Klachkova, Anastasiya (CSC/SCC)

From: Varsaneux Olivia (NHQ-AC)
Sent: March 8, 2021 11:00 AM
To: Morse Jennifer (NHQ-AC)
Cc: Clement Chris (NHQ-AC)
Subject: RE: REB 2020-017P - Amendment - outcome of REB review
Attachments: Appendix R-serology SOW for technician.docx

Jennfier,

Please find the attached statement of work reviewed by Madison, Dr, W and myself for consistency.

Best wishes,

Olivia

Olivia Varsaneux
Senior Epidemiologist | Épidémiologiste Senior
Health Services Sector | Services de santé
Correctional Service of Canada | Service Correctionnel du Canada
olivia.varsaneux@csc-scc.gc.ca | Desk: 613-943-9593/ Cell: 343-540-7393

From: Morse Jennifer (NHQ-AC) <Jennifer.Morse@CSC-SCC.GC.CA>
Sent: March 8, 2021 9:11 AM
To: Varsaneux Olivia (NHQ-AC) <Olivia.Varsaneux@CSC-SCC.GC.CA>
Cc: Clement Chris (NHQ-AC) <Chris.Clement@CSC-SCC.GC.CA>
Subject: RE: REB 2020-017P - Amendment - outcome of REB review

Olivia,

While I wait to meet with you, could you please provide me with the final SOW for the technicians? I notice the document you sent to the REB is still with track changes. I copied you on an email with contracting, I would like to send the final SOW today.
Can you please send to me ASAP?

Thank you,
Jennifer

From: Varsaneux Olivia (NHQ-AC) <Olivia.Varsaneux@CSC-SCC.GC.CA>
Sent: March 5, 2021 8:26 PM
To: 'hc.reb-cer.sc@canada.ca' <hc.reb-cer.sc@canada.ca>
Cc: VanDalen Madison (NHQ-AC) <Madison.VanDalen@CSC-SCC.GC.CA>; Worthington Dr. James (NHQ-AC) <Dr.James.Worthington@CSC-SCC.GC.CA>; Morse Jennifer (NHQ-AC) <Jennifer.Morse@CSC-SCC.GC.CA>; Clement Chris (NHQ-AC) <Chris.Clement@CSC-SCC.GC.CA>; 'trista.takacs@canada.ca' <trista.takacs@canada.ca>; 'suzi.vivolo@canada.ca' <suzi.vivolo@canada.ca>; 'gregory.huyer@canada.ca' <gregory.huyer@canada.ca>; 'gabriella.hilkes@canada.ca' <gabriella.hilkes@canada.ca>
Subject: FW: REB 2020-017P - Amendment - outcome of REB review

Dear Health Canada and Public Health Agency of Canada Research Ethics Board (REB),

We thank you for your thorough review of our materials and thoughtful questions. We have provided a response to your questions and recommendations in the below email.

The team has made the recommended changes from the REB, and has added changes to the study protocol since our last submission. These changes are reflected within our documents in track changes:

1. We have added two new sites due to the extent and recency of their outbreaks

Stony Mountain Institution, Stony Mountain, Manitoba; and Saskatchewan Penitentiary, Prince Albert, Saskatchewan

2. Changed role of Correctional Service Canada healthcare personnel external to the seven sites

Correctional Service Canada healthcare personnel external to the seven sites included in this study will be responsible for the recruitment of participants, guiding consent, and the administration of the questionnaires. The collection of blood samples, and the storing and transporting blood samples will be preformed by health care personnel external to CSC and will be sourced through a third party contract.

We are happy to answer any further questions you may have.

Best wishes,

Olivia

Olivia Varsaneux
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Health Services Sector | Services de santé
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From: reb / cer (HC/SC) <hc.reb-cer.sc@canada.ca>
Sent: January 28, 2021 4:01 PM
To: Martin Michael (NHQ-AC) <Michael.S.Martin@CSC-SCC.GC.CA>
Cc: Varsaneux Olivia (NHQ-AC) <Olivia.Varsaneux@CSC-SCC.GC.CA>; Worthington Dr. James (NHQ-AC) <Dr.James.Worthington@CSC-SCC.GC.CA>; Drebot, Mike (PHAC/ASPC) <mike.drebot@canada.ca>; Collard Joel (NHQ-AC) <Joel.Collard@CSC-SCC.GC.CA>; Clement Chris (NHQ-AC) <Chris.Clement@CSC-SCC.GC.CA>; Takacs, Trista (PHAC/ASPC) <trista.takacs@canada.ca>; Vivolo, Suzi (HC/SC) <suzi.vivolo@canada.ca>; Huyer, Gregory (HC/SC) <gregory.huyer@canada.ca>; Hilkes, Gabriella (HC/SC) <gabriella.hilkes@canada.ca>; reb / cer (HC/SC) <hc.reb-cer.sc@canada.ca>
Subject: REB 2020-017P - Amendment - outcome of REB review

