Dear Applicant:

Re: Your request for access to information under Part II of the Access to Information and Protection of Privacy Act [Our File #: HCS/156/2019]

On November 28, 2019, the Department of Health and Community Services (the Department) received your request for access to the following records:

“October 2019 briefing materials titled: - Decision Direction Note - Change in Suppliers for ISMT Incoming Calls Services - Decision/Direction Note - New link between the Janeway Hostel and the Health Sciences Centre - Decision Note Prescription Monitoring Regulations - Decision Note - Request for Fluoroscopy Unit, James Paton Memorial Regional Health Centre, Gander - Information Note - Tamoxifen Shortage - Information Note - Obstetrical Services at James Paton Memorial Regional Health Centre - Information Note - Outbreak of Shiga Toxin-Producing Escherichia coli (STEC) in the Eastern Health Region - Information Note - Outbreak of Shiga Toxin-Producing Escherichia coli (STEC) - Update October 2019 - Meeting Note - Sequence Bio Informatics (SBI) - October 2019”

I am pleased to inform you that a decision has been made by the Department to provide access to most of the requested information. Access to the remaining information contained within the records has been refused in accordance with the following exceptions to disclosure as specified in the Access to Information and Protection of Privacy Act (the Act):

Policy advice or recommendations
29. (1)(a) The head of a public body may refuse to disclose to an applicant information that would reveal advice, proposals, recommendations, analyses or policy options developed by or for a public body or minister.

Legal advice
30. (1)(a)(b) The head of a public body may refuse to disclose to an applicant information that is subject to solicitor and client privilege or litigation privilege of a public body; or that would disclose legal opinions provided to a public body by a law officer of the Crown.

Disclosure harmful to the financial or economic interests of a public body
35. (1)The head of a public body may refuse to disclose to an applicant information which could reasonably be expected to disclose:
(d) information, the disclosure of which could reasonably be expected to result in the premature disclosure of a proposal or project or in significant loss or gain to a third party;
(g) information, the disclosure of which could reasonably be expected to prejudice the financial or economic interest of the government of the province or a public body;
(f) positions, plans, procedures, criteria or instructions developed for the purpose of contractual or other negotiations by or on behalf of the government of the province or a public body, or considerations which relate to those negotiations.

Disclosure harmful to personal privacy

40. (1) The head of a public body shall refuse to disclose personal information to an applicant where the disclosure would be an unreasonable invasion of a third party's personal privacy.

Pages 3-4 and 6 have been withheld in their entirety under s. 29(1)(a) and s. 35(1)(d)(g). Page 29 has been withheld in its entirety under s. 40(1) of the Act as it comprises information that would identify patients. Pages 33-34 have been withheld in their entirety under s. 29(1)(a) and s. 30(1)(a)(b).

Please be advised that you may ask the Information and Privacy Commissioner to review the processing of your access request, as set out in section 42 of the Access to Information and Protection of Privacy Act (the Act). A request to the Commissioner must be made in writing within 15 business days of the date of this letter or within a longer period that may be allowed by the Commissioner.

The address and contact information of the Information and Privacy Commissioner is as follows:

Office of the Information and Privacy Commissioner
2 Canada Drive
P. O. Box 13004, Stn. A
St. John’s, NL. A1B 3V8
Telephone: (709) 729-6309
Toll-Free: 1-877-729-6309
Facsimile: (709) 729-6500

You may also appeal directly to the Supreme Court Trial Division within 15 business days after you receive the decision of the public body, pursuant to section 52 of the Act.

Please be advised that responsive records will be published following a 72 hour period after the response is sent electronically to you or five business days in the case where records are mailed to you. It is the goal to have the responsive records posted to the Completed Access to Information Requests website within one business day following the applicable period of time. Please note that requests for personal information will not be posted online.

If you have any further questions, please contact the undersigned by telephone at 709-729-7010 or by email at MichaelCook@gov.nl.ca.
Sincerely,

Michael Cook
Manager of Privacy and Information Security

/Enclosures
Access or correction complaint

42. (1) A person who makes a request under this Act for access to a record or for correction of personal information may file a complaint with the commissioner respecting a decision, act or failure to act of the head of the public body that relates to the request.

(2) A complaint under subsection (1) shall be filed in writing not later than 15 business days

(a) after the applicant is notified of the decision of the head of the public body, or the date of the act or failure to act; or

(b) after the date the head of the public body is considered to have refused the request under subsection 16 (2).

(3) A third party informed under section 19 of a decision of the head of a public body to grant access to a record or part of a record in response to a request may file a complaint with the commissioner respecting that decision.

(4) A complaint under subsection (3) shall be filed in writing not later than 15 business days after the third party is informed of the decision of the head of the public body.

(5) The commissioner may allow a longer time period for the filing of a complaint under this section.

(6) A person or third party who has appealed directly to the Trial Division under subsection 52 (1) or 53 (1) shall not file a complaint with the commissioner.

(7) The commissioner shall refuse to investigate a complaint where an appeal has been commenced in the Trial Division.

(8) A complaint shall not be filed under this section with respect to

(a) a request that is disregarded under section 21 ;

(b) a decision respecting an extension of time under section 23 ;

(c) a variation of a procedure under section 24 ; or

(d) an estimate of costs or a decision not to waive a cost under section 26 .

(9) The commissioner shall provide a copy of the complaint to the head of the public body concerned.
52. (1) Where an applicant has made a request to a public body for access to a record or correction of personal information and has not filed a complaint with the commissioner under section 42, the applicant may appeal the decision, act or failure to act of the head of the public body that relates to the request directly to the Trial Division.

(2) An appeal shall be commenced under subsection (1) not later than 15 business days

(a) after the applicant is notified of the decision of the head of the public body, or the date of the act or failure to act; or

(b) after the date the head of the public body is considered to have refused the request under subsection 16 (2).

(3) Where an applicant has filed a complaint with the commissioner under section 42 and the commissioner has refused to investigate the complaint, the applicant may commence an appeal in the Trial Division of the decision, act or failure to act of the head of the public body that relates to the request for access to a record or for correction of personal information.

(4) An appeal shall be commenced under subsection (3) not later than 15 business days after the applicant is notified of the commissioner’s refusal under subsection 45 (2).
Decision/Direction Note
Department of Health and Community Services

Title: Change in Suppliers (Call Service) for Income Support Medical Transportation Assistance Program (ISMT) Incoming Calls on an Interim Basis

Decision/Direction Required:
1. To cancel the current incoming daytime call service agreement with Telelink (the “Daytime Telelink Agreement” (within 31 days).

