Information Network Disclosures and Registry Disclosures, will occur after consultation with the EMR Management Committee.

PHIA S.39(4)(c) allows for the mandatory disclosure of personal health information to or via an information network designated in the regulations. In addition, S.39(4)(d) allows for the mandatory disclosure of personal health information to a Custodian designated in the regulations who compiles or maintains a registry of personal health information for purposes of facilitating or improving the provision of health care or that relates to the storage or donation of body parts or bodily functions.

Eastern Health is the Custodian of the Cancer Care Registry and NLCHI is the Custodian of the Chronic Disease Registry. Both registries will require EMR Data for the purposes of facilitating or improving the provision of health care.

Best efforts will be made to notify the EMR Management Committee in advance of, or if prior notification is impossible at the time of, the use of EMR Data for mandatory legislative

requirements that monitor or evaluate individually-identifiable patients, physicians or other healthcare providers that has not previously been documented in this Information Management Framework. Where prior or simultaneous disclosure is impossible, NLCHI or the RHA shall notify the EMR Management Committee within two business days.

5.4 Restrictions on the use of EMR Data

Identifiers related to patients, health professionals, and others may be used when linking data sets. The data must be de-identified and any key that may potentially re-identify an individual is held securely by a designated official within NLCHI who does not have access to the coded data set. If identifiable EMR Data is required to meet legislative purposes noted in section 5.3.6, best efforts will be made to notify the EMR Management Committee in advance of, or if prior notification is impossible at the time of, the use or disclosure as outlined in section 7.0. Where prior or simultaneous disclosure is impossible, NLCHI or the RHA shall notify the EMR Management Committee within two business days.

6.0 REPORTING OF SECONDARY USE OF EMR DATA

NLCHI and the RHAs will report semi-annually to the EMR Management Committee on the Secondary Use of EMR Data in their custody. The EMR Management Committee has an approved standard reporting template for use by NLCHI and the RHA, included in Appendix D.

7.0 Approval Process

The type of approval required for use and disclosure of EMR Data will depend on the type of EMR Data being used and disclosed and the type of requestor. Table 1 presents the approvals required for the use and disclosure of EMR Data. For most uses and disclosures described in sections 4.0 and 5.0, further approval by the EMR Management Committee will not be required (e.g., patient care and certain Secondary Uses). Instances where approval from the EMR Management Committee is required include uses and disclosures of EMR Data for Research and/or commercial purposes, and uses and disclosures by NLCHI that require identifiable individual physician information. However, if a FFS physician consents to or requests that NLCHI, an RHA, or the Minister of Health and Community Services use their identifiable data for a specific purpose, EMR Management Committee approval will not be required.

Table 1: Approvals Required for Use and Disclosure of EMR Data

Type of EMR Data User	Type of Use and Disclosure	Approval Required
Health Care Professionals and Providers	Primary use within the Circle of Care (Direct Patient Care)	No approvals required; permitted in accordance with PHIA.
	Disclosures to HEALThe NL to support patient care	EMR Management Committee will approve a list of data elements disclosed to HEALThe NL from FFS physician's EMRs.
NLCHI and RHAs (when using De-identified EMR Data).	Health System Planning and Management	EMR Management Committee approval when NLCHI or the RHA does not have policies reviewed by the EMR Management Committee, except when the
	Health Policy Development	
	Public Health Surveillance	

	Quality Improvement	disclosure is mandatory and required under legislation. EMR Data will be used and disclosed in accordance with PHIA S. 34(c), (d), (j) and (m) and PHIA S. 39(1)(d), (e) and (h) and the <i>Centre for Health information Act</i> S. 4(1).
	Clinical Practice and Program Management	
NLCHI and RHAs (when using identifiable physician EMR Data). The RHAs are exempt if they have policies for Secondary Use that are consistent with this framework, including policies on the collection of physician consent, and that have been reviewed by the EMR Management Committee,.	Health System Planning and Management	Approval from the EMR Management Committee.
	Health Policy Development	
	Public Health Surveillance	EMR Data will be used and disclosed in accordance with PHIA S. 34(c), (d), (j) and (m) and PHIA S. 39(1)(d), (e) and (h) and the <i>Centre for Health information Act</i> S. 4(1).
	Quality Improvement	
	Clinical Practice and Program Management	
	Disclosures to HEALThe NL to support patient care	EMR Management Committee will approve a list of data elements disclosed to HEALThe NL from FFS physician's EMRs.
NLCHI and RHAs	Mandatory disclosures required under legislation (e.g., <i>Medical Act</i> , <i>Prescription Monitoring Act</i> , etc.).	No approvals required. Best efforts will be made to notify the EMR Management Committee in advance of, or if prior notification is impossible at the time of, the use or disclosure. Where prior or simultaneous disclosure is impossible, NLCHI or the RHA shall notify the EMR Management Committee within two business days.
Custodian designated in the PHIA regulations	Information Network Disclosures and Registry Disclosures	No approvals required since this type of disclosure is a mandatory disclosure under PHIA S.39(4)(c) and S.39(4)(d). DHCS will make best efforts to take the advice of the EMR Management Committee on the EMR Data elements to be disclosed.
Any User	Research	Approval from the EMR Management Committee is required.
Memorial University (when acting as an agent	Health System Planning	Approval from the EMR Management Committee is required.