Protocol Number: REB 2020-017P – Amendment received on January 19, 2021
Project Title: Correctional Services Canada COVID-19 Serology Study
Date of Review: January 25, 2021 (delegated review)

Dear Dr. Martin,

The Health Canada and Public Health Agency of Canada Research Ethics Board (REB) has reviewed the submission referenced above.

The REB had the following questions and recommendations that need to be addressed before the board can make a final decision:

1. Please re-submit all documentation pertaining to this amendment in track changes in order to highlight the differences between the initial application and the changes being proposed.

2. The REB understands that Correctional Services Canada (CSC) employees external to the seven sites will now be responsible for recruiting participants and guiding consent. Comment as to whether having CSC healthcare personnel conduct these activities might raise the potential for undue influence on inmates or staff.

CSC healthcare personnel recruiting participants and guiding consent is a standard practice within CSC and we do not believe it will create any undue influence on inmates or staff. We will ensure staff who conduct these activities are from other institutions, regional headquarters or national headquarters and have no connection to the site.

3. With respect to the consent forms (inmate and staff), the REB had the following recommendations:
    a. In the "How will my study information be kept confidential" section, specify in the fourth paragraph that the data being shared with the CITF will be **coded**. Updated in documents
    b. In the "What data will be made available to the public?" section, the REB recommends making the following revision, "If data has already published ~~publically~~ withdrawal is not possible", or removing this sentence entirely as this information is repeated later in the "What happens if I decide to withdraw my consent to participate?" section of the consent form. Updated in documents
    c. The "How will my data be made available to researchers?" section specifies that the data may be used alone or in combination with other data, including other health data. Clarify what other types of data this is referrign to and specify whether you intend to collect other types of health information.

The CITF does not intend the collection of other kinds of information.

The sentence means that external researchers accessing de-identified (coded) CITF data can use the study's data in combination with the data of other serological studies and surveys centralized in the CITF. The de-identified (coded) CITF data can also be used by researchers in combination with other data that they have gathered for research purposes, in compliance with their local research ethics requirements.

The researchers are bound to confirm by way of a contract that their intended research project will not entail individual re-identification. A Data Access Committee is responsible for reviewing proposed research projects and confirming that there is no reasonably foreseeable risk of individual re-identification in the proposed use of data.

The Principal Investigator intends to collect only the data described in the research protocol and the informed consent materials.

    d. The REB recommends revising the "How will my data be stored?" section some of the information is not relevant to this section (e.g. sharing of anonymized data), and much of the information is repeated in other parts of the consent form (e.g., sharing of data with for profit organizations, sharing of data only after receiving DAC approval). Updated in documents

4. In light of the changes with respect to the sharing of data with the CITF, the REB recommends consulting with the Privacy Management Division (PMD) to notify them of this change (phac.privacy-vieprivee.aspc@canada.ca).

Please find the attached email correspondence between PMD and CSC.

5. Provide additional details on the CITF process for sharing coded data with researchers in Canada and internationally. Explain the role of the Data Access Committee (DAC) and/or submit documentation

demonstrating the process that is followed to ensure that data is shared in compliance with Canadian law and research ethics.

The Data Access Committee is an independent committee composed of:

- At least one (1) expert on the legal/ethical aspects of health research, data sharing, privacy, and data protection.
- At least two (2) experts on the scientific aspects of immunology, population health, or another related scientific discipline.
- At least one (1) expert on the technical aspects of database management and/or database security.
- At least one (1) member of the broader community.

The DAC reviews each proposed research use of the CITF data and verifies that legitimate scientific research is intended, that the institution and personnel are qualified to perform the proposed research, and that the proposed research use respects the privacy the research participants.

Detailed documentation detailing the CITF's data governance framework is attached.

6. Detail the arrangement between the CSC and CNPHI for sharing test results with staff, and specify whether data sharing agreements are required in order to facilitate this process.

CNPHI has indicated data sharing agreement is not needed as they have no intent to use the data. Their custom built technology for this project (LRP - Lab Results Portal) is simply facilitating our project. (wording discussed with Mike)

7. You are reminded to submit a copy of all French translated documents once available.

Revised documents have been sent to translation and will be resubmitted when available.