Recommendation: s. 29(1)(a), s. 35(1)(d)(g)

Background: s. 29(1)(a) s. 35(1)(d)(g)

- In June 2018, portions of the ISMT program (i.e. Avalon region, methadone services) were transferred from the Department of Advanced Education Skills and Labour (AESL) to HCS. At the time of the transfer, the Department signed the Initial Bell Agreement to provide an Answering Call Device (ACD) queue for staff answering incoming client calls during regular working hours.

- Due to the lack of ISMT resources to manage the ACD, many incoming client calls were either unanswered, or were not answered in a timely manner. This left clients in the queue for long periods of time, which restricted other calls from entering the queue.

- In September 2018, when the remaining pieces of the ISMT program were moved from AESL to HCS, the Department signed the On-Call Telelink Agreement. This agreement provided HCS with on-call and after-hour emergency service for its ISMT clients.

- Together, the Initial Bell Agreement and the On-Call Telelink Agreement enabled the Department to provide its ISMT clients with 24 hour service delivery.

- By November 2018, ISMT were receiving approximately 300 incoming calls a day with only a limited number being answered. The ACD queue, on-call phone system and staffing complement were not equipped to handle the extreme call volumes, creating significant
challenges for clients and staff. As clients continued to experience long response times or no service delivery, backlogs in the ISMT program became a matter of public concern.

- As a remedy to the significant call volume, HCS placed the Initial Bell Agreement on hold in November 2018 and signed the Daytime Telelink Agreement. This agreement would have all daytime calls answered by Telelink Operators as opposed to the current ISMT staff under the Initial Bell Agreement.

- The Telelink Operator’s role is to answer client calls, ask a series of scripted questions, and email the information to a HCS email address for appropriate action. ISMT staff return the call to the client and action the request.

Current Status:
- One year post-transfer of the ISMT program from AESL, clients are still experiencing long delays in phone call response times and are frustrated by interactions, or lack thereof, with ISMT staff.

- In July and August 2019, HCS hired an additional 10 temporary Client Service Officers to manage call response times. Along with the additional staff, ISMT also implemented processes to prepare for in-house answering services, including; returning client calls within 12-24 hours, completing reimbursements in a timelier manner and completing client requests as submitted in TRIM.

- Despite these much needed improvements, issues still remain with Telelink’s daytime call system. The daytime call system is not and has not been robust enough to service or capture all client incoming calls without receiving a busy signal.

Analysis:
- The Daytime Telelink Agreement outlined HCS’ costs as $11,800 monthly for 10,850 minutes and $1.15 for each additional minute. However, due to extremely high call volumes, the average cost per month from November 2018 – August 2019 was $24,000.

- The On-Call Telelink Agreement outlined HCS’ costs as $1,635 monthly for 1,500 minutes, and $1.15 for each additional minute. However, the average cost per month from September 2018 to August 2019 was $3,000. s. 29(1)(a) s. 35(1)(d)(g)
Decision/Direction Note
Department of Health and Community Services

Title: New link between the Janeway Hostel and the Health Science Centre

Decision/Direction Required:
- Whether or not to provide approval to Eastern Health to proceed with awarding the tender for the new link between the Janeway Hostel and the Health Sciences Centre.

- It is recommended that approval be provided to Eastern Health to proceed with awarding the tender for the new link between the Janeway Hostel and the Health Sciences Centre.

Background and Current Status:
- The New Adult Mental Health & Addictions Facility (NAMHAF) will be constructed on the Health Science Centre (HSC) site in the location of the existing Agnes Cowan Hostel, which requires the demolition of the Agnes Cowan Hostel.

- Access between the Janeway Hostel and the HSC is currently provided via a link through the Agnes Cowan Hostel which will be lost when the Agnes Cowan Hostel is demolished. Additionally, power and other utility service connections for the Janeway Hostel are currently routed through this link as well.

- A new, two level link connecting the Janeway Hostel directly to the HSC has previously been tendered by Eastern Health and is ready to award. Included in the tender are upgrades to the Janeway Hostel rooms to convert them to resident on-call which are currently housed in the Agnes Cowan Hostel but will be lost once that facility is demolished, as well as rerouting of the power/utility connections.

- Any new structural works related to this tender (which excludes rerouting of the power lines and the upgrades to the on-call rooms) requires approval of the Pippy Park Commission.

- Four (4) bids were received to the tender call with the lowest bid being $3,85M (plus HST). The bids are as follows:
  - Newfoundland HVAC Ltd. $3,850,000.00 + HST
  - Can-Am Platforms $4,075,277.00 + HST
  - JMJ Holdings Ltd. $4,644,521.00 + HST
  - Olympic Construction $5,067,585.84 + HST

Analysis:
- 

s. 29(1)(a) s. 35(1)(d)(g)
Decision / Direction Note  
Department of Health and Community Services

Title: Prescription Monitoring Regulations

Decision Required: Whether to approve the attached Prescription Monitoring Regulations made under the authority of the Prescription Monitoring Act.

Background and Current Status:
- The Prescription Monitoring Program (Program) has been operating since June 2018. The objects of the Program are to, using Pharmacy Network data, monitor, analyze and report information related to the prescribing, dispensing and use of monitored drugs. Currently, opioids are the only drugs being monitored.

- The Newfoundland and Labrador Centre for Health Information (NLCHI) has been delegated authority under the Prescription Monitoring Act (Act) to administer the Program on behalf of the Minister of Health and Community Services.

- In accordance with section 14 of the Act, the minister may establish committees to provide advice and recommendations related to the administration and enforcement of the Act. Where committees are established, the details regarding their composition, terms and duties must be set out in regulations.

- Two such committees have been contemplated: an advisory committee whose mandate will be to act in an advisory capacity and provide recommendations to HCS and Program officials regarding the administration of the Program; and, a consultants committee whose role will be to provide a clinical lens to reports generated through the Pharmacy Network to help identify issues that may require further action.

Analysis
- Section 22 of the Act grants the minister authority to make regulations in the following areas:
  - respecting the establishment of advisory committees, the appointment of members, terms of office, composition, terms of reference, duties and other matters; and
  - respecting time periods in which regulatory authorities and others are required to provide information to the minister and/or Program officials.

- The Prescription Monitoring Regulations include specific provisions for the following:
  - The establishment of an advisory committee whose mandate is:
    - to provide advice and recommendations regarding the drugs to be monitored by the Program, the policies developed for the operation and management of the Program, the reports to be generated from Pharmacy Network data, any issues with program risk management and data quality, and those other matters referred to the committee.
  - The composition of the advisory committee whose membership shall include physicians, dentists, pharmacists, nurse practitioners, as well as regulatory authorities,
policing agencies and a public representative appointed in accordance with the Public Service Commission Act.