of a Custodian and requiring identifiable physician EMR Data)		
Any User	Commercial	Approval from the EMR Management Committee is required.

Each Custodian using EMR Data for Secondary Uses that was collected by another Custodian must have a documented process for approving all uses and disclosures.

7.1 NLCHI Approval Process

Requests for EMR Data will be processed and reviewed by NLCHI's Secondary Uses Committee and in accordance with NLCHI's Secondary Uses Review and Approval procedure. Details of the NLCHI approval process are documented in Appendix E.

7.2 HREB Approval Process

All health Research being conducted in Newfoundland and Labrador must be reviewed and approved by the provincial Health Research Ethics Board (HREB). The HREB is established through legislation (the *Health Research Ethics Authority Act*) by the Health Research Ethics Authority (HREA). The HREA also has the ability to approve other research ethics bodies to review health research in the province. Currently, the HREB is the only REB that reviews Secondary Use of data for health research.

Most Secondary Use health Research is considered minimal risk Research. Where Research projects are considered to be of minimal risk, in accordance with the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS2), the application may be sent for delegated review. The HREB chair will invite one or more current or past members of the HREB to provide delegated review for that application. The decision of this delegated review is provided to the HREB-Non Clinical Trial subcommittee at the next full board meeting.

7.3 RHA Approval Process

Requests for EMR Data for Research purposes carried out by, or on behalf of the RHA will be reviewed by the respective RHA Research Review Committee. These committees examine applications for Research that require the use of its facilities, staff time, health records or other data, and/or services and programs that effect its operations. The application is reviewed with attention to resource utilization and impact on the organization, issues of stewardship of biologic samples and protection of patient/employee privacy and confidentiality. All RHAs approved Research also requires HREB approval, the respective organizational approval, and approval from the EMR Management Committee prior to disclosing EMR Data for Research purposes to a third party.

7.4 EMR Management Committee Approval Process

Requests that will require approval from the EMR Management Committee include uses and disclosures for Research and/or commercial purposes, and uses and disclosures by NLCHI that require identifiable

individual physician information. However, if a FFS physician consents to NLCHI using their identifiable data for a specific purpose, EMR Management Committee approval will not be required.

The process of obtaining approval from the EMR Management Committee is as follows:

- 1) Requests for EMR Data that require approval from the EMR Management Committee will be processed and reviewed by NLCHI or the RHAs in accordance with these organization's policies and procedures.
- 2) Once a request has been processed by NLCHI or an RHA, and have obtained HREB approval where applicable, a summary of the application and recommendation for approval is then presented to the EMR Data Governance Advisory Committee.
- 3) The EMR Data Governance Advisory Committee will make a recommendation for approval; approval with conditions; or rejection to the EMR Management Committee.
- 4) The EMR Management Committee will provide review and provide a final decision. If a request is approved by the EMR Management Committee, the committee can decide to provide approval for additional requests that are similar in nature. This would apply to on-going initiatives that would require EMR Data elements and time periods for Secondary Use that are similar to the originally approved request.
- 5) Upon receipt of all required approvals, the requestor will enter into an agreement outlining the conditions of data access with NLCHI or an RHA, depending on which organization will be disclosing the data.

Uses and disclosures of EMR Data for commercial or Research purposes or activities that involve individually-identifiable physician information requires separate EMR Management Committee approval.