Please provide your responses and any requested materials at your earliest convenience. If changes are required to any of the documents you submitted to the REB for review, use **track changes** to indicate what has been revised.

Note that you cannot implement the changes to the project without the written approval of the Public Health Agency of Canada's Decisional Authority, the Chief Science Officer.

If you have any questions or require further information, do not hesitate to contact the REB Secretariat at hc.reb-cer.sc@canada.ca.

Sincerely,
Melinda

Melinda Lee Choon

Senior Research Ethics Coordinator, Health Canada-PHAC Research Ethics Board Secretariat
Strategic Policy Branch / Health Canada / Government of Canada
70 Colombine Driveway, Tunney's Pasture, Ottawa, ON, K1A 0K9
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ANNEX A STATEMENT OF WORK

The Correctional Service of Canada (CSC) is mandated under the Corrections and Conditional Release Act (CCRA) to "provide every inmate with essential health care and reasonable access to non essential health care." Furthermore, health care services must respect gender, cultural, religious and linguistic differences, and be responsive to the special needs of women, Indigenous peoples, persons requiring mental health care and other groups.

1.1 Background

In light of the COVID-19 pandemic, inmates have been identified as a vulnerable priority population that may be at increased disease risk for virus transmission given their congregate living settings.

During the first and second waves of Covid-19 (to the end of January 2021), Correctional Service Canada (CSC) had fifteen COVID-19 outbreaks in their federal correctional institutions with 1241 lab confirmed positive SARS-CoV-2 PCR results for inmates and 523 reported by correctional staff. While these findings shed light on the number of CSC laboratory confirmed cases at COVID-19 outbreak sites, they do not necessarily reflect the extent of undetected asymptomatic, subclinical, and/or unreported SARS-CoV-2 infections. It is recognized in all settings that there are individuals who may experience SARS-CoV-2 infection, yet ar e undetected.

Canada has established a COVID-19 Immunity Task Force to collect information about how many people have been exposed to COVID-19. In collaboration with the Public Health Agency of Canada (PHAC) and the COVID-19 Immunity Task Force (CITF), CSC Health Services Sector is leading a SARS-CoV-2 serology study for federal correctional institutions identified as COVID-19 outbreak sites.

The study has two chief objectives:

1. To estimate the seroprevalence of SARS-CoV-2 infection for staff and inmates at Correctional Service Canada institutions, including determining the extent of undetected cases.
2. The secondary aim is to describe how SARS-CoV-2 how virus specific antibodies (including neutralizing antibody titres) change over time and between subgroups for the Correctional Service Canada inmate population.

This study will generate reliable first estimates on the extent of undetected SARS-CoV-2 infections in a priority at-risk inmate population, living in a congregate setting, and among correctional service staff. This study will also provide understanding of the seroprevalence of SARS-CoV-2 antibodies in the inmate population over time, and will shed light on the how this might differ between those with less and more severe disease outcomes.

This study requires obtaining participant's informed consent, collection and completion of questionnaires, sampling of blood, and the shipping of blood samples to Public Health Agency of Canada's (PHAC) National Microbiology Laboratory (NML). The work is required at the site of employment for CSC staff or the site of custody for inmates at the following institutions:

Mission Institution, Mission, British Columbia;
Grand Valley Institution, Kitchener, Ontario;
Port Cartier Institution, Port Cartier, Quebec;
Joliette Institution, Joliette, Quebec;
Federal Training Centre, Laval, Quebec;
Stony Mountain Institution, Stony Mountain, Manitoba; and
Saskatchewan Penitentiary, Prince Albert, Saskatchewan

1.2 Objectives:

To provide healthcare personnel responsible for carrying out site level research requirements which includes ensuring consent was obtained and questionnaires were completed, blood sampling, as well as storing and shipping of blood samples.

1.3 Scope:

The Contractor must ensure the consent form and questionnaire are properly filled out, collect the blood samples, and store, package, and arrange for transportation of the blood samples appropriately.

CSC will enrol the study participants (staff and inmates), administer the consent form and questionnaire, and debrief participants.

1.4 Tasks:

1.4.1 The Contractor must provide healthcare personnel who must:

a) Approach eligible staff and inmate participants during scheduled clinics in CSC institutions that had COVID-19 outbreaks;
b) Verify that staff and inmate participants have provided the appropriate signed consent form and questionnaire;
c) Collect a dried blood spot (DBS) sample from consenting inmates who agreed to take part in the research study and a DBS and/or whole blood sample from consenting staff ;
d) Ensure the sample has been labelled with the participant's assigned random unique study ID. Double check to verify that the label matches that of the questionnaire; and
e) Package all blood samples labelled with random unique study ID for staff and inmates for shipment to the National Microbiology Laboratory (NML) in Winnipeg, Manitoba, as per Annex C.