- The establishment of a consultants committee whose mandate is:
  - To review reports generated through the Pharmacy Network in order to monitor the prescribing, dispensing and use of monitored drugs, as well as identifying any unusual or potentially inappropriate activity trends.
- The composition of the consultants committee whose membership shall include physicians, dentists, pharmacists and nurse practitioners.
- The appointment process for members of both committees, including the term of appointments, quorum requirements and meeting frequency.
- The requirement for regulatory authorities to notify Program Officials within 24 hours after the decision to restrict, suspend or revoke the licence of a prescriber or dispenser has been communicated to the prescriber or dispenser.
- The requirement for any person who receives a request for information to respond to that request within seven days of receiving the request.

- HCS officials have worked closely with key stakeholders, including NLCHI, the College of Physicians and Surgeons of NL, the NL Pharmacy Board and the College of Registered Nurses of NL, in the development of the Prescription Monitoring Regulations, which have been drafted by the Office of Legislative Counsel.

**Alternatives**

- **Option 1: Approval of the attached Prescription Monitoring Regulations (Recommended)**

  **Advantages:**
  - Will enable the Program to be fully operationalized;
  - Will meet the expectations of stakeholders;
  - Will allow Program officials to benefit from clinical expertise in interpreting reports generated through the Pharmacy Network; and
  - Will keep stakeholders engaged and informed of the administration and management of the Program.

  **Disadvantages:**
  - None identified

- **Option 2: Do not approve the attached Prescription Monitoring Regulations (Not recommended)**

  **Advantages:**
  - None identified

  **Disadvantages:**
  - Will not enable the Program to be fully operationalized;
  - Will not meet the expectations of stakeholders; and
  - Will not allow Program officials to benefit from the expertise of clinicians, regulatory authorities and policing agencies in the ongoing administration and management of the Program.
• If the Regulations are acceptable to the minister, the Regulations should be signed where flagged. HCS officials will then arrange for publication of the Regulations in the Newfoundland and Labrador Gazette.

• The Regulations will come into force upon publication.

Recommendation:
• Approval of the attached Prescription Monitoring Regulations.

Prepared/Approved by: Gerrie Smith/K. Stone
Ministerial Approval: Received from Hon. Dr. John Haggie, MD

October 23, 2019
NEWFOUNDLAND AND LABRADOR
REGULATION /19

Prescription Monitoring Regulations
under the
Prescription Monitoring Act

(Filed , 2019)

Under the authority of section 22 of the Prescription Monitoring Act, I make the following regulations.

Dated at St. John's,

Dr. John Haggie
Minister of Health and Community Services

REGULATIONS

Analysis

1. Short title
2. Definitions
3. Advisory committee
4. Advisory committee members
5. Advisory committee meetings
6. Consultants committee
7. Consultants committee members
8. Consultants committee meetings
9. Time periods

1. These regulations may be cited as the Prescription Monitoring Regulations.

2. In these regulations

(a) "Act" means the Prescription Monitoring Act;
(b) "advisory committee" means the committee established under section 3;

(c) "consultants committee" means the committee established under section 6;

(d) "department" means the department presided over by the minister;

(e) "Newfoundland and Labrador Centre for Health Information" means the Newfoundland and Labrador Centre for Health Information continued under the Centre for Health Information Act, 2018;

(f) "nurse practitioner" means a nurse practitioner as defined in the Registered Nurses Act, 2008;

(g) "pharmacist" means a pharmacist as defined in the Pharmacy Act, 2012; and

(h) "physician" means a medical practitioner as defined in the Medical Act, 2011.

3. (1) The advisory committee is established.

(2) The advisory committee shall provide advice and recommendations regarding

(a) drugs or classes of drugs to be monitored by the program;

(b) policies developed for the operation and management of the program;

(c) reports generated from the pharmacy network data;

(d) program risk management and data quality issues; and

(e) those matters referred to the advisory committee by the minister or his or her delegate.

4. (1) The advisory committee shall consist of
(a) a physician appointed by the minister from a list of physicians submitted by the College of Physicians and Surgeons of Newfoundland and Labrador;

(b) a physician appointed by the minister from a list of physicians submitted by the Newfoundland and Labrador Medical Association;

(c) a pharmacist appointed by the minister from a list of pharmacists submitted by the Newfoundland and Labrador Pharmacy Board;

(d) a pharmacist appointed by the minister from a list of pharmacists submitted by the Pharmacists' Association of Newfoundland and Labrador;

(e) a nurse practitioner appointed by the minister from a list of nurse practitioners submitted by the College of Registered Nurses of Newfoundland and Labrador;

(f) a person representing the public interest and appointed in accordance with the Public Service Commission Act;

(g) a member of the Royal Newfoundland Constabulary appointed by the Royal Newfoundland Constabulary;

(h) a member of the Royal Canadian Mounted Police appointed by the Royal Canadian Mounted Police;

(i) a representative of the College of Physicians and Surgeons of Newfoundland and Labrador appointed by the College of Physicians and Surgeons of Newfoundland and Labrador;

(j) a representative of the Newfoundland and Labrador Dental Board appointed by the Newfoundland and Labrador Dental Board;

(k) a representative of the College of Registered Nurses of Newfoundland and Labrador appointed by the College of Registered Nurses of Newfoundland and Labrador;

(l) a representative of the Newfoundland and Labrador Pharmacy Board appointed by the Newfoundland and Labrador Pharmacy Board;
(m) at least one employee of the Newfoundland and Labrador Centre for Health Information appointed by the chief executive officer of the Newfoundland and Labrador Centre for Health Information;

(n) at least one employee of the Department of Justice and Public Safety appointed by the deputy minister of the Department of Justice and Public Safety;

(o) at least one employee of the department appointed by the deputy minister of the department; and

(p) the deputy minister of the department or his or her designate.

(2) Where an organization referred to in paragraph (1)(a), (b), (c), (d) or (e) fails to provide a list of names in accordance with paragraph (1)(a), (b), (c), (d) or (e) within 30 days of the minister's request to provide the list, the minister may appoint a physician, pharmacist or nurse practitioner, as the case may be, notwithstanding that a list has not been provided by the organization.

(3) The chairperson of the advisory committee shall be the deputy minister of the department or his or her designate.

(4) The members of the advisory committee appointed under paragraphs (1)(a) to (f) shall be appointed for a term of 3 years and are eligible for reappointment.

(5) Where the term of office of a member appointed under paragraphs (1)(a) to (f) expires, the member shall continue to be a member until replaced.