7.5 EMR Management Committee Appearance

An organization or person whose request for EMR Data is not approved by the Data Governance Advisory Committee may make a short presentation to the EMR Management Committee when the Committee considers the recommendation of the Data Governance Advisory Committee. A decision of the EMR Management Committee that is not unanimous may be appealed to the EMR Executive Committee.

8.0 CONCLUSIONS

This Information Management Framework provides direction to Custodians of EMR Data which is collected, used, disclosed, stored, and retained for patient care and Secondary Uses, as part of eDOCSNL. The EMR Management Committee is responsible for ensuring the protection of personal health information throughout all stages of the EMR program.

All physicians and RHAs can be assured that NLCHI and others who receive EMR Data from them are using it in accordance with PHIA and under the oversight of the EMR Management Committee. This Information Management Framework establishes rules to be followed by any Custodian or entity in Newfoundland and Labrador using EMR Data for Secondary Uses. These are:

- **EMR Data disclosures may only be done with a data sharing agreement that details the use and disclosure requirements of the recipient and references the eDOCSNL Information Management Framework.**
- **Each person or organization who uses EMR Data for Secondary Use must have policies and procedures in place that are compliant with the *Personal Health Information Act* and consistent with this Information Management Framework.**
- **Any Custodian, including Fee for Service Physicians, who uses personal health information for direct patient care and Secondary Uses must have policies and practices that clearly delineate the two roles under taken by the Custodian.**
- **An up to date list of all data elements used for Secondary Use will be maintained and published on the eDOCSNL website www.edocsnl.ca.**
- **Best efforts will be made to notify the EMR Management Committee in advance of, or if prior notification is impossible at the time of, the use of EMR Data for mandatory legislative requirements that monitor or evaluate individual patients, physicians or other healthcare providers that has not previously been documented in this Information Management Framework or policy of the EMR Management Committee. Where prior or simultaneous disclosure is impossible, NLCHI or the RHA shall notify the EMR Management Committee within two business days.**
- **Each Custodian using EMR Data for Secondary Uses that was collected by another Custodian must have a documented process for approving all uses and disclosures.**
- **Uses and disclosures of EMR Data for commercial or Research purposes or activities that involve identifiable-physician information requires Management Committee approval, unless previously approved in this Information Management Framework.**

Appendix A: NLCHI's Data De-identification and Re-identification Procedure

1. Background and Current Status

Through the recent Data Lab Project, a more robust process of de-identification and de-identified record linkage was created which utilizes a new and more effective privacy-protective patient ID (i.e., W_PAT_ID). Based on the provincial Client Registry unique identifier logic, the W_PAT_ID is generated and used within the data warehouse (DW) as well as the internal analytic environment (NIMS) at the Centre. For NIMS data holdings, the W_PAT_ID is applied via a Linkage Key which is a SAS file that is generated from the DW and stored for de-identified record linkage purposes in NIMS.

For most Secondary Uses of the Centre's data holdings¹, personal identifiers are not required. Rather, it is preferable to minimize exposure of such identifiers by having direct and indirect identifiers removed, to the extent possible, and replaced by a randomly assigned unique identifier that enables use and linkage of an individual's records across disparate datasets in a privacy-protective manner. All data holdings¹ managed by the Centre that contain personally identifiable or other sensitive information are stored securely in the Centre's Data Lab environment, and de-identified there for Secondary Use. Data holdings¹ that are used frequently and for multiple purposes are typically stored in the Data Warehouse environment; data that tends to be project- or use-specific is typically stored and managed in the NIMS environment. These environments are linked so that linkage of files in both environments is possible. The Centre's De-identification process involves two levels of de-identification, one for internal users on one for external users.

2. Level 1 De-identification

2.1 Data Warehouse (DW) De-identification (Level 1 De-identification)

All data holdings flowing into the DW are assessed and modeled to fit with the structure of the DW. All files with personal identifiers are mapped to the Master Patient table which holds all identifiers associated with a unique person in a single record. Access to identifiable information in the Master Patient table is based on assignment of a user to a specific user group and limited to only Centre staff who need access to this information to perform their work duties. All individuals in a group have access to the same data; assignment to a user group involves a process of application, assessment and approval. Identifiable information is visible only to those user groups with approved access.