1.4.2 The Contractor must store temporarily all DBS and whole blood samples in accordance with the National Microbiology Lab (NML) Storage Requirements;

1.4.3 The Contractor must return to CSC designated sites as requested to take additional DBS samples from inmates who had COVID-19 antibodies detected. The Contractor must ensure CSC has obtained ongoing consent for continued participation, must collect DBS samples and label said samples with their existing assigned random unique ID in accordance with the inmate master line list created during the first visit. Repeated sampling will be required approximately every 8 weeks for up to 12 months, as determined by the Project Authority. This requirement would be dependant on the seroprevalence findings from the previous visit.

1. 5 Requirements

a) Healthcare personnel must attend a mandatory information session prior to entering a CSC Institution.
b) The Contractor must provide the laboratory specimen collection supplies which must be shipped to the Institution, in advance of clinic dates.
c) The Contractor must provide the names of the healthcare personnel in advance of arriving at the institution.
d) The Contractor must conduct ## clinics per institution, on dates and times mutually agreed upon between the Contractor, the Project Authority and the Chief of Health Services at the site.
e) The Contractor must call the Site Coordinator prior to going to the Institution to ensure the Institution is accessible and confirm that the scheduled clinic will proceed. The Contractor will be subject to local security requirements that can vary from moment to moment depending on inmate activities. The Contractor may be faced with delay or refusal of entry to certain areas at certain times despite prior arrangements for access having been made. The Contractor must be able to accommodate the cancellation or rescheduling of clinics due to unforeseen circumstances such as a lockdown or a new COVID-19 outbreak.
f) The Contractor must arrange the packaging of the laboratory samples and specimens that meet industry standards and NML requirements. Service must include biohazard labels and packaging as required.
g) The Contractor must ensure proper and accurate records are maintained in the delivery of the services.

1.6 Performance standards:

The Contractor must complete all work according to professionally accepted standards.

The Contractor must provide healthcare professionals to collect the DBS and whole blood samples. These healthcare professionals must have blood draws within their scope of practice and within their authority based on their licensing body within the province of practice.

1.7 Location of work:

The Contractor must perform the work under this contract at the following locations:

Institution	Security	Location
Federal Training Centre	Multi	6099 Lévesque Boulevard East, Laval, Québec
Federal Training Centre	Minimum	6099 Lévesque Boulevard East, Laval, Québec
Joliette Institution	Multi	400 Marsolais Street, Joliette, Quebec

Port-Cartier Institution	Maximum	Chemin de l'Aéroport Port-Cartier, Québec
Grand Valley Institution for Women	Multi	1575 Homer Watson Blvd. Kitchener, Ontario
Mission Institution	Medium	8751 Stave Lake Street, Mission, British Columbia
Mission Institution	Minimum	33737 Dewdney Trunk Road Mission, British Columbia
Stony Mountain Institution	Multi	10002 E Road #73 North, Stony Mountain Manitoba
Saskatchewan Penitentiary	Multi	15th Street West, Prince Albert, Saskatchewan

1.8 Language of Work:

The Contractor must provide at least one Bilingual speaking healthcare personnel who can communicate orally and in writing in French and English without any assistance and with minimal errors at all CSC locations.

1.9 Contractor Correctional Service of Canada Responsibilities:

During the contract period, CSC will:

a) Provide the Contractor with a mandatory information session for the contractor's healthcare personnel that will be working at CSC sites on the serology study, which includes but is not limited to information sharing, verification of informed consent, privacy and confidentiality, secure forms of information collection, sharing, storage of samples.
b) Assign a Project Manager who is available Monday to Friday during regular business hours who will be responsible for any issues that arise.
c) Provide personal protective equipment for all the healthcare personnel.
d) Approach eligible staff and inmate participants in CSC institutions that had COVID-19 outbreaks during scheduled clinics
e) Make the necessary arrangements at the site to set up the blood clinics.
f) Guide staff and inmate participants through their respective consent forms. Ensure that all participants are well informed and complete and sign their respective consent forms. Ensure that all staff and inmate participants are provided a copy of their signed consent form if requested.
g) Confirm whether the participant is a staff member or an inmate and assign each participant a random unique study ID.