(6) A person appointed under paragraphs (1)(a) to (f) may resign as a member by written notice to the minister.

(7) A person appointed under paragraphs (1)(g) to (l) may resign as a member by written notice to the organization that appointed him or her.

(8) Where a member resigns in accordance with subsection (7), the organization that appointed the member shall immediately appoint a member of the organization to replace the person who resigned and notify the minister, in writing, of that person's name.
5. (1) The advisory committee shall meet at least 4 times a year.

(2) A quorum of the advisory committee shall be 8 members of which

(a) one member shall be an employee of the Newfoundland and Labrador Centre for Health Information appointed under paragraph 4(1)(m);

(b) one member shall be the deputy minister of the department or his or her designate; and

(c) 6 members shall be members appointed under paragraphs 4(1)(a) to (l).

6. (1) The consultants committee is established.

(2) The consultants committee shall, upon the request of the minister or his or her delegate, review reports generated from the pharmacy network data for the purpose of

(a) monitoring the prescribing, dispensing and use of monitored drugs; and

(b) identifying any unusual or potentially inappropriate activity trends.

(3) The consultants committee shall advise the minister or his or her delegate of the results of its monitoring of monitored drugs and may recommend one or more of the following to the minister or his or her delegate:

(a) that information be provided to prescribers, dispensers and patients for educational purposes;

(b) that an inspection be conducted under the Act;

(c) that information be provided to the appropriate regulatory authority;

(d) that information be provided to the appropriate law enforcement authority; or

(e) that no action be taken.
(4) In conducting its review the consultants committee may review:

(a) de-identified prescriber, dispenser and patient profiles which depict prescribing, dispensing or use history in comparison to area and provincial averages;

(b) de-identified patient health information relating to prescriptions for monitored drugs including patient records, charts and reports;

(c) reports, statistical data and other information prepared by employees of the department or the Newfoundland and Labrador Centre for Health Information;

(d) evidence obtained from prescribers, dispensers and patients including sworn statements; and

(e) other information it determines necessary to complete its review.

(5) The consultants committee may, with the approval of the minister or his or her delegate, obtain the services of a person with expertise in a particular area.

7. (1) The consultants committee shall consist of

(a) a physician appointed by the minister from a list of physicians submitted by the College of Physicians and Surgeons of Newfoundland and Labrador which list shall include the name of at least one family physician;

(b) a physician appointed by the minister from a list of physicians submitted by the Newfoundland and Labrador Medical Association which list shall include the name of at least one family physician;

(c) a pharmacist appointed by the minister from a list of pharmacists submitted by the Newfoundland and Labrador Pharmacy Board which list shall include the name of at least one community pharmacist;

(d) a pharmacist appointed by the minister from a list of pharmacists submitted by the Pharmacists' Association of New-
foundland and Labrador which list shall include the name of
at least one community pharmacist;

(e) a dentist appointed by the minister from a list of dentists
submitted by the Newfoundland and Labrador Dental Board;

(f) a nurse practitioner appointed by the minister from a list of
nurse practitioners submitted by the College of Registered
Nurses of Newfoundland and Labrador;

(g) at least one employee of the Newfoundland and Labrador
Centre for Health Information appointed by the chief execu-
tive officer of the Newfoundland and Labrador Centre for
Health Information; and

(h) at least one employee of the department appointed by the
department minister of the department.

(2) One of the persons appointed under

(a) paragraph (1)(a) or (b) shall be a family physician; and

(b) paragraph (1)(c) or (d) shall be a community pharmacist.

(3) Where an organization referred to in paragraph (1)(a), (b),
(c), (d), (e) or (f) fails to provide a list of names in accordance with
paragraph (1)(a), (b), (c), (d), (e) or (f) within 30 days of the minister's
request to provide the list, the minister may appoint a physician, phar-
macist, dentist or nurse practitioner, as the case may be, notwithstanding
that a list has not been provided by the organization.

(4) The chairperson of the consultants committee shall be a per-
son appointed under paragraph (1)(h).

(5) The members of the consultants committee appointed under
paragraphs (1)(a) to (f) shall be appointed for a term of 3 years and are
eligible for reappointment.

(6) Where the term of office of a member appointed under para-
graphs (1)(a) to (f) expires, the member shall continue to be a member
until replaced.

(7) A person appointed under paragraphs (1)(a) to (f) may resign
as a member by written notice to the minister.
(8) Members of the committee who do not receive a salary from funds voted by the legislature shall be remunerated for their committee service in accordance with the Newfoundland and Labrador Centre for Health Information Guidelines on Honoraria for Clinicians.

8. (1) The consultants committee shall meet at the call of the chairperson.

(2) A quorum of the consultants committee shall be 6 members of which

(a) one member shall be an employee of the Newfoundland and Labrador Centre for Health Information appointed under paragraph 7(1)(g);

(b) one member shall be an employee of the department appointed under paragraph 7(1)(h); and

(c) 4 members shall be members appointed under paragraphs 7(1)(a) to (f).

9. (1) A notice required under section 9 of the Act shall be provided in writing no later than 24 hours after the decision to suspend or revoke the licence of a prescriber or dispenser has been communicated to the prescriber or dispenser.

(2) A person who receives a request from the minister or his or her delegate under subsection 10(2) of the Act shall respond to that request no later than 7 days from the date the person receives the request.

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Decision/Direction Note
Department of Health and Community Services

Title: Fluoroscopy Unit, James Paton Memorial Regional Health Centre, Gander

Decision Required:
- Whether or not to provide $120,000 in funding from the Department’s 2019-20 capital equipment allocation, as well as approval to utilize $530,000 in deferred revenue, to allow Central Health to purchase a new fluoroscopy unit for use in the Diagnostic Imaging Program at the James Paton Memorial Regional Health Centre (JPMRHC) in Gander.

Background and Current Status:
- A fluoroscopy unit is an imaging technique that uses x-rays to obtain real-time moving images of the interior of an object.
- Central Health (CH) advises that the existing fluoroscopy unit at the JPMRHC is at end of life and became non-operational on September 18, 2019. An assessment of the unit confirmed that the power supply and relay had malfunctioned.
- CH advises that in the last six months, 132 procedures were completed using the fluoroscopy unit at JPMRHC. With this unit not functioning, patients will have to travel to the Central Newfoundland Regional Health Centre in Grand Falls-Windsor to obtain this service.
- CH estimates the total cost to replace the fluoroscopy unit at $650,000 and is requesting approval to utilize $530,000 in funding that they received in 2019-20 to replace the nuclear medicine system at the JPMRHC to partially fund the new fluoroscopy unit. CH advises while it continues to plan for replacement of the nuclear medicine system, the $530,000 will not be required in this fiscal year. Rather, given that the fluoroscopy unit is of higher priority for replacement at the current time, the $530,000 in funding be utilized to purchase the fluoroscopy unit and funding to replace the nuclear medicine system will be requested in its 2020-21 capital equipment listing.
- In 2019-20, the Department of Health and Community Services was provided with $22M in capital equipment funding. To date $21,088,500 in funding has been allocated thereby leaving $941,500 in funding remaining available.