2.2 NIMS De-identification (Level 1 De-identification)

Similarly, access to identifiable information managed in NIMS is based on user group assignment and limited to only Centre staff who need access to this information to perform their work duties. Only those with approved access can see identifiable information. All other access involves de-identified data holdings only. The new Linkage Key generated from the DW is updated weekly in the NIMS environment and applied to all files managed in the NIMS that have been flagged for de-identification. Using the new Linkage Key, an identifiable patient record is assigned a W_PAT_ID that is used to link patient records

¹ **Data Holdings** include any databases and/or datasets acquired and/or created by the Centre for analytical, evaluation or research purposes. (Policy IM-05 "Information Management")

across datasets, in place of the patient's health care number. The Linkage Key can accommodate instances where a patient has been issued multiple health care numbers and used variously across the spectrum of health care services in the province. All health care numbers associated with a patient (including those issued by other jurisdictions) are consolidated into a single W_PAT_ID, resulting in more effective linkage of patient records.

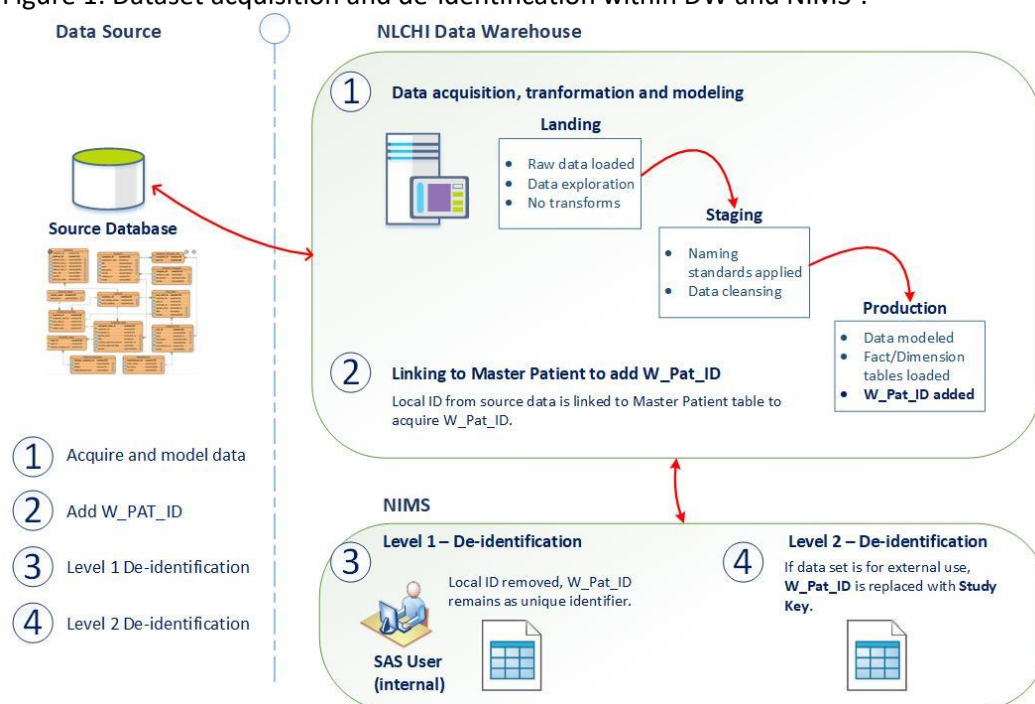
Following replacement of patients' health care numbers with W_PAT_ID in NIMS datasets, all direct identifiers (as prescribed by the Safe Harbor method and in consultation with dataset business owners), including health care numbers, are then stripped from the record. The result is a pseudonymized NIMS dataset that is linkable with other datasets stored in NIMS or the DW.

3. Level 2 De-identification

3.1 NIMS De-identification (Level 2 De-identification)

Datasets that are made available to external requestors have another layer of de-identification applied to a prepared data set before it is made available outside the Centre's internal DW and NIMS environments (i.e., the Research and Evaluation environment). For each dataset prepared for an external audience, the W_PAT_ID is removed and replaced with a new unique study key that is not used with any other dataset. As such, the dataset cannot be reasonably linked to any other existing dataset as there is no common identifier available across files.

Figure 1. Dataset acquisition and de-identification within DW and NIMS².



² Some data sets may come into NIMS directly in addition to DW data acquisition.

Appendix B: Examples of Secondary Use Activities that do not require Separate Approval

This Appendix lists examples of the approved uses and disclosures of EMR Data that do not require specific EMR Management Committee approval when the user has policies that have been reviewed by the EMR Management Committee.