   For all staff participants:
   (i) Collect the staff participant's email address and record it along with their unique study ID directly into an excel document on a computer.
   (ii) Provide consenting staff participants with a document containing a label with their unique study ID and a CSC phone number that can be called in the event that they do not have their result emailed to them by a specified date.

   For inmate participants:
   (i) Ask the inmate participant for their ID card to verify the name and personal identifier number. This information must be recorded along with their unique study ID directly into an excel document on a computer.

h) Interview staff and inmate participants, complete their respective serology research questionnaire and ensure that the staff or inmate's assigned unique study ID has been labelled on their questionnaire and that all questions have been completed.

i) Provide the Contractor with the list of perspective participants.

j) Provide the Contractor with the recruitment infographic materials for information.

k) Debrief all participants following the blood sample collection.

l) Ship all blood samples to the National Microbiology Lab, 1015 Arlington St, Winnipeg, MB in accordance with NML Shipping Requirements (see Annex C).

1.10 Meetings:

The Project Authority or the Serology Study Project Manager will schedule a planning meeting after Contract Award. Follow-up meetings may be scheduled on an as-needed basis.

ANNEX C - Storage and Shipping Guidelines - National Microbiology Laboratory/ Infectious Disease Prevention and Control Branch

Samples must be shipped to the National Microbiology Laboratory (NML) in Winnipeg, Manitoba according to NML Shipping Guidelines.

NML Contact:
National Microbiology Laboratory/ Infectious Disease Prevention and Control Branch
Public Health Agency of Canada - Government of Canada
Telephone (866)262-8433

Timelines:
- Blood Samples must be shipped weekly to the NML

Specimen Parameters:
- All blood samples must be collected, packaged, labeled, stored, and shipped in accordance with Transport of Dangerous Goods requirements. https://tc.canada.ca/en/initiatives/covid-19-measures-updates-guidance-issued-transport-canada/covid-19-measures-updates-guidance-transportation-dangerous-goods-issued-transport-canada#toc1

- See the following SARS-CoV-2 (Severe acute respiratory syndrome-related coronavirus 2) Biosafety Advisory https://www.canada.ca/en/public-health/services/laboratory-biosafety-biosecurity/biosafety-directives-advisories-notifications/novel-coronavirus-january-27.html
- Refer to the NML "Important Tips for drying DBS"

Package Preparation and Storage of Dry Blood Samples (DBS)
- Unique identifier must be on DBS card
- Place dry DBS card in it's own coin envelope
- Place 5-10 coin envelopes in a gas impermeable Bitran bag
- Place in bag one Humidity Card and 1 large Dessicant pack (3 if smaller size)
- If collecting on multiple days, must DO batch card shipment
- Store up to one week at room temperature
- Store at 4 Celcius or lower if greater than one week
- Shipment can be at room temperature if previous storage conditions have been followed
- Indicate on package method of storage:
  - ☐ 1 week or less at room temperature
  - ☐ More than one week at 4C

Notes:
- DBS Cards are non-infectious once dried
- Shipment of Cards does not require Transportation of Dangerous Goods Training
- Blood samples must be stored, secured, and safeguarded by healthcare personnel and must only be accessible by them.
- Verify the specimen reference number (or other unique identifier) is included on the card and matches that listed on the requisition sheet.
- Do NOT email patient information; for inquiries, please utilize the unique patient identifier.

Shipping:
- Complete the NML's COVID-19 testing requisition (available on the NML's Guide to Services): https://cnphi.canada.ca/gts/downloadFile?source=reqForm&id=4151&lang=en
- The requisition should be placed OUTSIDE the sample bag/container when shipping.
- Packaging, labelling and shipping should be done in accordance to Transport of Dangerous Goods requirements.
- For shipments that are expected to arrive on weekends or holidays, please refer to the NML after hours shipping guide. This is ONLY for specimens expected to arrive outside normal M-F business hours.
- Shipments expected to arrive on a WEEKEND, must be labelled "Hold for Pickup".

Shipments should be directed to:

Influenza and Respiratory Viruses Attn: Specimen Receiving
1015 Arlington Street Winnipeg, MB R3E 3P6
Ph: 204-789-6096/204-781-5014

- When the shipment is prepped and ready*, please notify the NML Operations Centre Ops Chief (phac.ocnml.operations.lnmco.aspc@canada.ca) with the following information:

- **Where the shipment is from**
- **Courier**
- **Waybill #**
- **# of samples**

For all other shipping inquiries contact NML specimen receiving:

Mobile: 204-781-5014; Phone 204-789-6096

Email: phac.nml.specimen.receiving.aspc@canada.ca