Recommendation:
- Provide $120,000 in funding from the Department’s 2019-20 capital equipment allocation, as well as approval to utilize $530,000 in deferred revenue, to allow Central Health to purchase a new fluoroscopy unit for use in the Diagnostic Imaging Program at the James Paton Memorial Regional Health Centre in Gander.

Prepared/Approved by: P. Greene/H. Hanrahan/K. Stone
Ministerial Approval: Received from Hon. John Haggie, MD.

October 21, 2019
Information Note
Department of Health and Community Services

Title: Shortage of the drug product Tamoxifen in the Canadian market.

Issue: To inform of a Canada-wide shortage of the drug product Tamoxifen, used in the treatment of breast cancer.

Background and Current Status:
- Tamoxifen is a hormonal therapy used to treat hormone receptor-positive breast cancer. When used as part of adjuvant therapy for the treatment of early breast cancer, patients may take tamoxifen between five and ten years.

- Tamoxifen is administered orally and is dispensed in the community setting via pharmacies. Many patients receiving Tamoxifen have been discharged from the Cancer Care program and are being followed by their family physician.

- Tamoxifen is marketed by three companies in Canada. AstraZeneca (AZ) is the manufacturer for the brand name product. Apotex and Teva Canada are the manufacturers for the generic products.

- PTs have been informed of a supply interruption from all three companies who currently manufacture this product for the Canadian market, affecting both the 10 mg and 20 mg strengths. At present time, the duration of this supply interruption is unknown. However, resupply is estimated to be in effect by January 21, 2020.

- The supply interruption has been escalated to Health Canada and deemed to be a Tier 3 shortage, meaning that it is a drug shortage with greatest potential impact.

- The PT Drug Shortages Task Team is engaged with this issue and has been communicating with the Cancer Care programs via the Canadian Association of Provincial Cancer Agencies (CAPCA).

- The RHA Drug Shortages Core Team is meeting regularly to discuss how the shortage will be managed in the province. Officials from both the Pharmaceutical Services Division and Pharmacists’ Association of Newfoundland and Labrador (PANL) have been present at these meetings.

Analysis:
- Managing this particular shortage is unique in that Tamoxifen is not dispensed in hospital but is a common treatment initiated by oncologists in the RHAs. As such, the Cancer Care Program has a significant role to play in managing access to this therapy.

- According to data compiled by the Newfoundland and Labrador Center for Health Information (NLCHI), 414 patients filled a prescription for Tamoxifen at a pharmacy in the province from October 1, 2018 to October 9, 2019. 

**s. 29(1)(a)**
• Health Canada is investigating the possibility of importing Tamoxifen from the US market to get through the shortage. If importation is approved, the shortage should ease in December 2019.

• The Newfoundland and Labrador Prescription Drug Program is in the process of listing Fulvestrant, an alternative treatment that will be appropriate for a portion of the patient population affected by the shortage of Tamoxifen. Fulvestrant was one of the 15 drugs approved for funding in the 2019 Budget.

Action Being Taken:

• All community pharmacies have been notified by PANL that they should limit dispensing amounts to 30-day supplies for new and refill prescriptions in an attempt to ration inventory.

• Eastern Health officials have collaborated with the NLMA to inform physicians that prescriptions for Tamoxifen should be limited to 30 days’ supply.

• Medical Oncologists with the Provincial Cancer Care Program have created treatment plan guidelines for patients affected by the Tamoxifen shortage. These physicians are in the process of reviewing patient lists and contacting high risk patients.

• Eastern Health will mail 414 registered letters to patients affected by the tamoxifen shortage on October 24, 2019. The letters instruct patients to contact their local pharmacy if they have concerns about refilling their prescription. If their pharmacy is unable to obtain a supply of Tamoxifen, then patients are instructed to call a toll free number that the Cancer Program has set up to discuss next steps.

• Eastern Health plans to release a media statement regarding the National Tamoxifen Shortage on October 24, 2019. (Annex A)

• The RHA Drug Shortages Core Team and the PT Drug Shortages Task Team will meet regularly in the upcoming weeks to monitor the shortage.

Annex A: Eastern Health Media Release

Prepared/Approved by: J. O’Dea/P. Smith/K. Stone
Ministerial Approval: Received from Hon. John Haggie, MD

October 24, 2019
Annex A – Eastern Health Media Release

Eastern Health Implements Plan for Patients Affected by National Tamoxifen Drug Shortage

October 24, 2019 – St. John’s, NL: Eastern Health has developed guidelines to assist patients during the Canada-wide Tamoxifen drug shortage.

Health Canada has identified a shortage of the oral drug Tamoxifen, an anti-estrogen drug most commonly given as part of hormonal therapy. It is used mainly to treat breast cancer; however, it is also used to treat other conditions.

While the estimated time for the supply to be back to normal is not currently known, Health Canada is actively working with the companies involved to increase production of Tamoxifen within Canada by January 2020.

In addition, the Cancer Care Program is working with its oncologists, the Pharmacists’ Association of NL, the Department of Health and Community Services and various programs within Eastern Health to develop a contingency plan to address the shortage. The program is also contacting patients who have been prescribed Tamoxifen via registered mail.

The Cancer Care team at Eastern Health has developed a plan for those patients unable to renew their prescription. If you have any concerns about refilling your prescription, please:
- Call your local pharmacy to see if the pharmacist can get the drug from another pharmacy in the area.
- If your pharmacy is not able to obtain Tamoxifen, call the Cancer Care Centre at 1-844-923-1336 and health-care staff will assist you with the next steps. The telephone line is available between Monday to Friday, 8:30 a.m. to 4:30 p.m.

Additional information about the shortage is available on the Cancer Care Program website at www.cancercare.easternhealth.ca/tamoxifen.

Patients remain our top priority during this drug shortage and we will take all necessary measures to ensure they continue to receive high quality care.

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Media Contact:
Allison Barter
A/ Media Relations Manager
Eastern Health
T: (709) 777.1412
Allison.Barter@easternhealth.ca
Information Note
Department of Health and Community Services

Title: Obstetrical Services at James Paton Memorial Regional Health Centre

Issue: Update on Central Health’s plan to re-establish obstetrical services at James Paton Memorial Regional Health Centre fall 2019.