1) Health System Planning, Management, and Health Policy Development

Examples of health system planning, management, and health policy development include but are not limited to:

Describing Patient Populations and Health Care Needs

To effectively plan, deliver, and manage health services, information about the patient population and the health status of the population is required. Examples of the type of information produced to support this type of activity includes the following:

- Demographic information such as the number of patients residing in a geographic area and their age structure;
- Immunization information;
- Types and incidence of chronic disease;
- Management of chronic disease (e.g., blood pressure testing, smoking cessation/healthy eating/physical activity advice, foot exams for individuals with diabetes, etc.), and;
- Cancer screening.

Describing Availability and Location of Health Care Services

For most patients, family physicians are the first point of contact for obtaining health care services. Therefore, an understanding of what health services are currently available is important to identify gaps in services available to patients. Examples of the type of information produced to support this type of activity includes the following:

- Number of patients who have a regular provider;
- The types of patients without a regular provider;
- Other characteristics that describe access to primary care services in communities and regions of the province, and among target populations;
- The locations services are provided, and
- Number of referrals to selected healthy living/self-management programs and services.

Describing Health Service Utilization

Patient's interactions with the health care system generates demographic, utilization and clinical information. Analyzing health service utilization data reveals important information that is used to inform individual care decisions, and broader health system planning, management, and health policy development. Current health service utilization patterns can also be used to predict future health service utilization. This information can be used to inform health system design and resource allocation. Examples of the type of information produced to support this type of activity includes the following:

- Number and frequency of physician visits;

- Number of repeat visits;
- Number of patients who do not keep their appointments;
- Cancellation rates, and;
- Number of patients seeing multiple providers.

Producing Information to Inform Potential Interventions

Information about patient populations, their health care needs, what services are available, and how patients are utilizing these services can be used to inform potential interventions. For example, this type of information could be used to determine whether new services, or a walk-in clinic are needed in a certain geographic area.

Evaluating and Monitoring Programs and Services

Once an intervention is implemented, evaluation and monitoring is required to determine if the health system change is meeting the needs of the patient population. Health service utilization and patient outcomes pre and post implementation of the intervention would need to be assessed. Examples of the type of information produced to support this type of activity includes the following:

- Patient populations;
- Patient health care needs;
- What services are available, and;
- How patients are utilizing these services to measure and report on health system performance.

2) Public Health Surveillance

Identifying and Reporting of Immunizations

EMR Data will be used to report the number of publicly funded vaccines that are administered by physicians.

3) Quality Improvement

Evaluate and Monitor Quality of Care and Patient Outcomes

Information required for monitoring quality of care and patient outcomes includes the following:

- Number of physician visits;
- Number of repeat visits;
- Number of patients that do not keep their appointments;
- Cancellation rates, and;
- Number of patients seeing multiple providers;
- Type of treatment provided for various conditions;
- Reduction in blood pressure in patients with hypertension, and;
- Wait times for health care services.

Data Quality Initiatives

EMR Data will also be used to support data quality and standardization processes related to datasets used and maintained by NLCHI and the RHAs.

Appendix C: Examples of Secondary Use Activities that Require Separate Approval or Consent

1) Health System Planning, Management, and Health Policy Development

Producing Information to Support the Family Practice Renewal Program when individual physician information is used

The Family Practice Renewal Program (FPRP) was established in late 2015, through a MOA between the NLMA and the Department of Health and Community Services. There are three core initiatives within the program:

- Family Practice Networks: These networks will provide a structure and mechanism through which physician groups will have the opportunity to address common practice needs, as well as local population health needs, in collaboration with their RHAs;
- Fee Code Program: This program is designed to achieve patient, physician, and health system benefits such as comprehensive care, collaboration with other providers, and improvements in patient access; and
- Practice Improvement Program: This program will provide physician practices with education and support for clinical and workflow issues.

NLCHI will be working with the FPRP to evaluate this initiative. Information will be produced to inform decisions related to program design, plans for sustainability, decisions regarding spread of innovations, programs and concepts that are working, and to demonstrate accountability for achieving intended outcomes. To complete this evaluation, with the approval of the FPRP Management Committee, NLCHI will link FPRP program data to EMR Data for analysis of program uptake and to assess other evaluation issues. Analysis and disclosure related to FPRP will, consistent with other Secondary Uses above, use De-Identified data and will not be used for monitoring or auditing the activity of individual physicians, except when related to the FPRP and with the physician's express consent.