Background and Current Status:
- While Obstetrical Services (OBS) are typically provided at both James Paton Memorial Regional Health Centre (JPMRHC) in Gander and Central Newfoundland Regional Health Centre (CNRHC) in Grand Falls-Windsor, a long-term diversion from JPMRHC to CNRHC has been in place since February 16, 2018. At that time Central Health (CH) were challenged in maintaining a physician schedule that delivered a safe, quality service.

- Diversion plans have been put in place in the past for various periods. CH is working to re-establish the services in a manner that will reduce the likelihood of future short and long-term diversions. CH’s goal is to provide a safe, quality and sustainable service for patients.

- CH has identified the following human resource requirements needed for a successful obstetrical service at JPMRHC:
  - 2.5 FTE Obstetricians
  - 2-3 FTE Family Physicians
  - 4 FTE Midwives

- Two obstetricians, Dr. Orefuwa and Dr. Akinsola commenced employment with CH in November 2018 and January 2019 respectively.

- In the interim, there are several family physicians in Grand Falls-Windsor area who are willing to support the JPMRHC team for a three month period, allowing time for the local physicians to complete the required training.

- CH is currently exploring interest from a number of obstetricians to provide locum coverage to assist with restarting and stabilizing obstetrical services in Gander. CH had initially planned for obstetrical services to resume in the fall of 2019; however, services are now anticipated to resume effective January 1, 2020.

- Four midwives have been recruited since September 2018. One midwife started in June 2019, the second will start on November 1, 2019 and a third midwife will begin work December 9, 2019.
A working group has been developing a collaborative intake and risk assessment process for midwifery clients. The team is gathering feedback and input from internal stakeholders on the proposed process.

HCS staff have been working with CH to establish a facility access agreement that will provide midwives with the authority to admit and discharge clients, independently order laboratory and diagnostic imaging tests, and prescribe and order medications.

CH is in Year 4 of the MOREob program which is a comprehensive patient safety, professional development, and performance improvement program for caregivers in Obstetrical units. In moving into Year 5, the plan is to focus on components necessary to re-establish the service at JPMRHC. There has been a timeline scheduled to ensure completion of required chapters with associated skills drills.

During the diversion period, CH has completed significant work internally to review the staffing model and the patient follow-up processes. As well, internal engagement has been on-going with OBS staff, nursing, Emergency Department, Paramedicine, Pediatrics, CH senior leadership, Midwifery, Medical Services, Communications, and Family Medicine to develop improved processes for obstetrical patients.

CH recognizes that it is necessary to maintain a continued partnership with internal stakeholders as service is re-established, in particular the Department of Pediatrics and Surgical Services.

The Chief of Obstetrical Service has requested that CH offer an ALARM (Advances in Labour and Risk Management) course to staff. This two day course will evaluate, update and maintain the competence of the obstetrical team and will help to ensure the safe re-establishment of service at JPMRHC after the long-term diversion of service.

CH has also been engaged with Medical Services Division staff in HCS as they have been developing their plan for re-establishing obstetrical services.

Throughout the diversion period, CH has had ongoing communication with key external and internal stakeholders, including HCS; Town of Gander; Women’s Centre; Health Line NL; and internal CH employees and Physicians.

The general public have been kept advised of the service availability through traditional and social media to ensure consistent messaging to the affected women and their families.

CH is continuing with their current plan to ensure a safe, quality and sustainable obstetrical service delivery model that aligns with dimensions of quality and is collaborative and supportive of interdisciplinary model of care including Nursing, Midwifery, Primary Care Family Physicians, and Obstetricians.
Analysis:

- CH has been successful in recruiting the obstetricians necessary to re-establish obstetrical services in JPMRHC, as two are in place. Three obstetricians have expressed interest in doing locums in Gander. CH is investigating the use of locums for three to six month coverage periods as a means to support the two obstetricians already recruited.

- CH is continuing to work with local family physicians to support them in obtaining the necessary OBS/Gyne training to actively support the obstetrical service at JPMRHC.

- The introduction of midwifery services in CH will provide a significant level of support to the service and lead to the successful re-establishment of obstetrical services at JPMRHC. Beginning December 1, 2019, the midwives will begin seeing patients for prenatal care.

- Every jurisdiction in Canada, except Quebec, using a birth centre model of midwifery care have midwives credentialed, with hospital privileges, through Health Practitioner or Physician and Midwife Staff Bylaws. The establishment of a facility access agreement will serve this purpose in the short term in CH, with the establishment of bylaws for midwives as the long-term objective. Further discussion on the facility access agreement will occur at the obstetrics planning meeting on September 26.

- CH has delayed re-establishing obstetrical services until the identified human resource model could be recruited. CH was committed to introducing a model that would successfully support a sustainable service in JPRMHC.

Action Being Taken:

- CH will continue to implement their plan to ensure obstetrical services are re-established at JPMRHC on January 1, 2020.

- HCS will continue to be updated and advised of progress in meeting the target date of January 1, 2020.

Ministerial Approval: Received from Hon. John Haggie, MD

October 2, 2019
Information Note
Department of Health and Community Services

Title: Multi-regional outbreak of Shiga Toxin-producing Escherichia coli (STEC)

Issue: To inform the Minister of a current multi-regional outbreak of STEC and actions being taken to address the outbreak.

Background and Current Status:
- STEC is a form of E. coli that produces shiga toxin. This bacterium and the toxin it produces can cause illness characterized by abdominal cramping, nausea, vomiting, and/or bloody diarrhea. Illness may require hospitalization. In some cases, infection with STEC can result in hemolytic uremic syndrome (HUS), which may lead to serious sequelae and/or necessitate renal dialysis. Treatment for STEC is supportive.

- The following case definitions are being used to identify confirmed and suspected cases of STEC:

- The Department of Health and Community Services was first informed of [redacted] cases of STEC that appeared to be associated with Memorial University in the EH region on September 30, 2019. As of October 4, 2019, there are 19 confirmed cases and 21 suspect cases of STEC reported from Eastern, Central and Western Health regions, many of whom are associated with Memorial University.

- As of October 4, 2019, bacterial cultures from [redacted] cases have been sent to the National Microbiology Lab (NML) in Winnipeg for genotyping. Genotyping results should be available 7-10 days after receipt of the samples by the NML.

- Service NL is leading the response to the outbreak investigation, with support and coordination from HCS and the Regional Health Authorities.