2) Clinical Practice and Program Management

Physician Performance and Benchmarking

Choosing Wisely Newfoundland and Labrador (CWNL) launched in October 2016 and is coordinated by the Translational and Personalized Medicine Initiative (TPMI) at Memorial University. CWNL works in partnership with the RHAs, NLCHI, NLMA and the Patient Advisory Council (NL SUPPORT). CWNL also works in partnership with Choosing Wisely Canada in implementing their practice recommendations. CWNL will take various practice recommendations from Choosing Wisely Canada and implement change strategies which involve physician awareness and education on test ordering or prescribing patterns. To achieve this goal, CWNL will require the following identifiable physician information:

- Types of tests individual providers are ordering;
- Medications individual providers are prescribing, and;
- Frequency of test ordering and prescribing patterns.

Patient information will be de-identified, and providers will only have access to their own practice data. Identifiable physician data disclosed for these purposes will require EMR Management Committee approval.

NLCHI will also use EMR Data to provide physician dashboards. Patient data would be aggregated and various indicators would be included on these dashboards to provide individual physicians with an easy-to-interpret visual displays of their patient information. The ability to trend indicator results over time, and compare with peers and guidelines would also be available. Examples of the type of information needed to achieve this goal include the following:

- Individual physician's patient population;
- Patient health status;
- Test ordering, and;
- Prescribing practices.

The end user of physician dashboards is for the benefit of individual physicians. The data used to produce these dashboards is not available to any other user or organization, or for any other purpose or disclosure, unless specifically approved by the EMR Management Committee.

Meaningful Use

NLCHI will also use EMR Data to determine what components of the EMR are used by physicians as a group or by individual physicians with the physician's consent. EMR practice advisors will use this information to improve the meaningful use of the EMR by the physician. The end use of this information is for the benefit of individual physicians and practices. The information is not available to any other user or organization, or for any other purpose or disclosure, unless specifically approved by the Management Committee.

Clinical Decision Support Triggers

NLCHI will use EMR Data to create clinical decision support triggers for the purpose of supporting clinician decision making during the process of providing patient care. Examples of clinical decision support triggers include the following:

- Preventive care reminders (e.g., immunizations, cancer screening, etc.);
- Program referral eligibility (e.g., diabetes collaborative, remote patient monitoring, smoking cessation, etc.), and;
- Chronic disease management (e.g., blood glucose and blood pressure monitoring, etc.).

The end use of this information is for the benefit of individual physicians and practices. The information is not available to any other user or organization, or for any other purpose or disclosure, unless specifically approved by the Management Committee.

Appendix D: Template for Reporting Use and Disclosures of EMR Data

Type of Activity	Category of Secondary Use	Project Title	Type of EMR Data	EMR Management Committee Approval
<i>Use</i>	<i>Health System Planning</i>		<i>De-identified</i>	<i>Not Required</i>
<i>Disclosure</i>	<i>Research</i>		<i>De-identified</i>	<i>Approved</i>

Appendix E: NLCHI Approval Process

NLCHI's Secondary Uses Review and Approval procedure establishes requirements for the uses and disclosures of record-level data, including identifiable and De-identified Data, by the NLCHI. Requests to access record-level data are received by NLCHI's Information Request Coordinator (IRC). A consultation meeting is usually arranged where the requestor and various subject matter experts meet to discuss the details of the request.

Once all required documents are received (i.e., final application, HREB application and approval if required), the Secondary Uses Committee chair determines the type of review required, including where approval by the EMR Management Committee is required (i.e., full committee/expedited). Applications requiring full review are reviewed by the Secondary Uses Committee. Applications deemed appropriate for expedited review are reviewed only by the chair of the Secondary Uses Committee.

Following review of the application and supporting documents, the VP Data and Information Services is briefed on the application and a recommendation is made by the Secondary Uses Committee chair to NLCHI's VP responsible for privacy regarding application approval. If approved, an approval letter is provided to the requestor, signed by the VP responsible for privacy, and includes terms and conditions of use. The requestor is asked to sign to accept the terms and conditions and return a signed copy of the letter to NLCHI. Upon receipt of all required approvals, NLCHI and the requestor enter into a service agreement. This agreement refers to the terms and conditions of use specified in the approval letter and includes additional statements related to use of the data, data transfer, confidentiality and intellectual property associated with the data.