Analysis:
- As of October 4, 2019, the following data have been collected:
  - the age range of the confirmed cases is 17 to 39 years;
  - twelve (30%) of the confirmed cases are male and 28 (70%) of the confirmed cases are female; and,
  - [redacted]

- Service NL Environmental Health Officers (EHOs) continue to interview confirmed and suspect cases to gather exposure history data. Preliminary data suggests a possible source of infection related to the salad bar in the Memorial University dining hall.
• An EHO conducted a routine inspection of the Memorial University dining hall on September 30, 2019, and noted two critical hazards which were corrected during the inspection: improper hot holding of a cooked ground beef dish, and cold holding of raw chicken in a cooler intended for produce only. It was also noted that the dishwasher was not in use due to mechanical problems. As an alternative, cooking utensils were washed and sanitized in a three-compartment sink, and disposable plates and cutlery were available for patrons.

• Following the inspection, the EHO met with the kitchen manager and chef as well as university health and safety staff to discuss the reported illnesses and the health inspection results.

• A more in-depth inspection of the dining hall and its salad preparation processes was conducted by two EHOs on October 3, 2019. The inspection revealed several conditions and practices that could have potentially contributed to the spread of contaminated salad ingredients. s. 29(1)(a)

Action Being Taken:
• An outbreak management team (OMT), consisting of the regional Medical Officer of Health, the Manager of Environmental Health and the Director of Communications with EH, a Communicable Disease Control Nurse with CH, Service NL, the Manager of Environmental Health and the Epidemiologist with HCS, and representatives from the Public Health and Microbiology Laboratory, has been formed to investigate the outbreak.

• The OMT first met on October 2, 2019, and continues to meet regularly to assess the data collected.

• Environmental Health Officers (EHOs) with Service NL will continue to interview any new confirmed or suspect cases. HCS officials are continuing to analyze this exposure history data.

• Results from the National Microbiology Laboratory are expected the week of October 14-18, which will provide further information regarding the linkage of these cases.

• On October 4, 2019, HCS shared a public health alert with other provinces and territories on the Public Health Agency of Canada secure website.

• The Regional Medical Officer of Health will inform physicians, nurse practitioners and emergency departments of the outbreak and advise them to test all suspected cases for STEC.

Prepared/Approved by: D. Howse/J. Fitzgerald/A. McKenna/H. Hanrahan
Ministerial Approval: Received from Hon. John Haggie, MD

October 4, 2019
Information Note
Department of Health and Community Services

Title: Update on a multi-regional outbreak of Shiga Toxin-producing *Escherichia coli* (STEC)

Issue: To update the Minister on the multi-regional outbreak of STEC and actions being taken to address the outbreak. See related BN-2019-00548.

Background and Current Status:
- Since October 2, 2019, the Outbreak Management Team has met seven times.
- The outbreak case definitions for confirmed and suspected cases of STEC have been updated to reflect new information as follows:
  - [Redacted]
  - [Redacted]
  - [Redacted]
  - [Redacted]
- As of October 11, 2019, there are 26 confirmed cases and 19 suspect cases of STEC reported from Eastern, Central and Western Health regions. Service NL (SNL) Environmental Health Officers (EHOs) continue to interview confirmed and suspect cases. Twenty-seven completed and one partial food exposure histories have been submitted to HCS (22 from confirmed cases), and eight of the confirmed cases are known to be unaffiliated with Memorial University.
- On October 4, 2019, the Regional Medical Officer of Health informed physicians, nurse practitioners and emergency departments of the outbreak and advised them to test all suspected cases for STEC.
- On October 7, 2019, HCS began statistical analysis of all exposure history data received to date, by comparing the food consumption patterns with those of the general NL population, as published in the National Foodbook survey.
- On October 10, HCS provided suspect food product information to the CFIA for their Office of Food Safety and Recall to investigate further.
As of October 11, 2019, bacterial cultures from twenty confirmed cases have been sent to the National Microbiology Lab (NML) in Winnipeg for genotyping. Preliminary information shows that the first samples were E. coli O26, with confirmation of verotoxigenic Stx 1 genotyping. Whole genome sequencing is expected October 15, 2019.

Analysis:
- As of October 11, 2019, the following data has been collected:
  - the age range of all cases is 17 to 39 years, with a median of 20 years;
  - fourteen (31%) of the cases are male and 31 (69%) of the cases are female; and,
- To date, no suspected spinach products from the exposure window has been located for testing.
- The case onset dates suggest that the outbreak is related to a single source, and not related to ongoing exposures.
- No other province or territory has contacted HCS regarding the Public Health Alert posted on the Public Health Agency of Canada (PHAC) secure website. The PHAC Outbreak Management Division and Field Epidemiology Program have offered their support, if requested.

Action Being Taken:
- EHOs continue to interview any new confirmed or suspect cases. HCS officials continue to analyze this exposure history data as it is submitted.

- Cases with shopper loyalty cards have been asked for their consent to collect their purchase records from food retailers in order to identify specific suspect food products.

Prepared/Approved by: D. Howse/J. Fitzgerald/A. McKenna/K. Stone
Ministerial Approval: Received from Hon. John Haggie, MD

October 11, 2019
Meeting Note
Department of Health and Community Services
Meeting with Sequence Bio Informatics (SBI)
October 28, 2019, 3:30-4:30PM
Executive Boardroom, HCS

Attendees: Hon. John Haggie, Minister, HCS
Ms. Karen Stone, Deputy Minister, HCS
Ms. Alicia Anderson, Executive Assistant to the Minister, HCS
Ms. Gerrie Smith, Legislative Consultant, HCS
Mr. Seamus Breen, Director, Policy, Planning and Evaluation, HCS
Ms. Neala Quigley, Director of Community Engagement, SBI
Mr. Dan Brake, VP, Engineering and Information Security, SBI
Ms. Joy Buckle, VP, Policy and Planning, SBI

Purpose of Meeting:
- To provide an update on the Newfoundland and Labrador Genome Project (NLGP) pilot study and discuss the relationship between the Department of Health and Community Services (HCS) and Sequence Bio Informatics (SBI).

Background:
- Given our founder population status and highly integrated Electronic Health Record (EHR), interest in conducting commercial genetic health research in the province is growing. Government committed in "The Way Forward: Building Our Future", to initiate the development of a regulatory framework for the commercial use of health and genetics data that is respectful of existing privacy legislation and ensures a scientific and financial return to Newfoundland and Labrador. SBI is one of the first companies to pursue commercial genetic health research in the province.

- Founded in 2013, SBI is a start-up company based in St. John's. It intends to create a Research and Analysis Platform to accelerate commercial drug research by collecting genetic samples from Newfoundlanders and Labradorians and linking genomic information and qualitative data from questionnaires and interviews to corresponding personal health information in the EHR, which SBI would access from the Newfoundland and Labrador Centre for Health Information (NLCHI). SBI refers to this project as the NLGP, which will involve collecting personal health information and genetic samples from 100,000 residents of the province.

- The company is currently focused on its pilot project, the NLGP-Pilot, which will primarily assess the viability of the study protocol, including its proof-of-concept research platform, by enrolling 2500 participants through family physician clinics. A research nurse/coordiator located at the participating clinics will assess participant eligibility, obtain consent, enroll study participants, and collect contact information, a baseline questionnaire and a saliva sample from all participants.
Agenda Item #1a: Status Update on the NLGP Pilot Study

- SBI received final ethics approval of the NLGP-Pilot on March 27, 2019 from the Health Research Ethics Board (HREB). SBI provided their HREB-approved proposal to NLCHI to request secondary access to EHR data in April 2019.

- SBI officially launched the NLGP-Pilot at an event held on July 24, 2019.

- Following the launch event, SBI began the process of enrolling 2500 participants for the NLGP-Pilot through three participating family physician clinics in the Metro area: Dr. Dennis O'Keefe, Dr. David Brentnall, and Dr. Karl Misik. It is unknown whether they have successfully recruited any participants at this time; however in a media appearance on Out of the Fog on October 3, 2019, Mr. Chris Gardner, CEO of SBI, announced that over 1500 participants had signed up to participate at that time.

- On August 23, 2019, SBI announced that the company received investment from Y Combinator (YC), a company that provides seed funding to start-ups.
Potential Speaking Points
• Congratulations on receiving ethics approval for the Newfoundland and Labrador Genome pilot project. I look forward to seeing the study unfold.

• Congratulations on your recent partnership with Y Combinator. It is great to see a local company succeed in making multinational partnerships. I encourage you to also use this opportunity to collaborate with local stakeholders, like Memorial University and NLCHI, to strengthen the province’s research community.

Proposed Actions
• SBI to continue to update HCS on the progress of the NLGP-Pilot.

Agenda Item #1b: NLCHI Data Access Request
• On January 16, 2019, Minister Haggie directed NLCHI to move forward with implementing a Provincial Data Lab to provide researchers who have the requisite ethics and privacy approvals with secure access to health data, and to develop policies for the Provincial Data Lab that aligns with provincial policies, legislation, and programming. To this end, NLCHI has been developing a governance framework to support the Provincial Data Lab that encompasses provincial policies and legislation.

• The Provincial Data Lab is a secure environment where records containing personal health information held by NLCHI will be available for researchers to access within the virtual confines of NLCHI without taking possession of the data. This is an improvement on the current process where NLCHI discloses data to researchers who receive the requisite ethics and privacy approvals. Under the Provincial Data Lab, researchers may still access data, without data being transferred from the custody or control of NLCHI.

• In April 2019, NLCHI received SBI's application for secondary access to EHR data, consisting of the NLGP-Pilot protocol and consent documents, for their assessment and review. This was an opportunity for NLCHI to review SBI's application to determine whether they have any concerns with the protocol from a privacy and data security perspective and if NLCHI can accommodate SBI's request.
Analysis

- Given SBI has received ethics approval from the HREB and submitted their proposal for access to the EHR data to NLCHI for consideration, it is possible that they may seek to recommence negotiations on the MOU with HCS.

Potential Speaking Points

- We remain willing to continue discussions on the MOU on the basis of the most recent draft officials sent you.

Proposed Actions

- SBI will contact HCS to recommence the negotiation of the MOU as warranted.

Agenda item #3: Amendments to the Health Research Ethics Authority Act

- On March 13, 2018, SBI filed an application with the Supreme Court against the HREA, the HREB and Dr. Craig Pochni (the Chair of the HREB Clinical Trials subcommittee) seeking mandamus, i.e. an order of the court requiring that a decision be made by the HREB regarding SBI's research application. After receiving the HREB decision, SBI amended its application to the Supreme Court seeking a declaration from the court that under subsection 9(4) of the Health Research Ethics Authority Act (HREA Act), the HREB is required to make a determination on a research application within 30 days.

- On January 31, 2019, Justice Vikas Khaladkar rendered the decision that while SBI has the right under the legislation to ask the HREB to reconsider its application and/or to appeal a decision of the HREB to an independent Appeal Panel in accordance with Section 14 of the HREA Act, it does not have the right to appeal the procedures employed by the HREB to arrive at its decisions. However, Justice Khaladkar interpreted subsection 9(4) to mean that the HREB shall consider and render a decision on applications within 30 days of receipt of the
application as provided in the HREA Act (Sequence Bioinformatics Inc. v Health Research Ethics Authority for Newfoundland and Labrador, 2019 NLSC 21 at para 69). Following the decision, SBI CEO, Mr. Chris Gardner, contacted Minister Haggie on February 13, 2019 requesting a meeting to discuss the decision and potential legislative changes to the HREA Act. The meeting was scheduled for April 17, 2019, but was cancelled due to the dropping of the writ for the 2019 provincial election.

Analysis
- As part of its work, the HREA Legislative Review Working Group has drafted a consultation plan to consult with local key stakeholders via targeted key stakeholder interviews and an online survey of the local research community. This includes proposed consultations with third party entities like SBI. The working group has also conducted a jurisdictional scan to assess how Research Ethics Boards are operationalized in other jurisdictions.

- The working group experienced delays in its operations due to government entering into the caretaker period during the 2019 provincial election. A decision note seeking executive approval of the consultation plan is currently under development.

- NLCHI, the HREA, and the regional health authorities are working together to develop a centralized consultation service for researchers wishing to access data. This uses a privacy-by-design approach and will streamline the ethics and privacy approval processes and resolve any major ethics or privacy concerns early in the review process.

Potential Speaking Points
- I am interested in your views on potential changes to the HREA Act. My officials will be in touch to consult with you, and other stakeholders, on this matter.

- I remain committed to core principles of the HREA Act: that studies involving human participants, particularly genetic or genomic research, must be reviewed in Newfoundland and Labrador, under the authority of the Act and by non-profit review boards.
Proposed Actions

- Pending approval of the draft consultation plan, the HREA Legislative Review Working Group will consult with SBI via targeted consultations for the legislative review of the HREA Act.

Prepared/Approved by: N. Porter/S. Breen/G. Smith/K. Stone in consultation with J. Caines (JPS) and D. Roche (NLCHI)

Ministerial Approval: Received from Hon. John Haggie, MD

October 23, 2019